

(別添 3)

e	F.r.5	正常範囲 高値	50AN	Physical Quantity (PQ)	value=Real Number (REAL)	値	<pre> /MCCI_IN200100UV01[@ITSVersion='XML_1.0']/@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd'/PORR_IN049016UV/r/controlActProcess[@classCode='CACT']/@moo dCode=EVN'/subject[@typeCode='SUBJ']/investigationEvent[@classCode='INVTG']/@moodCo de=EVN'/component[@typeCode='COMP']/adverseEventAssessment[1]/adverseEventAssessment [classCode='INVTG']/@moodCode=EVN'/subject[1]/typeCode='SBJ'[/primaryRole/@classC ode='INVSBJ']/subjectOf2[@typeCode='SBJ']/organizer/code[@code='3']/@codeSystem='2.16.840.1 113883.3.989.2.1.1.20'[/organizer/@classCode='CATEGORY']/@moodCode='EVN'/component[@typeCode='COMP']/observation/code[@codeSystem='2.16.840.1.113883.6.163']/r/observation/@ classCode='OBS']/@moodCode='EVN'/referenceRange/@typeCode='REFV']/observationRange/int erpretationCode[@code='H']/@codeSystem='2.16.840.1.113883.5.83'[/observationRange/@class Code='OBS']/@moodCode='EVN_CRT']value[@xsi:type='PQ']/@value </pre>
e	F.r.6	備考	2000AN	Encapsulated Data (ED)		値	<pre> /MCCI_IN200100UV01[@ITSVersion='XML_1.0']/@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd'/PORR_IN049016UV/r/controlActProcess[@classCode='CACT']/@moo dCode=EVN'/subject[@typeCode='SUBJ']/investigationEvent[@classCode='INVTG']/@moodCo de=EVN'/component[@typeCode='COMP']/adverseEventAssessment[1]/adverseEventAssessment [classCode='INVTG']/@moodCode='EVN'/subject[1]/typeCode='SBJ'[/primaryRole/@classC ode='INVSBJ']/subjectOf2[@typeCode='SBJ']/organizer/code[@code='3']/@codeSystem='2.16.840.1 113883.3.989.2.1.1.20'[/organizer/@classCode='CATEGORY']/@moodCode='EVN'/component[@typeCode='COMP']/observation/code[@codeSystem='2.16.840.1.113883.6.163']/r/observation/@ classCode='OBS']/@moodCode='EVN'/outboundRelationship[2]/@typeCode='PERT']/observation/co de[@code='10']/@codeSystem='2.16.840.1.113883.3.989.2.1.1.19'[/observation/@classCode='OBS ']/@moodCode='EVN']value[@xsi:type='ED'][/text] </pre>
e	F.r.7	その他の情報	ブール型	Boolean (BL)		値	<pre> /MCCI_IN200100UV01[@ITSVersion='XML_1.0']/@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd'/PORR_IN049016UV/r/controlActProcess[@classCode='CACT']/@moo dCode=EVN'/subject[@typeCode='SUBJ']/investigationEvent[@classCode='INVTG']/@moodCo de=EVN'/component[@typeCode='COMP']/adverseEventAssessment[1]/adverseEventAssessment [classCode='INVTG']/@moodCode='EVN'/subject[1]/typeCode='SBJ'[/primaryRole/@classC ode='INVSBJ']/subjectOf2[@typeCode='SBJ']/organizer/code[@code='3']/@codeSystem='2.16.840.1 113883.3.989.2.1.1.20'[/organizer/@classCode='CATEGORY']/@moodCode='EVN'/component[@typeCode='COMP']/observation/code[@codeSystem='2.16.840.1.113883.6.163']/r/observation/@ classCode='OBS']/@moodCode='EVN'/outboundRelationship[2]/@typeCode='REFR']/observation/co de[@code='25']/@codeSystem='2.16.840.1.113883.3.989.2.1.1.19'[/observation/@classCode='OBS ']/@moodCode='EVN']value[@xsi:type='BL'][/value] </pre>
h	G.k	医薬品情報 (必要に応じ繰り返し)				繰り返し ノード	<pre> /MCCI_IN200100UV01[@ITSVersion='XML_1.0']/@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd'/PORR_IN049016UV/r/controlActProcess[@classCode='CACT']/@moo dCode=EVN'/subject[@typeCode='SUBJ']/investigationEvent[@classCode='INVTG']/@moo de=EVN'/component[@typeCode='COMP']/adverseEventAssessment[1]/adverseEventAssessment [classCode='INVTG']/@moodCode='EVN'/subject[1]/typeCode='SBJ'[/primaryRole/@classC ode='INVSBJ']/subjectOf2[@typeCode='SBJ']/organizer/code[@code='4']/@codeSystem='2.16.840.1 113883.3.989.2.1.1.20'[/organizer/@classCode='CATEGORY']/@moodCode='EVN'/component[@typeCode='COMP']/substanceAdministration[id] </pre>

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e	G.k.1	医薬品関与の位置付け	1N	Coded With Equivalents (CE)	code=Character String (ST)	値	/MCCL_IN200100UV01@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/PDRR_IN049016UV[1]/controlActProcess/@classCode=CACT][@moodCode=EVN]/subject/@typeCode=SUBJ][1]/investigationEvent/@classCode=INVTG][@moodCode=EVN]/component/@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment/@classCode=INVTG][@moodCode=EVN]/component/@typeCode=COMP][causalityAssessment[1]/causalityAssessment/@classCode=OBS][@moodCode=EVN]/subject2/@typeCode=SUBJ]/productUseReference/@classCode=SBADM][@moodCode=EVN]/root=UID drug][value[CE]][@codeSystem=2.16.840.1.113883.3.989.2.1.13]]@code
h	G.k.2	医薬品の識別					
h	G.k.2.1	医薬品の固有識別子/製剤の固有識別子					
e	G.k.2.1.1a	MPIDバージョン日付/番号	M5 ガイド ラインを参照	Coded With Equivalents (CE)	codeSystemVersion=Character String (ST)	値	/MCCL_IN200100UV01@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/PDRR_IN049016UV[1]/investigationEvent/@classCode=CACT][@moodCode=EVN]/subject/@typeCode=SUBJ][1]/investigationEvent/@classCode=INVTG][@moodCode=EVN]/component/@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment/@classCode=INVTG][@moodCode=EVN]/subject1/@typeCode=SUBJ][1]/primaryRole/@classCode=INVSBJ]/subjectO2/@typeCode=SBJ]/organizer/@code=4][@codeSystem=2.16.840.1.113883.3.989.2.1.1.20][1]/organizer/@classCode=CATEGORY][@moodCode=EVN]/component/@typeCode=COMP][substanceAdministration/1][substanceAdministration/@classCode=SBADM][@moodCode=EVN]/consumable/@typeCode=CSM][1]/instanceOfKind/@classCode=INST]/kindOfProduct/@classCode=MMA][1]/determinerCode=KIND]/code/@codeSystem=TBD-MPID]]@codeSystemVersion
e	G.k.2.1.1b	医薬品製品識別子 (MPID)	M5 ガイド ラインを参照	Coded With Equivalents (CE)	code=Character String (ST)	値	/MCCL_IN200100UV01@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/PDRR_IN049016UV[1]/investigationEvent/@classCode=CACT][@moodCode=EVN]/subject/@typeCode=SUBJ][1]/investigationEvent/@classCode=INVTG][@moodCode=EVN]/component/@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment/@classCode=INVTG][@moodCode=EVN]/subject1/@typeCode=SUBJ][1]/primaryRole/@classCode=INVSBJ]/subjectO2/@typeCode=SBJ]/organizer/@code=4][@codeSystem=2.16.840.1.113883.3.989.2.1.1.20][1]/organizer/@classCode=CATEGORY][@moodCode=EVN]/component/@typeCode=COMP][substanceAdministration/1][substanceAdministration/@classCode=SBADM][@moodCode=EVN]/consumable/@typeCode=CSM][1]/instanceOfKind/@classCode=INST]/kindOfProduct/@classCode=MMA][1]/determinerCode=KIND]/code/@codeSystem=TBD-MPID]]@code
e	G.k.2.1.2a	PPRIDバージョン日付/番号	M5 ガイド ラインを参照	Coded With Equivalents (CE)	codeSystemVersion=Character String (ST)	値	/MCCL_IN200100UV01@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/PDRR_IN049016UV[1]/investigationEvent/@classCode=CACT][@moodCode=EVN]/subject/@typeCode=SUBJ][1]/investigationEvent/@classCode=INVTG][@moodCode=EVN]/component/@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment/@classCode=INVTG][@moodCode=EVN]/subject1/@typeCode=SUBJ][1]/primaryRole/@classCode=INVSBJ]/subjectO2/@typeCode=SBJ]/organizer/@code=4][@codeSystem=2.16.840.1.113883.3.989.2.1.1.20][1]/organizer/@classCode=CATEGORY][@moodCode=EVN]/component/@typeCode=COMP][substanceAdministration/1][substanceAdministration/@classCode=SBADM][@moodCode=EVN]/consumable/@typeCode=CSM][1]/instanceOfKind/@classCode=INST]/kindOfProduct/@classCode=MMA][1]/determinerCode=KIND]/code/@codeSystem=TBD-PPRID]]@codeSystemVersion

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e	G.k.2.1.2b	製剤識別子 (PHPID)	M5 ガイド ラインを参 照	Coded With Equivalents (CE)	code=Character String (ST)	/MCC1_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCC1_IN200100UV01.xsd]/PDRR_IN049016UVJr/controlActProcess[@classCode=CACT][@mooc dCode=EVN]/subject[@typeCode=SUBJ][@typeCode=EVN]/investigationEvent[@classCode=INVSIG][@mooc dCode=EVN]/component[@typeCode=COMP][@typeCode=EVN]/subject1[@typeCode=SBJ][@typeCode=EVN]/primaryRole[@classC ode=INVSIG][@typeCode=EVN]/subject1[@typeCode=SBJ][@typeCode=EVN]/organizer[@code=4][@codeSystem=2.16.840.1 113883.3.988.2.1.1.20][@typeCode=CAATEGORY][@moocCode=EVN]/component [1][@typeCode=COMP][@typeCode=EVN]/substanceAdministration[id][@typeCode=EVN]/component [1][@typeCode=EVN]/consumable[@typeCode=CSM][1][instanceOfKind[@classCode=INST]/kind OfProduct[@classCode=MMA][@determinerCode=KIND]/code[@codeSystem=TBD-PhPID][@c ode
e	G.k.2.2	第一次情報源により報告さ れた医薬品名	250AN	Entity Name (EN)	name=Entity Name Part (ENXP)	/MCC1_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCC1_IN200100UV01.xsd]/PDRR_IN049016UVJr/controlActProcess[@classCode=CACT][@mooc dCode=EVN]/subject[@typeCode=SUBJ][@typeCode=EVN]/investigationEvent[@classCode=INVSIG][@mooc dCode=EVN]/component[@typeCode=COMP][@typeCode=EVN]/subject1[@typeCode=SBJ][@typeCode=EVN]/primaryRole[@classC ode=INVSIG][@typeCode=EVN]/subject1[@typeCode=SBJ][@typeCode=EVN]/organizer[@code=4][@codeSystem=2.16.840.1 113883.3.988.2.1.1.20][@typeCode=CAATEGORY][@moocCode=EVN]/component [1][@typeCode=COMP][@typeCode=EVN]/substanceAdministration[id][@typeCode=EVN]/component [1][@typeCode=EVN]/consumable[@typeCode=CSM][1][instanceOfKind[@classCode=INST]/kind OfProduct[@classCode=MMA][@determinerCode=KIND]/name[1]/text()
h	G.k.2.3.r	成分/特定成分の識別子と 含量 (必要に応じ繰り返し)	繰り返し ノード			/MCC1_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCC1_IN200100UV01.xsd]/PDRR_IN049016UVJr/controlActProcess[@classCode=CACT][@mooc dCode=EVN]/subject[@typeCode=SUBJ][@typeCode=EVN]/investigationEvent[@classCode=INVSIG][@mooc dCode=EVN]/component[@typeCode=COMP][@typeCode=EVN]/subject1[@typeCode=SBJ][@typeCode=EVN]/primaryRole[@classC ode=INVSIG][@typeCode=EVN]/subject1[@typeCode=SBJ][@typeCode=EVN]/organizer[@code=4][@codeSystem=2.16.840.1 113883.3.988.2.1.1.20][@typeCode=CAATEGORY][@moocCode=EVN]/component [1][@typeCode=COMP][@typeCode=EVN]/substanceAdministration[id][@typeCode=EVN]/component [1][@typeCode=EVN]/consumable[@typeCode=CSM][1][instanceOfKind[@classCode=INST]/kind OfProduct[@classCode=MMA][@determinerCode=KIND]/ingredient[@classCode=ACT]
e	G.k.2.3.r.1	成分/特定成分名	250AN	Trivial Name (TN)	name=Entity Name Part (ENXP)	/MCC1_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCC1_IN200100UV01.xsd]/PDRR_IN049016UVJr/controlActProcess[@classCode=CACT][@mooc dCode=EVN]/subject[@typeCode=SUBJ][@typeCode=EVN]/investigationEvent[@classCode=INVSIG][@mooc dCode=EVN]/component[@typeCode=COMP][@typeCode=EVN]/subject1[@typeCode=SBJ][@typeCode=EVN]/primaryRole[@classC ode=INVSIG][@typeCode=EVN]/subject1[@typeCode=SBJ][@typeCode=EVN]/organizer[@code=4][@codeSystem=2.16.840.1 113883.3.988.2.1.1.20][@typeCode=CAATEGORY][@moocCode=EVN]/component [1][@typeCode=COMP][@typeCode=EVN]/substanceAdministration[id][@typeCode=EVN]/component [1][@typeCode=EVN]/consumable[@typeCode=CSM][1][instanceOfKind[@classCode=INST]/kind OfProduct[@classCode=MMA][@determinerCode=KIND]/ingredient[@classCode=ACT]

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<p>e</p> <p>G.k.2.3.r.2a</p> <p>成分/特定成分の ID パー ジョン日付/番号</p> <p>M5 ガイド ラインを参 照</p> <p>Coded With Equivalents (CE)</p> <p>codeSystemVersion= Character String (ST)</p> <p>値</p>	<pre>/MCCI_IN200100UV01[@ITSVersion='XML_1.0']/@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd')/P/RR_IN049016UV/r/controlActProcess/@classCode='CACT'[@moo dCode='EVN']/subject/@typeCode='SUBJ'[/investigationEvent/@classCode='INVTG'[@moodCo de='EVN']/component/@typeCode='COMP'[/adverseEventAssessment[1]/adverseEventAssessment /@classCode='INVTG'[@moodCode='EVN']/subject[1]/typeCode='SBJ'[/primaryRole/@class Code='INVSBJ'[/subjectOf2/@typeCode='SBJ'[/organizer/code/@code='4']/@codeSystem='2.16.840.1 13883.3.989.2.1.1.20'[/1]/organizer/@classCode='CATEGORY'[@moodCode='EVN']/component[1]/typeCode='COMP'[/substanceAdministration/id[/k/substanceAdministration]/@classCode='SBADM '[@moodCode='EVN']/consumable/@typeCode='CSMT'[/instanceOfKind/@classCode='INST'[/kind OfProduct/@classCode='MMA'[/determinerCode='KIND'[/ingredient/@classCode='ACT'[/r]/ingre dientSubstance/@classCode='MMA'[/determinerCode='KIND'[/code/@codeSystem='TBD-Substa nce'[/codeSystemVersion]</pre>
<p>e</p> <p>G.k.2.3.r.2b</p> <p>成分/特定成分の ID</p> <p>M5 ガイド ラインを参 照</p> <p>Coded With Equivalents (CE)</p> <p>code=Character String (ST)</p> <p>値</p>	<pre>/MCCI_IN200100UV01[@ITSVersion='XML_1.0']/@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd')/P/RR_IN049016UV/r/controlActProcess/@classCode='CACT'[@moo dCode='EVN']/subject/@typeCode='SUBJ'[/investigationEvent/@classCode='INVTG'[@moodCo de='EVN']/component/@typeCode='COMP'[/adverseEventAssessment[1]/adverseEventAssessment /@classCode='INVTG'[@moodCode='EVN']/subject[1]/typeCode='SBJ'[/primaryRole/@class Code='INVSBJ'[/subjectOf2/@typeCode='SBJ'[/organizer/code/@code='4']/@codeSystem='2.16.840.1 13883.3.989.2.1.1.20'[/1]/organizer/@classCode='CATEGORY'[@moodCode='EVN']/component[1]/typeCode='COMP'[/substanceAdministration/id[/k/substanceAdministration]/@classCode='SBADM '[@moodCode='EVN']/consumable/@typeCode='CSMT'[/instanceOfKind/@classCode='INST'[/kind OfProduct/@classCode='MMA'[/determinerCode='KIND'[/ingredient/@classCode='ACT'[/r]/ingre dientSubstance/@classCode='MMA'[/determinerCode='KIND'[/code/@codeSystem='TBD-Substa nce'[/codeSystemVersion]</pre>
<p>e</p> <p>G.k.2.3.r.3a</p> <p>含量 (数)</p> <p>10N</p> <p>Physical Quantity (PQ)</p> <p>value=Real Number (REAL)</p> <p>値</p>	<pre>/MCCI_IN200100UV01[@ITSVersion='XML_1.0']/@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd')/P/RR_IN049016UV/r/controlActProcess/@classCode='CACT'[@moo dCode='EVN']/subject/@typeCode='SUBJ'[/investigationEvent/@classCode='INVTG'[@moodCo de='EVN']/component/@typeCode='COMP'[/adverseEventAssessment[1]/adverseEventAssessment /@classCode='INVTG'[@moodCode='EVN']/subject[1]/typeCode='SBJ'[/primaryRole/@class Code='INVSBJ'[/subjectOf2/@typeCode='SBJ'[/organizer/code/@code='4']/@codeSystem='2.16.840.1 13883.3.989.2.1.1.20'[/1]/organizer/@classCode='CATEGORY'[@moodCode='EVN']/component[1]/typeCode='COMP'[/substanceAdministration/id[/k/substanceAdministration]/@classCode='SBADM '[@moodCode='EVN']/consumable/@typeCode='CSMT'[/instanceOfKind/@classCode='INST'[/kind OfProduct/@classCode='MMA'[/determinerCode='KIND'[/ingredient/@classCode='ACT'[/r]/quant ity[denominator/@value='1']/numerator/@value]</pre>
<p>e</p> <p>G.k.2.3.r.3b</p> <p>含量 (単位)</p> <p>50AN</p> <p>Physical Quantity (PQ)</p> <p>unit=Coded Simple Value (CS)</p> <p>値</p>	<pre>/MCCI_IN200100UV01[@ITSVersion='XML_1.0']/@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd')/P/RR_IN049016UV/r/controlActProcess/@classCode='CACT'[@moo dCode='EVN']/subject/@typeCode='SUBJ'[/investigationEvent/@classCode='INVTG'[@moodCo de='EVN']/component/@typeCode='COMP'[/adverseEventAssessment[1]/adverseEventAssessment /@classCode='INVTG'[@moodCode='EVN']/subject[1]/typeCode='SBJ'[/primaryRole/@class Code='INVSBJ'[/subjectOf2/@typeCode='SBJ'[/organizer/code/@code='4']/@codeSystem='2.16.840.1 13883.3.989.2.1.1.20'[/1]/organizer/@classCode='CATEGORY'[@moodCode='EVN']/component[1]/typeCode='COMP'[/substanceAdministration/id[/k/substanceAdministration]/@classCode='SBADM '[@moodCode='EVN']/consumable/@typeCode='CSMT'[/instanceOfKind/@classCode='INST'[/kind OfProduct/@classCode='MMA'[/determinerCode='KIND'[/ingredient/@classCode='ACT'[/r]/r]/quant ity[denominator/@value='1']/numerator/@unit]</pre>

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e	G.k.2.4	医薬品を入手した国の識別	2A	Postal Address (AD) country=Address Part (ADXP)	/MCC1_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCC1_IN200100UV01.xsd]/PORR_IN049016UV1/controlActProcess[@classCode=CACT][@moodCode=EVN]/subject/@typeCode=SUBJ[1]/investigationEvent[@classCode=INVESTG][@moodCode=EVN]/component/@typeCode=COMP[1]/adverseEventAssessment[1]/adverseEventAssessment[@classCode=INVESTG][@moodCode=EVN]/subject1/@typeCode=SBJ[1]/primaryRole[@classCode=INVSBJ][@moodCode=EVN]/subjectO2/@typeCode=SBJ[1]/organizer/code=4[1]/codeSystem=2.16.840.1.113883.3.989.2.1.1.20[1]/organizer/@classCode=CATEGORY[1]/substanceAdministration[@classCode=SBADM][@moodCode=EVN]/consumable/@typeCode=CSM[1]/instanceOfKind[@classCode=INST]/subjectOf/@typeCode=SBJ[1]/productEvent[@classCode=ACT][@moodCode=EVN]/code/@code=1[1]/codeSystem=2.16.840.1.113883.3.989.2.1.1.18[1]/performer/@typeCode=PRF[1]/assignedEntity/@classCode=ASSIGNED[1]/representedOrganization/@classCode=ORG[1]/determinerCode=INSTANCE[1]/addr/country[1]/text()
e	G.k.2.5	治験薬の蓄積状況	ブール型	Boolean (BL)	/MCC1_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCC1_IN200100UV01.xsd]/PORR_IN049016UV1/controlActProcess[@classCode=CACT][@moodCode=EVN]/subject/@typeCode=SUBJ[1]/investigationEvent[@classCode=INVESTG][@moodCode=EVN]/component/@typeCode=COMP[1]/adverseEventAssessment[1]/adverseEventAssessment[@classCode=INVESTG][@moodCode=EVN]/subjectO2/@typeCode=SBJ[1]/organizer/code=4[1]/codeSystem=2.16.840.1.113883.3.989.2.1.1.20[1]/organizer/@classCode=CATEGORY[1]/substanceAdministration[@classCode=SBADM][@moodCode=EVN]/outboundRelationship2/@typeCode=PERT[1]/observation/code/@code=6[1]/codeSystem=2.16.840.1.113883.3.989.2.1.1.19[1]/observation/@classCode=OBS[1]/moodCode=EVN[1]/value/@xsi:type=BL[1]/@value
h	G.k.3	医薬品の承認の取得者及び承認/申請番号			/MCC1_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCC1_IN200100UV01.xsd]/PORR_IN049016UV1/controlActProcess[@classCode=CACT][@moodCode=EVN]/subject/@typeCode=SUBJ[1]/investigationEvent[@classCode=INVESTG][@moodCode=EVN]/component/@typeCode=COMP[1]/adverseEventAssessment[1]/adverseEventAssessment[@classCode=INVESTG][@moodCode=EVN]/subjectO2/@typeCode=SBJ[1]/organizer/code=4[1]/codeSystem=2.16.840.1.113883.3.989.2.1.1.20[1]/organizer/@classCode=CATEGORY[1]/substanceAdministration[@classCode=SBADM][@moodCode=EVN]/consumable/@typeCode=CSM[1]/instanceOfKind[@classCode=INST]/kindOfProduct/@classCode=MMA[1]/determinerCode=KIND[1]/asManufacturedProduct/@classCode=MANU[1]/subjectOf/@typeCode=SBJ[1]/approval/@classCode=CNTRCT[1]/moodCode=EVN[1]/id/@root=2.16.840.1.113883.3.989.2.1.3.4[1]/@extension
e	G.k.3.1	承認/申請番号	35AN	Instance Identifier (II) extension=Character String (ST)	

(別添3)

e	G.k.3.2	承認/申請国	2A	Coded With Equivalents (CE)	code=Character String (ST)	値	/MCC1_IN200100UV01[@ITSVersion='XML_1.0']/@xsi:schemaLocation=urn:hl7-org:v3 MCC1_IN200100UV01.xsd/PORR_IN049016UV/r/controlActProcess[@classCode=CACTI]@moodCode=EVN/subject[@typeCode=SUBJ/1]/investigationEvent[@classCode=INVTG]@moodCode=EVN/component[@typeCode=COMP]adverseEventAssessment[1]adverseEventAssessment[@classCode=INVTG]@moodCode=SBJ/1/primaryRole[@classCode=INVSBJ/subjectOf2/@typeCode=SBJ/organizer/code/@code=4]@codeSystem=2.16.840.1.113883.3.989.2.1.1.20/1/organizer/@classCode=CATEGORY/@moodCode=EVN/component/1/@typeCode=COMP]substanceAdministration[id[k]/substanceAdministration/@classCode=SBADM]@moodCode=EVN/consumable/@typeCode=CSMJ/1/instanceOfKind[@classCode=INST]kindOfProduct[@classCode=MMA/1/@determinerCode=KIND/asManufacturedProduct/@classCode=MANU/subjectOf/@typeCode=SBJ/1/approval/@classCode=CNTRCT]@moodCode=EVN/author/@typeCode=AUT/territory/@classCode=TERR/territory/@classCode=NAT]@delete/@typeCode=INSTANCE]/code/@codeSystem=1.0.3166.1.2.2/@code
e	G.k.3.3	承認の取得者/申請者の名称	60AIN	Organization Name (ON)	name=Entity Name Part (ENXP)	値	/MCC1_IN200100UV01[@ITSVersion='XML_1.0']/@xsi:schemaLocation=urn:hl7-org:v3 MCC1_IN200100UV01.xsd/PORR_IN049016UV/r/controlActProcess[@classCode=CACTI]@moodCode=EVN/subject[@typeCode=SUBJ/1]/investigationEvent[@classCode=INVTG]@moodCode=EVN/component[@typeCode=COMP]adverseEventAssessment[1]adverseEventAssessment[@classCode=INVTG]@moodCode=SBJ/1/primaryRole[@classCode=INVSBJ/subjectOf2/@typeCode=SBJ/organizer/code/@code=4]@codeSystem=2.16.840.1.113883.3.989.2.1.1.20/1/organizer/@classCode=CATEGORY/@moodCode=EVN/component/1/@typeCode=COMP]substanceAdministration[id[k]/substanceAdministration/@classCode=SBADM]@moodCode=EVN/consumable/@typeCode=CSMJ/1/instanceOfKind[@classCode=INST]kindOfProduct[@classCode=MMA/1/@determinerCode=KIND/asManufacturedProduct/@classCode=MANU/subjectOf/@typeCode=SBJ/1/approval/@classCode=CNTRCT]@moodCode=EVN/author/@typeCode=HLD/1/role/@classCode=HLD/playingOrganization/@classCode=ORG]@delete/@typeCode=INSTANCE]/name/text()
h	G.k.4.r	投与量及び関連情報 必要に 応じ繰り返す)				繰り返し ノード	/MCC1_IN200100UV01[@ITSVersion='XML_1.0']/@xsi:schemaLocation=urn:hl7-org:v3 MCC1_IN200100UV01.xsd/PORR_IN049016UV/r/controlActProcess[@classCode=CACTI]@moodCode=EVN/subject[@typeCode=SUBJ/1]/investigationEvent[@classCode=INVTG]@moodCode=EVN/component[@typeCode=COMP]adverseEventAssessment[1]adverseEventAssessment[@classCode=INVTG]@moodCode=SBJ/1/primaryRole[@classCode=INVSBJ/subjectOf2/@typeCode=SBJ/organizer/code/@code=4]@codeSystem=2.16.840.1.113883.3.989.2.1.1.20/1/organizer/@classCode=CATEGORY/@moodCode=EVN/component/1/@typeCode=COMP]substanceAdministration[id[k]/substanceAdministration/@classCode=SBADM]@moodCode=EVN/outboundRelationship2[@typeCode=COMP]substanceAdministration]
e	G.k.4.r.1a	投与量 (数)	8N	Physical Quantity (PQ)	value=Real Number (REAL)	値	/MCC1_IN200100UV01[@ITSVersion='XML_1.0']/@xsi:schemaLocation=urn:hl7-org:v3 MCC1_IN200100UV01.xsd/PORR_IN049016UV/r/controlActProcess[@classCode=CACTI]@moodCode=EVN/subject[@typeCode=SUBJ/1]/investigationEvent[@classCode=INVTG]@moodCode=EVN/component[@typeCode=COMP]adverseEventAssessment[1]adverseEventAssessment[@classCode=INVTG]@moodCode=SBJ/1/primaryRole[@classCode=INVSBJ/subjectOf2/@typeCode=SBJ/organizer/code/@code=4]@codeSystem=2.16.840.1.113883.3.989.2.1.1.20/1/organizer/@classCode=CATEGORY/@moodCode=EVN/component/1/@typeCode=COMP]substanceAdministration[id[k]/substanceAdministration/@classCode=SBADM]@moodCode=EVN/outboundRelationship2[@typeCode=COMP]substanceAdministration]

(別添 3)

<p>e</p>	<p>value=Real Number (REAL)</p>	<p>B.4.k.4.r.3 の単位が 合計の場合： Physical Quantity (PQ)</p>	<p>AMCCL_IN200100UV01[ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCCL_IN200100UV01.xsd]/PORR_IN049016UV1/controlActProcess[@classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUBJ][investigationEvent[@classCode=INVESTG][@moodCode=EVN]/component[@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment[@classCode=INVESTG][@moodCode=EVN]/subject1[@typeCode=SBJ][1]/primaryRole[@classCode=INVSBJ]/subjectO2[@typeCode=SBJ]/organizer/code[@code=4][@codesSystem=2.16.840.1.113883.3.989.2.1.1.20][1]/organizer[@classCode=CATEGORY][@moodCode=EVN]/component[1][@moodCode=COMP][substanceAdministration[id][k]/substanceAdministration[@classCode=SBADM][@typeCode=COMP][substanceAdministration[2][@typeCode=COMP][substanceAdministration][r]/substanceAdministration[@classCode=SBADM][@numerator/@xsi:type=PQ][@value</p>
<p>e</p>	<p>unit=Coded Simple Value (CS)</p>	<p>Physical Quantity (PQ)</p>	<p>50AN 投与量 (単位)</p>
<p>e</p>	<p>unit=Coded Simple Value (CS)</p>	<p>B.4.k.4.r.3 の単位が 合計の場合： Physical Quantity (PQ)</p>	<p>AMCCL_IN200100UV01[ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCCL_IN200100UV01.xsd]/PORR_IN049016UV1/controlActProcess[@classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUBJ][investigationEvent[@classCode=INVESTG][@moodCode=EVN]/component[@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment[@classCode=INVESTG][@moodCode=EVN]/subject1[@typeCode=SBJ][1]/primaryRole[@classCode=INVSBJ]/subjectO2[@typeCode=SBJ]/organizer/code[@code=4][@codesSystem=2.16.840.1.113883.3.989.2.1.1.20][1]/organizer[@classCode=CATEGORY][@moodCode=EVN]/component[1][@moodCode=COMP][substanceAdministration[id][k]/substanceAdministration[@classCode=SBADM][@typeCode=COMP][substanceAdministration[2][@typeCode=COMP][substanceAdministration][r]/substanceAdministration[@classCode=SBADM][@numerator/@xsi:type=PQ][@unit</p>

<p>e</p> <p>G.k.4.r.2</p> <p>投与間隔の単位数</p>	<p>4N</p>	<p>1.以下のデータ項目の2つを超える値が表示される場合:</p> <ol style="list-style-type: none"> G.k.4.r.2, G.k.4.r.3 G.k.4.r.4 G.k.4.r.5 G.k.4.r.6a, G.k.4.r.6b <p>データ型 SXPР を伴う最初の comp 項目</p> <p>Parenthetic Set Expression of Time (SXPР_TS) [Periodic Interval of Time (PVL_TS)]</p>	<p>値</p> <p>period/value=Real Number (REAL)</p>	<pre>/MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3:MCCI_IN200100UV01.xsd]/PORR_IN049016UV/r/controlActProcess[@classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUBJ][1]/investigationEvent[@classCode=INVTG][@moodCode=EVN]/component[@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment[@classCode=INVTG][@moodCode=EVN]/subject1[@typeCode=SBJ][1]/primaryRole[@classCode=INVSBJ]/subjectOf2[@typeCode=SBJ][organizer/code[@code=4]][@codeSystem=2,16,840,113883,3,989,2,1,1,20][1]/organizer[@classCode=CATEGORY][@moodCode=EVN]/component[@typeCode=COMP][substanceAdministration[id][k]/substanceAdministration[@classCode=SBADM][@moodCode=EVN]/outboundRelationship2[@typeCode=COMP][substanceAdministration][r]/substanceAdministration[@classCode=SBADM][@moodCode=EVN]/effectiveTime[@xsi:type=SXPР_TS]/comp[@xsi:type=PVL_TS]/period/@value</pre>
<p>e</p> <p>G.k.4.r.2</p> <p>投与間隔の単位数</p>	<p>4N</p>	<p>2.以下のデータ項目の2つを超える値が表示される場合:</p> <ol style="list-style-type: none"> G.k.4.r.2, G.k.4.r.3 G.k.4.r.4 G.k.4.r.5 G.k.4.r.6a, G.k.4.r.6b <p>データ型 SXPР を伴う2番目の comp 項目</p> <p>Parenthetic Set Expression of Time (SXPР_TS) [Periodic Interval of Time (PVL_TS)]</p>	<p>値</p>	<pre>/MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3:MCCI_IN200100UV01.xsd]/PORR_IN049016UV/r/controlActProcess[@classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUBJ][1]/investigationEvent[@classCode=INVTG][@moodCode=EVN]/component[@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment[@classCode=INVTG][@moodCode=EVN]/subject1[@typeCode=SBJ][1]/primaryRole[@classCode=INVSBJ]/subjectOf2[@typeCode=SBJ][organizer/code[@code=4]][@codeSystem=2,16,840,113883,3,989,2,1,1,20][1]/organizer[@classCode=CATEGORY][@moodCode=EVN]/component[@typeCode=COMP][substanceAdministration[id][k]/substanceAdministration[@classCode=SBADM][@moodCode=EVN]/outboundRelationship2[@typeCode=COMP][substanceAdministration][r]/substanceAdministration[@classCode=SBADM][@moodCode=EVN]/effectiveTime[@xsi:type=SXPР_TS]/comp[@xsi:type=PVL_TS][@operator=A]/period/@value</pre>

<p>3.以下の子ータ項目の1つの値のみが表示される場合</p> <ol style="list-style-type: none"> 1) G.k.4.r.2、G.k.4.r.3 2) G.k.4.r.4 3) G.k.4.r.5 4) G.k.4.r.6a、G.k.4.r.6b <p>Periodic Interval of Time (PVL_TS)</p>	<p>値</p> <p>period/value=Real Number (REAL)</p>	<pre> /MCCI_IN200100UV01[@ITSVersion='XML_1.0']/@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd'/PORR_IN049016UV/r/controlActProcess[@classCode='CACT']/@moodCode='EVN']/subject[@typeCode='SUBJ']/investigationEvent[@classCode='INVTG']/@moodCode='EVN']/component[@typeCode='COMP']/adverseEventAssessment[1]/adverseEventAssessment[@classCode='INVSBJ']/subjectOf2[@typeCode='EVN']/subject[1]/organizer/code[@code='4']/@codesSystem='2.16.840.1.113883.3.988.2.1.1.20']/organizer[@classCode='CATEGORY']/@moodCode='EVN']/component[1]/typeCode='COMP']/substanceAdministration[id]/substanceAdministration[@classCode='SBADM']/@moodCode='EVN']/youthboundRelationship2[@typeCode='COMP']/substanceAdministration[id]/substanceAdministration[@classCode='SBADM']/@moodCode='EVN']/effectiveTime/@xsi:type='PVL_TS']/period/@value </pre>
<p>1.以下の子ータ項目の2つの値が表示される場合</p> <ol style="list-style-type: none"> 1) G.k.4.r.2、G.k.4.r.3 2) G.k.4.r.4 3) G.k.4.r.5 4) G.k.4.r.6a、G.k.4.r.6b <p>50AN</p> <p>投与間隔の定義</p>	<p>値</p> <p>period/unit=Coded Simple Value (CS)</p>	<pre> /MCCI_IN200100UV01[@ITSVersion='XML_1.0']/@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd'/PORR_IN049016UV/r/controlActProcess[@classCode='CACT']/@moodCode='EVN']/subject[@typeCode='SUBJ']/investigationEvent[@classCode='INVTG']/@moodCode='EVN']/component[@typeCode='COMP']/adverseEventAssessment[1]/adverseEventAssessment[@classCode='INVSBJ']/subjectOf2[@typeCode='EVN']/subject[1]/organizer/code[@code='4']/@codesSystem='2.16.840.1.113883.3.988.2.1.1.20']/organizer[@classCode='CATEGORY']/@moodCode='EVN']/component[1]/typeCode='COMP']/substanceAdministration[id]/substanceAdministration[@classCode='SBADM']/@moodCode='EVN']/youthboundRelationship2[@typeCode='COMP']/substanceAdministration[id]/substanceAdministration[@classCode='SBADM']/@moodCode='EVN']/effectiveTime/@xsi:type='SXPR_TS']/comp/@xsi:type='PVL_TS']/period/@unit </pre>
<p>データ型 SXPR を伴う最初の comp 項目</p> <p>Parenthetic Set Expression of Time (SXPR_TS)</p> <p>[Periodic Interval of Time (PVL_TS)]</p>		

<p>2.以下の子ータ項目の2つを超える値が表示される場合:</p> <ol style="list-style-type: none"> 1) G.k.4.r.2, G.k.4.r.3 2) G.k.4.r.4 3) G.k.4.r.5 4) G.k.4.r.6a, G.k.4.r.6b <p>子ータ型 SXPX を伴う 2 番目の comp 項目</p> <p>Parenthetic Set Expression of Time (SXPX_TS) Periodic Interval of Time (PVL_TS)</p>	<p>値</p> <pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:n7-org:v3 MCCL_IN200100UV01.xsd]/PQRR_IN049016UV/r/controlActProcess[@classCode=CACT][@mo dCode=EVN]/subject/@typeCode="SUBJ"/investigationEvent[@classCode=INVSTG][@moodCo de=EVN]/component/@typeCode=COMP/adverseEventAssessment[1]/adverseEventAssessment [1]/classCode=INVSTG[@moodCode=EVN]/subject[1]/typeCode=SBJ[1]/primaryRole[1]/classC ode=INVSBJ[1]/subjectOid[1]/typeCode=SBJ[1]/organizer/code[@code=4][@codeSystem=2.16.840.1 13883.3.989.2.1.1.20][1]/organizer/@classCode=CATEGORY[1]/moodCode=EVN/component[1]/typeCode=COMP[1]/substanceAdministration[id]/k/substanceAdministration[1]/@classCode=SBADM [1]/moodCode=EVN[1]/outboundRelationship[2]/typeCode=COMP[1]/substanceAdministration[r]/sub stanceAdministration[1]/classCode=SBADM[1]/@moodCode=EVN[1]/effectiveTime[1]/@xsi:type=SXPX_ TS]/comp[1]/@xsi:type=PVL_TS[1]/operator=A/period/@unit </pre>
<p>3.以下の子ータ項目の1つの値のみが表示される場合</p> <ol style="list-style-type: none"> 1) G.k.4.r.2, G.k.4.r.3 2) G.k.4.r.4 3) G.k.4.r.5 4) G.k.4.r.6a, G.k.4.r.6b <p>Periodic Interval of Time (PVL_TS)</p>	<p>値</p> <pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:n7-org:v3 MCCL_IN200100UV01.xsd]/PQRR_IN049016UV/r/controlActProcess[@classCode=CACT][@mo dCode=EVN]/subject/@typeCode="SUBJ"/investigationEvent[@classCode=INVSTG][@moodCo de=EVN]/component/@typeCode=COMP[1]/adverseEventAssessment[1]/adverseEventAssessment [1]/classCode=INVSTG[1]/moodCode=EVN[1]/subject[1]/typeCode=SBJ[1]/primaryRole[1]/classC ode=INVSBJ[1]/subjectOid[1]/typeCode=SBJ[1]/organizer/code[@code=4][@codeSystem=2.16.840.1 13883.3.989.2.1.1.20][1]/organizer/@classCode=CATEGORY[1]/moodCode=EVN[1]/component[1]/typeCode=COMP[1]/substanceAdministration[id]/k/substanceAdministration[1]/@classCode=SBADM [1]/moodCode=EVN[1]/outboundRelationship[2]/typeCode=COMP[1]/substanceAdministration[r]/sub stanceAdministration[1]/classCode=SBADM[1]/@moodCode=EVN[1]/effectiveTime[1]/@xsi:type=PVL_ TS]/period/@unit </pre> <p>period/unit=Coded Simple Value (CS)</p>

<p>e</p> <p>G.k.4.r.4</p> <p>医薬品の投与開始日</p>	<p>日付/時間</p>	<p>1.以下の子データ項目の2つを超える値が表示される場合:</p> <ul style="list-style-type: none"> 1) G.k.4.r.2, G.k.4.r.3 2) G.k.4.r.4 3) G.k.4.r.5 4) G.k.4.r.6a, G.k.4.r.6b <p>データ型 SXPР を伴う最初の comp 項目</p> <p>Parenthetic Set Expression of Time (SXPР_TS) [Interval of Point in Time (IVL_TS)]</p>	<p>low=Interval Boundary (IVXB)</p>	<p>値</p> <pre> /MCCL_IN200100UV01[@ITSVersion='XML_1.0']/@xsi:schemaLocation='urn:hl7-org:v3 /MCCL_IN200100UV01.xsd/yPQRR_IN049016UV/r/controlActProcess/@classCode='CACT']/@moodCode='EVN']/subject/@typeCode='SUBJ']/investigationEvent/@classCode='INVESTG']/@moodCode='EVN']/component/@typeCode='COMP']/adverseEventAssessment[1]/adverseEventAssessment/@classCode='INVESTG']/@moodCode='EVN']/subject1/@typeCode='SBJ']/primaryRole/@classCode='INVSBJ']/subjectO2/@typeCode='SBJ']/organizer/code/@code='4']/@codesSystem='2.16.840.1.113883.3.989.2.1.1.20']/organizer/@classCode='CATEGORY']/@moodCode='EVN']/component/@typeCode='COMP']/substanceAdministration[id]/substanceAdministration/@classCode='SBADM']/@moodCode='EVN']/outboundRelationship2/@typeCode='COMP']/substanceAdministration/@classCode='SBADM']/@moodCode='EVN']/effectiveTime/@xsi:type='SXPР_TS']/comp[@xsi:type='IVL_TS']/low/@value </pre>	<pre> /MCCL_IN200100UV01[@ITSVersion='XML_1.0']/@xsi:schemaLocation='urn:hl7-org:v3 /MCCL_IN200100UV01.xsd/yPQRR_IN049016UV/r/controlActProcess/@classCode='CACT']/@moodCode='EVN']/subject/@typeCode='SUBJ']/investigationEvent/@classCode='INVESTG']/@moodCode='EVN']/component/@typeCode='COMP']/adverseEventAssessment[1]/adverseEventAssessment/@classCode='INVESTG']/@moodCode='EVN']/subject1/@typeCode='SBJ']/primaryRole/@classCode='INVSBJ']/subjectO2/@typeCode='SBJ']/organizer/code/@code='4']/@codesSystem='2.16.840.1.113883.3.989.2.1.1.20']/organizer/@classCode='CATEGORY']/@moodCode='EVN']/component/@typeCode='COMP']/substanceAdministration[id]/substanceAdministration/@classCode='SBADM']/@moodCode='EVN']/outboundRelationship2/@typeCode='COMP']/substanceAdministration/@classCode='SBADM']/@moodCode='EVN']/effectiveTime/@xsi:type='SXPР_TS']/comp[@xsi:type='IVL_TS']/low/@nullFlavor </pre> <p>NullFlavor</p>
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<p>2.以下のデータ項目の2つを超える値が表示される場合:</p> <ul style="list-style-type: none"> 1) G.k.4.r.2, G.k.4.r.3 2) G.k.4.r.4 3) G.k.4.r.5 4) G.k.4.r.8a, G.k.4.r.6b <p>データ型 SXPР を伴う 2 番目の comp 項目</p> <p>Parenthetic Set Expression of Time (SXPР_TS) [Interval of Point in Time (IVL_TS)]</p>	<p>値</p>	<pre> /MCCL_IN200100UV01[@ITSVersion='XML_1.0']/@xsi:schemaLocation='urn:hl7-org:v3 MCCL_IN200100UV01.xsd']/PORR_IN049016UV/r/controlActProcess[@classCode='CACT']/@moodCode=EVN']/subject[@typeCode='SUBJ']/investigationEvent[@classCode='INVTG']/@moodCode=EVN']/component[@typeCode='COMP']/adverseEventAssessment[1]/adverseEventAssessment[@classCode='INVTG']/@moodCode=EVN']/subject1[@typeCode='SBJ']/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ']/organizer/code[@code=4]/@codeSystem='2.16.840.1.113883.3.989.2.1.1.20'[1]/organizer/@classCode='CATEGORY']/@moodCode='EVN']/component[1]/typeCode='COMP']/substanceAdministration[id][k]/substanceAdministration[@classCode='SBADM']/@moodCode=EVN']/youtboundRelationship2[@typeCode='COMP']/substanceAdministration[id][k]/substanceAdministration[@classCode='SBADM']/@moodCode=EVN']/effectiveTime[@xsi:type='SXPР_TS']/comp[@xsi:type='IVL_TS']/@operator='A']/flow/@value </pre>
	<p>NullFlavor</p>	<pre> /MCCL_IN200100UV01[@ITSVersion='XML_1.0']/@xsi:schemaLocation='urn:hl7-org:v3 MCCL_IN200100UV01.xsd']/PORR_IN049016UV/r/controlActProcess[@classCode='CACT']/@moodCode=EVN']/subject[@typeCode='SUBJ']/investigationEvent[@classCode='INVTG']/@moodCode=EVN']/component[@typeCode='COMP']/adverseEventAssessment[1]/adverseEventAssessment[@classCode='INVTG']/@moodCode=EVN']/subject1[@typeCode='SBJ']/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ']/organizer/code[@code=4]/@codeSystem='2.16.840.1.113883.3.989.2.1.1.20'[1]/organizer/@classCode='CATEGORY']/@moodCode='EVN']/component[1]/typeCode='COMP']/substanceAdministration[id][k]/substanceAdministration[@classCode='SBADM']/@moodCode=EVN']/youtboundRelationship2[@typeCode='COMP']/substanceAdministration[id][k]/substanceAdministration[@classCode='SBADM']/@moodCode=EVN']/effectiveTime[@xsi:type='SXPР_TS']/comp[@xsi:type='IVL_TS']/@operator='A']/flow/@nullFlavor </pre>

(別添3)

<p>e</p> <p>3. 以下の子データ項目の1つの値のみが表示される場合</p> <ol style="list-style-type: none"> 1) G.k.4.r.2, G.k.4.r.3 2) G.k.4.r.4 3) G.k.4.r.5 4) G.k.4.r.6a, G.k.4.r.6b <p>Interval of Point in Time (IVL_TS)</p>	<p>値</p> <p>low=Interval Boundary (IVXB)</p>	<pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]P_ORR_IN049016UV(r)/controlActProcess/@classCode=CACT][@moo dCode=EVN]/subject/@typeCode=SUBJ[1]/investigationEvent/@classCode=INVTG][@moo dCode=EVN]/component/@typeCode=COMP[1]adverseEventAssessment[1]/adverseEventAssessment [@classCode=INVTG][@moodCode=EVN]/subject1/@typeCode=SBJ[1]/primaryRole/@classC ode=INVSBJ]/subjectOf2/@typeCode=SBJ]/organizer/@code=4][@codeSystem=2.16.840.1 .113883.3.989.2.1.1.20][1]/organizer/@classCode=CATEGORY][@moodCode=EVN]/component [1].113883.3.989.2.1.1.20][1]/organizer/@classCode=CATEGORY][@moodCode=EVN]/component [1]/typeCode=COMP][substanceAdministration[id][K]/substanceAdministration/@classCode=SBADM][@moodCode=EVN]/youtboundRelationship2[1/@typeCode=COMP][substanceAdministration]/sub stanceAdministration/@classCode=SBADM][@moodCode=EVN]/effectiveTime/@xsi:type=IVL_TS]/low/@value </pre>
<p>e</p> <p>1. 以下の子データ項目の2つを超える値が表示される場合:</p> <ol style="list-style-type: none"> 1) G.k.4.r.2, G.k.4.r.3 2) G.k.4.r.4 3) G.k.4.r.5 4) G.k.4.r.6a, G.k.4.r.6b <p>日付/時間</p> <p>G.k.4.r.5 医薬品の投与終了日</p>	<p>NullFlavor</p>	<pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]P_ORR_IN049016UV(r)/controlActProcess/@classCode=CACT][@moo dCode=EVN]/subject/@typeCode=SUBJ[1]/investigationEvent/@classCode=INVTG][@moodCo de=EVN]/component/@typeCode=COMP[1]adverseEventAssessment[1]/adverseEventAssessment [@classCode=INVTG][@moodCode=EVN]/subject1/@typeCode=SBJ[1]/primaryRole/@classC ode=INVSBJ]/subjectOf2/@typeCode=SBJ]/organizer/@code=4][@codeSystem=2.16.840.1 .113883.3.989.2.1.1.20][1]/organizer/@classCode=CATEGORY][@moodCode=EVN]/component [1].113883.3.989.2.1.1.20][1]/organizer/@classCode=CATEGORY][@moodCode=EVN]/component [1]/typeCode=COMP][substanceAdministration[id][K]/substanceAdministration/@classCode=SBADM][@moodCode=EVN]/youtboundRelationship2[1/@typeCode=COMP][substanceAdministration]/sub stanceAdministration/@classCode=SBADM][@moodCode=EVN]/effectiveTime/@xsi:type=IVL_TS]/low/@nullFlavor </pre>
<p>e</p> <p>日付/時間</p> <p>G.k.4.r.5 医薬品の投与終了日</p>	<p>値</p> <p>high=Interval Boundary (IVXB)</p>	<pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]P_ORR_IN049016UV(r)/controlActProcess/@classCode=CACT][@moo dCode=EVN]/subject/@typeCode=SUBJ[1]/investigationEvent/@classCode=INVTG][@moodCo de=EVN]/component/@typeCode=COMP[1]adverseEventAssessment[1]/adverseEventAssessment [@classCode=INVTG][@moodCode=EVN]/subject1/@typeCode=SBJ[1]/primaryRole/@classC ode=INVSBJ]/subjectOf2/@typeCode=SBJ]/organizer/@code=4][@codeSystem=2.16.840.1 .113883.3.989.2.1.1.20][1]/organizer/@classCode=CATEGORY][@moodCode=EVN]/component [1].113883.3.989.2.1.1.20][1]/organizer/@classCode=CATEGORY][@moodCode=EVN]/component [1]/typeCode=COMP][substanceAdministration[id][K]/substanceAdministration/@classCode=SBADM][@moodCode=EVN]/youtboundRelationship2[1/@typeCode=COMP][substanceAdministration]/sub stanceAdministration/@classCode=SBADM][@moodCode=EVN]/effectiveTime/@xsi:type=IXPR_ TS]/comp/@xsi:type=IVL_TS]/high/@value </pre>

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<pre> /MCCI_IN200100UV01/@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UV/p/controlActProcess/@classCode=CACT][@moodCode=EVN]/subject/@typeCode=SUBJ][1]/investigationEvent/@classCode=INVTG][@moodCode=EVN]/component/@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment/@classCode=INVTG][@typeCode=EVN]/subject/@typeCode=SBJ][1]/primaryRole/@classCode=INVSBJ]/subjectOr2/@typeCode=SBJ][organizer/@code=4][@codeSystem=2.16.840.1.113883.3.989.2.1.1.20][1]/organizer/@classCode=CATEGORY][@moodCode=EVN]/component/@typeCode=COMP][substanceAdministration/fd][k]/substanceAdministration/@classCode=SBADM][@moodCode=EVN]/outboundRelationship2/@typeCode=COMP][substanceAdministration/@classCode=SBADM][@moodCode=EVN]/effectiveTime/@xsi:type=SXPR_TS][comp/@xsi:type=IVL_TS]/high/@nullFlavor </pre>	<p>NullFlavor</p>	
<pre> /MCCI_IN200100UV01/@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UV/p/controlActProcess/@classCode=CACT][@moodCode=EVN]/subject/@typeCode=SUBJ][1]/investigationEvent/@classCode=INVTG][@moodCode=EVN]/component/@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment/@classCode=INVTG][@typeCode=EVN]/subject/@typeCode=SBJ][1]/primaryRole/@classCode=INVSBJ]/subjectOr2/@typeCode=SBJ][organizer/@code=4][@codeSystem=2.16.840.1.113883.3.989.2.1.1.20][1]/organizer/@classCode=CATEGORY][@moodCode=EVN]/component/@typeCode=COMP][substanceAdministration/fd][k]/substanceAdministration/@classCode=SBADM][@moodCode=EVN]/outboundRelationship2/@typeCode=COMP][substanceAdministration/@classCode=SBADM][@moodCode=EVN]/effectiveTime/@xsi:type=SXPR_TS][comp/@xsi:type=IVL_TS][@operator=A]/high/@value </pre>	<p>NullFlavor</p>	
<pre> /MCCI_IN200100UV01/@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UV/p/controlActProcess/@classCode=CACT][@moodCode=EVN]/subject/@typeCode=SUBJ][1]/investigationEvent/@classCode=INVTG][@moodCode=EVN]/component/@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment/@classCode=INVTG][@typeCode=EVN]/subject/@typeCode=SBJ][1]/primaryRole/@classCode=INVSBJ]/subjectOr2/@typeCode=SBJ][organizer/@code=4][@codeSystem=2.16.840.1.113883.3.989.2.1.1.20][1]/organizer/@classCode=CATEGORY][@moodCode=EVN]/component/@typeCode=COMP][substanceAdministration/fd][k]/substanceAdministration/@classCode=SBADM][@moodCode=EVN]/outboundRelationship2/@typeCode=COMP][substanceAdministration/@classCode=SBADM][@moodCode=EVN]/effectiveTime/@xsi:type=SXPR_TS][comp/@xsi:type=IVL_TS][@operator=A]/high/@nullFlavor </pre>	<p>NullFlavor</p>	

2.以下のデータ項目の2つを超える値が表示される場合:

- 1) G.k.4.r.2, G.k.4.r.3
- 2) G.k.4.r.4
- 3) G.k.4.r.5
- 4) G.k.4.r.6a, G.k.4.r.6b

データ型 SXPR を伴う 2 番目の comp 項目

Parentetic Set Expression of Time (SXPR_TS)
[Intervale of Point in Time (IVL_TS)]

<p>3. 以下の子データ項目の1つの値のみが表示される場合</p> <ol style="list-style-type: none"> 1) G.k.4.r.2, G.k.4.r.3 2) G.k.4.r.4 3) G.k.4.r.5 4) G.k.4.r.6a, G.k.4.r.6b <p>Interval of Point in Time (IVL_TS)</p>	<p>high=Interval Boundary (IVXB)</p>	<p>値</p>	<pre> /MCCI_IN200100UV01[@ITSVersion='XML_1.0']/@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd')/PORR_IN049016UV/r/controlActProcess[@classCode='CACT']/@moodCode=EVN/subject/@typeCode='SUBJ'/investigationEvent/@classCode='INVTG'/@moodCode=EVN/subject/@typeCode='SUBJ'/adverseEventAssessment/primaryRole/@classCode='INVTG'/@moodCode=EVN/subject/@typeCode='SUBJ'/organizer/code/@code=4/@codeSystem=2.16.840.1.113883.3.989.2.1.1.20/organizer/@classCode='CATEGORY'/@moodCode='EVN'/component/@typeCode='COMP'/@substanceAdministration/id/@typeCode='SBADM'/@moodCode='SBADM'/@moodCode='EVN'/youthboundRelationship2/@typeCode='COMP'/@substanceAdministration/r/substanceAdministration/@classCode='SBADM'/@moodCode='EVN'/effectiveTime/@xsi:type='IVL_TS'/'high/@value </pre>
<p>Interval of Point in Time (IVL_TS)</p>	<p>width=value=Real Number (REAL)</p>	<p>値</p>	<pre> /MCCI_IN200100UV01[@ITSVersion='XML_1.0']/@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd')/PORR_IN049016UV/r/controlActProcess[@classCode='CACT']/@moodCode=EVN/subject/@typeCode='SUBJ'/investigationEvent/@classCode='INVTG'/@moodCode=EVN/subject/@typeCode='SUBJ'/adverseEventAssessment/primaryRole/@classCode='INVTG'/@moodCode=EVN/subject/@typeCode='SUBJ'/organizer/code/@code=4/@codeSystem=2.16.840.1.113883.3.989.2.1.1.20/organizer/@classCode='CATEGORY'/@moodCode='EVN'/component/@typeCode='COMP'/@substanceAdministration/id/@typeCode='SBADM'/@moodCode='SBADM'/@moodCode='EVN'/youthboundRelationship2/@typeCode='COMP'/@substanceAdministration/r/substanceAdministration/@classCode='SBADM'/@moodCode='EVN'/effectiveTime/@xsi:type='IVL_TS'/'high/@value </pre>
<p>1. 以下の子データ項目の2つを超える値が表示される場合:</p> <ol style="list-style-type: none"> 1) G.k.4.r.2, G.k.4.r.3 2) G.k.4.r.4 3) G.k.4.r.5 4) G.k.4.r.6a, G.k.4.r.6b <p>データ型 SXPР を伴う最初の comp 項目</p> <p>Parenthetic Set Expression of Time (SXPР_TS) [Interval of Point in Time (IVL_TS)]</p>	<p>width=value=Real Number (REAL)</p>	<p>値</p>	<pre> /MCCI_IN200100UV01[@ITSVersion='XML_1.0']/@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd')/PORR_IN049016UV/r/controlActProcess[@classCode='CACT']/@moodCode=EVN/subject/@typeCode='SUBJ'/investigationEvent/@classCode='INVTG'/@moodCode=EVN/subject/@typeCode='SUBJ'/adverseEventAssessment/primaryRole/@classCode='INVTG'/@moodCode=EVN/subject/@typeCode='SUBJ'/organizer/code/@code=4/@codeSystem=2.16.840.1.113883.3.989.2.1.1.20/organizer/@classCode='CATEGORY'/@moodCode='EVN'/component/@typeCode='COMP'/@substanceAdministration/id/@typeCode='SBADM'/@moodCode='SBADM'/@moodCode='EVN'/youthboundRelationship2/@typeCode='COMP'/@substanceAdministration/r/substanceAdministration/@classCode='SBADM'/@moodCode='EVN'/effectiveTime/@xsi:type='IVL_TS'/'width/@value </pre>
<p>G.k.4.r.6a</p> <p>医薬品投与期間 (数)</p> <p>5N</p>	<p>width=value=Real Number (REAL)</p>	<p>値</p>	<pre> /MCCI_IN200100UV01[@ITSVersion='XML_1.0']/@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd')/PORR_IN049016UV/r/controlActProcess[@classCode='CACT']/@moodCode=EVN/subject/@typeCode='SUBJ'/investigationEvent/@classCode='INVTG'/@moodCode=EVN/subject/@typeCode='SUBJ'/adverseEventAssessment/primaryRole/@classCode='INVTG'/@moodCode=EVN/subject/@typeCode='SUBJ'/organizer/code/@code=4/@codeSystem=2.16.840.1.113883.3.989.2.1.1.20/organizer/@classCode='CATEGORY'/@moodCode='EVN'/component/@typeCode='COMP'/@substanceAdministration/id/@typeCode='SBADM'/@moodCode='SBADM'/@moodCode='EVN'/youthboundRelationship2/@typeCode='COMP'/@substanceAdministration/r/substanceAdministration/@classCode='SBADM'/@moodCode='EVN'/effectiveTime/@xsi:type='IVL_TS'/'width/@value </pre>

<p>2. 以下のデータ項目の2つを代入する値が表示される場合:</p> <ol style="list-style-type: none"> 1) G.k.4.r.2, G.k.4.r.3 2) G.k.4.r.4 3) G.k.4.r.5 4) G.k.4.r.6a, G.k.4.r.6b <p>データ型 SXPR を伴う 2 番目の comp 項目</p> <p>Parenthetic Set Expression of Time (SXPR_TS) [Intervale of Point in Time (IVL_TS)]</p>	<p>値</p>	<pre> /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUBJ][1]/investigationEvent[@classCode=INVTG][@moodCode=EVN]/component[@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment[@classCode=INVTG][@moodCode=EVN]/subject[1]/primaryRole[@classCode=INVSBJ]/subjectOrZi[@typeCode=SBJ][organizer/code[@code=4]][@codeSystem=2.16.840.1.113883.3.989.2.1.1.20][1]/organizer[@classCode=CATEGORY][@moodCode=EVN]/component[1]/typeCode=COMP][substanceAdministration/d[k]/substanceAdministration[@classCode=SBADM][@moodCode=EVN]/outboundRelationship2[@typeCode=COMP][substanceAdministration/r]/substanceAdministration[@classCode=SBADM][@moodCode=EVN]/effectiveTime[@xsi:type=IVL_TS][@operator=A]/width/@value </pre>
<p>3. 以下のデータ項目の1つの値のみが表示される場合</p> <ol style="list-style-type: none"> 1) G.k.4.r.2, G.k.4.r.3 2) G.k.4.r.4 3) G.k.4.r.5 4) G.k.4.r.6a, G.k.4.r.6b <p>Interval of Point in Time (IVL_TS)</p>	<p>値</p> <p>width/value=Real Number (REAL)</p>	<pre> /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUBJ][1]/investigationEvent[@classCode=INVTG][@moodCode=EVN]/component[@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment[@classCode=INVTG][@moodCode=EVN]/subject[1]/primaryRole[@classCode=INVSBJ]/subjectOrZi[@typeCode=SBJ][organizer/code[@code=4]][@codeSystem=2.16.840.1.113883.3.989.2.1.1.20][1]/organizer[@classCode=CATEGORY][@moodCode=EVN]/component[1]/typeCode=COMP][substanceAdministration/d[k]/substanceAdministration[@classCode=SBADM][@moodCode=EVN]/outboundRelationship2[@typeCode=COMP][substanceAdministration/r]/substanceAdministration[@classCode=SBADM][@moodCode=EVN]/effectiveTime[@xsi:type=IVL_TS]/width/@value </pre>

<p>1.以下のデータ項目の2つを超える値が表示される場合:</p> <ol style="list-style-type: none"> 1) G.k.4.r.2, G.k.4.r.3 2) G.k.4.r.4 3) G.k.4.r.5 4) G.k.4.r.6a, G.k.4.r.6b 	<p>50AN</p>	<p>医薬品投与期間 (単位)</p>	<p>値</p> <p>width/unit=Coded Simple Value (CS)</p>	<pre> /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]PDRR_IN049016UV1f/controlActProcess[@classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUBJ][investigationEvent[@classCode=INVTG][@moodCode=EVN]/component[@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment[@classCode=INVTG][@moodCode=EVN]/subject1[@typeCode=SBJ][primaryRole[@classCode=INVSBJ/subjectOf2[@typeCode=SBJ][organizerCode=@code=4][@codeSystem=2.16.840.113883.3.989.2.1.1.20][1]/organizer[@classCode=CATEGORY][@moodCode=EVN]/component[@typeCode=COMP][substanceAdministration[id][y/substanceAdministration[@classCode=SBADM][@moodCode=EVN]/effectiveTime[@xsi:type=SXPRTS]/comp[@xsi:type=IVL_TS]/width/@unit </pre>
<p>2.以下のデータ項目の2つを超える値が表示される場合:</p> <ol style="list-style-type: none"> 1) G.k.4.r.2, G.k.4.r.3 2) G.k.4.r.4 3) G.k.4.r.5 4) G.k.4.r.6a, G.k.4.r.6b <p>データ型 SXPRTS を伴う 2 番目の comp 項目</p> <p>Parenthetic Set Expression of Time (SXPRTS) [Intervale of Point in Time (IVL_TS)]</p>			<p>値</p>	<pre> /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]PDRR_IN049016UV1f/controlActProcess[@classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUBJ][investigationEvent[@classCode=INVTG][@moodCode=EVN]/component[@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment[@classCode=INVTG][@moodCode=EVN]/subject1[@typeCode=SBJ][primaryRole[@classCode=INVSBJ/subjectOf2[@typeCode=SBJ][organizerCode=@code=4][@codeSystem=2.16.840.113883.3.989.2.1.1.20][1]/organizer[@classCode=CATEGORY][@moodCode=EVN]/component[@typeCode=COMP][substanceAdministration[id][y/substanceAdministration[@classCode=SBADM][@moodCode=EVN]/effectiveTime[@xsi:type=SXPRTS]/comp[@xsi:type=IVL_TS][@operator=A]/width/@unit </pre>

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e	G.k.4.r.9.1	医薬品剤形 (自由記載)	60AN	Coded With Equivalents (CE)	originalText=Encapsulated Data (ED)	<pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/PDRR_IN049016UV/r/controlActProcess[@classCode=CACT][@moodCo dCode=EVN]/subject[@typeCode=SUBJ][investigationEvent[@classCode=INVTG][@moodCo dCode=EVN]/component[@typeCode=COMP][adverseEventAssessment[1][adverseEventAssessment [1][classCode=INVTG][@moodCode=EVN]/subject[1][typeCode=SBJ][1]/primaryRole[@classC ode=INVSBJ]/subjectOf2[@typeCode=SBJ][organizerCode=@code=4][@codeSystem=2.16.840.1 .113883.3.989.2.1.1.20][1]/organizer[@classCode=CATEGORY][@moodCode=EVN]/component[1][@moodCode=EVN]/youtboundRelationship2[@typeCode=COMP][substanceAdministration][r/sub stanceAdministration[@classCode=SBADM][@moodCode=EVN]/consumable[@typeCode=CSM][1]/instanceOfKind[@classCode=INST]/kindOfProduct[@classCode=MMA][1][determinerCode=KI ND]/formCode[@codeSystem=TBDDoseForm]/originalText</pre> </pre>
e	G.k.4.r.9.2a	医薬品剤形の ID ハージョン 白付/番号	M5 ガイド ラインを参 照	Coded With Equivalents (CE)	codeSystemVersion= Character String (ST)	<pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/PDRR_IN049016UV/r/controlActProcess[@classCode=CACT][@moodCo dCode=EVN]/subject[@typeCode=SUBJ][investigationEvent[@classCode=INVTG][@moodCo dCode=EVN]/component[@typeCode=COMP][adverseEventAssessment[1][adverseEventAssessment [1][classCode=INVTG][@moodCode=EVN]/subject[1][typeCode=SBJ][1]/primaryRole[@classC ode=INVSBJ]/subjectOf2[@typeCode=SBJ][organizerCode=@code=4][@codeSystem=2.16.840.1 .113883.3.989.2.1.1.20][1]/organizer[@classCode=CATEGORY][@moodCode=EVN]/component[1][@moodCode=EVN]/youtboundRelationship2[@typeCode=COMP][substanceAdministration][r/sub stanceAdministration[@classCode=SBADM][@moodCode=EVN]/consumable[@typeCode=CSM][1]/instanceOfKind[@classCode=INST]/kindOfProduct[@classCode=MMA][1][determinerCode=KI ND]/formCode[@codeSystem=TBDDoseForm]/originalText</pre> </pre>
e	G.k.4.r.9.2b	医薬品剤形の ID	M5 ガイド ラインを参 照	Coded With Equivalents (CE)	code=Character String (ST)	<pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/PDRR_IN049016UV/r/controlActProcess[@classCode=CACT][@moodCo dCode=EVN]/subject[@typeCode=SUBJ][investigationEvent[@classCode=INVTG][@moodCo dCode=EVN]/component[@typeCode=COMP][adverseEventAssessment[1][adverseEventAssessment [1][classCode=INVTG][@moodCode=EVN]/subject[1][typeCode=SBJ][1]/primaryRole[@classC ode=INVSBJ]/subjectOf2[@typeCode=SBJ][organizerCode=@code=4][@codeSystem=2.16.840.1 .113883.3.989.2.1.1.20][1]/organizer[@classCode=CATEGORY][@moodCode=EVN]/component[1][@moodCode=EVN]/youtboundRelationship2[@typeCode=COMP][substanceAdministration][r/sub stanceAdministration[@classCode=SBADM][@moodCode=EVN]/consumable[@typeCode=CSM][1]/instanceOfKind[@classCode=INST]/kindOfProduct[@classCode=MMA][1][determinerCode=KI ND]/formCode[@codeSystem=TBDDoseForm]/originalText</pre> </pre>
h	G.k.4.r.10	投与経路				<pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/PDRR_IN049016UV/r/controlActProcess[@classCode=CACT][@moodCo dCode=EVN]/subject[@typeCode=SUBJ][investigationEvent[@classCode=INVTG][@moodCo dCode=EVN]/component[@typeCode=COMP][adverseEventAssessment[1][adverseEventAssessment [1][classCode=INVTG][@moodCode=EVN]/subject[1][typeCode=SBJ][1]/primaryRole[@classC ode=INVSBJ]/subjectOf2[@typeCode=SBJ][organizerCode=@code=4][@codeSystem=2.16.840.1 .113883.3.989.2.1.1.20][1]/organizer[@classCode=CATEGORY][@moodCode=EVN]/component[1][@moodCode=EVN]/youtboundRelationship2[@typeCode=COMP][substanceAdministration][r/sub stanceAdministration[@classCode=SBADM][@moodCode=EVN]/consumable[@typeCode=CSM][1]/instanceOfKind[@classCode=INST]/kindOfProduct[@classCode=MMA][1][determinerCode=KI ND]/formCode[@codeSystem=TBDDoseForm]/originalText</pre> </pre>

(別添3)

e	G.k.4.r.10.1	投与経路 (自由記載)	60AN	Coded With Equivalents (CE)	originalText=Encapsulated Data (ED)	値	/MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:n7-org:v3 MCCI_IN200100UV01.xsd]/PDRR_IN049016UVJ/controlActProcess[@classCode=INVESTG][@moodCode=EVN]/subject[@typeCode=SUBJ][/investigationEvent[@classCode=INVESTG][@moodCode=EVN]/component[@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment[@classCode=INVESTG][@moodCode=EVN]/subject[1]/primaryRole[@classCode=INVSBJ]/subjectOfZ[@typeCode=SBJ][organizer/code[@code=4]][@codeSystem=2.16.840.1.113883.3.989.2.1.1.20][1]/organizer[@classCode=CATEGORY][@moodCode=EVN]/component[1]/@typeCode=COMP][substanceAdministration[id][k]/substanceAdministration[@classCode=SBADM][@moodCode=EVN]/outboundRelationship2[@typeCode=COMP][substanceAdministration[id][r]/substanceAdministration[@classCode=SBADM][@moodCode=EVN]/routeCode[@codeSystem=2.16.840.1.113883.3.989.2.1.1.14]/originalText/text)]
e				NullFlavor		値	/MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:n7-org:v3 MCCI_IN200100UV01.xsd]/PDRR_IN049016UVJ/controlActProcess[@classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUBJ][/investigationEvent[@classCode=INVESTG][@moodCode=EVN]/component[@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment[@classCode=INVESTG][@moodCode=EVN]/subject[1]/primaryRole[@classCode=INVSBJ]/subjectOfZ[@typeCode=SBJ][organizer/code[@code=4]][@codeSystem=2.16.840.1.113883.3.989.2.1.1.20][1]/organizer[@classCode=CATEGORY][@moodCode=EVN]/component[1]/@typeCode=COMP][substanceAdministration[id][k]/substanceAdministration[@classCode=SBADM][@moodCode=EVN]/outboundRelationship2[@typeCode=COMP][substanceAdministration[id][r]/substanceAdministration[@classCode=SBADM][@moodCode=EVN]/routeCode[@codeSystem=2.16.840.1.113883.3.989.2.1.1.14]/originalText/@nullFlavor]
e	G.k.4.r.10.2a	投与経路の ID パージョン 付/番号	M5 ガイド ラインを参 照	Coded With Equivalents (CE)	codeSystemVersion= Character String (ST)	値	/MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:n7-org:v3 MCCI_IN200100UV01.xsd]/PDRR_IN049016UVJ/controlActProcess[@classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUBJ][/investigationEvent[@classCode=INVESTG][@moodCode=EVN]/component[@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment[@classCode=INVESTG][@moodCode=EVN]/subject[1]/primaryRole[@classCode=INVSBJ]/subjectOfZ[@typeCode=SBJ][organizer/code[@code=4]][@codeSystem=2.16.840.1.113883.3.989.2.1.1.20][1]/organizer[@classCode=CATEGORY][@moodCode=EVN]/component[1]/@typeCode=COMP][substanceAdministration[id][k]/substanceAdministration[@classCode=SBADM][@moodCode=EVN]/outboundRelationship2[@typeCode=COMP][substanceAdministration[id][r]/substanceAdministration[@classCode=SBADM][@moodCode=EVN]/routeCode[@codeSystem=2.16.840.1.113883.3.989.2.1.1.14]/@codeSystemVersion]
e	G.k.4.r.10.2b	投与経路の ID	M5 ガイド ラインを参 (3N) を参 照	Coded With Equivalents (CE)	code=Character String (ST)	値	/MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:n7-org:v3 MCCI_IN200100UV01.xsd]/PDRR_IN049016UVJ/controlActProcess[@classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUBJ][/investigationEvent[@classCode=INVESTG][@moodCode=EVN]/component[@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment[@classCode=INVESTG][@moodCode=EVN]/subject[1]/primaryRole[@classCode=INVSBJ]/subjectOfZ[@typeCode=SBJ][organizer/code[@code=4]][@codeSystem=2.16.840.1.113883.3.989.2.1.1.20][1]/organizer[@classCode=CATEGORY][@moodCode=EVN]/component[1]/@typeCode=COMP][substanceAdministration[id][k]/substanceAdministration[@classCode=SBADM][@moodCode=EVN]/outboundRelationship2[@typeCode=COMP][substanceAdministration[id][r]/substanceAdministration[@classCode=SBADM][@moodCode=EVN]/routeCode[@codeSystem=2.16.840.1.113883.3.989.2.1.1.14]/@code]
h	G.k.4.r.11	親への投与経路 (親一子/胎 児報告の場合)					

(別添 3)

<p>e</p> <p>G.k.4.r.11.1</p>	<p>親への投与経路 (自由記載)</p> <p>60AN</p>	<p>Coded With Equivalents (CE)</p> <p>originalText=Encapsulated Data (ED)</p>	<p>値</p>	<pre>/MCCI_IN200100UV01[@ITSVersion='XML_1.0']/@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd'/P/RR_IN049016UV/r/controlActProcess/@classCode='CACTI'[@moodCode='EVN']/subject/@typeCode='SUBJ'[/investigationEvent/@classCode='INVTG'[@moodCode='EVN']/component/@typeCode='COMP'[/adverseEventAssessment[1]/adverseEventAssessment/@classCode='INVTG'[@moodCode='EVN']/subject[1]/@typeCode='SBJ'[/primaryRole/@classCode='INVSBJ']/subjectOf2/@typeCode='SBJ'[/organizer/code=4]/@codeSystem='2.16.840.1.113883.3.989.2.1.1.20'[/organizer/@classCode='CATEGORY'[@moodCode='EVN']/component[1]/@typeCode='COMP'[/substanceAdministration[id]/substanceAdministration/@classCode='SBADM'[@moodCode='EVN']/outboundRelationship[2]/@typeCode='COMP'[/substanceAdministration]/substanceAdministration/@classCode='SBADM'[@moodCode='EVN']/inboundRelationship/@typeCode='REFR'[/observation/code/@code='28']/@codeSystem='2.16.840.1.113883.3.989.2.1.1.19'[/observation/@classCode='OBS']/@moodCode='EVN']/value/@xsi:type='CE'[@codeSystem='2.16.840.1.113883.3.989.2.1.1.14']]/originalText/text() /MCCI_IN200100UV01[@ITSVersion='XML_1.0']/@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd'/P/RR_IN049016UV/r/controlActProcess/@classCode='CACTI'[@moodCode='EVN']/subject/@typeCode='SUBJ'[/investigationEvent/@classCode='INVTG'[@moodCode='EVN']/component/@typeCode='COMP'[/adverseEventAssessment[1]/adverseEventAssessment/@classCode='INVTG'[@moodCode='EVN']/subject[1]/@typeCode='SBJ'[/primaryRole/@classCode='INVSBJ']/subjectOf2/@typeCode='SBJ'[/organizer/code=4]/@codeSystem='2.16.840.1.113883.3.989.2.1.1.20'[/organizer/@classCode='CATEGORY'[@moodCode='EVN']/component[1]/@typeCode='COMP'[/substanceAdministration[id]/substanceAdministration/@classCode='SBADM'[@moodCode='EVN']/outboundRelationship[2]/@typeCode='COMP'[/substanceAdministration]/substanceAdministration/@classCode='SBADM'[@moodCode='EVN']/inboundRelationship/@typeCode='REFR'[/observation/code/@code='28']/@codeSystem='2.16.840.1.113883.3.989.2.1.1.19'[/observation/@classCode='OBS']/@moodCode='EVN']/value/@xsi:type='CE'[@codeSystem='2.16.840.1.113883.3.989.2.1.1.14']]/originalText/@nullFlavor</pre>
<p>e</p> <p>G.k.4.r.11.2a</p>	<p>親への投与経路の ID パー ジョン日付/番号</p> <p>M5 ガイド ラインを参 照</p>	<p>Coded With Equivalents (CE)</p> <p>codeSystemVersion= Character String (ST)</p>	<p>値</p>	<pre>/MCCI_IN200100UV01[@ITSVersion='XML_1.0']/@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd'/P/RR_IN049016UV/r/controlActProcess/@classCode='CACTI'[@moodCode='EVN']/subject/@typeCode='SUBJ'[/investigationEvent/@classCode='INVTG'[@moodCode='EVN']/component/@typeCode='COMP'[/adverseEventAssessment[1]/adverseEventAssessment/@classCode='INVTG'[@moodCode='EVN']/subject[1]/@typeCode='SBJ'[/primaryRole/@classCode='INVSBJ']/subjectOf2/@typeCode='SBJ'[/organizer/code=4]/@codeSystem='2.16.840.1.113883.3.989.2.1.1.20'[/organizer/@classCode='CATEGORY'[@moodCode='EVN']/component[1]/@typeCode='COMP'[/substanceAdministration[id]/substanceAdministration/@classCode='SBADM'[@moodCode='EVN']/outboundRelationship[2]/@typeCode='COMP'[/substanceAdministration]/substanceAdministration/@classCode='SBADM'[@moodCode='EVN']/inboundRelationship/@typeCode='REFR'[/observation/code/@code='28']/@codeSystem='2.16.840.1.113883.3.989.2.1.1.19'[/observation/@classCode='OBS']/@moodCode='EVN']/value/@xsi:type='CE'[@codeSystem='2.16.840.1.113883.3.989.2.1.1.14']]/originalText/@nullFlavor</pre>

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e	G.k.6b	曝露時の妊娠期間 (単位)	50AN	Physical Quantity (PQ)	unit=Coded Simple Value (CS)	値	<pre> /MCCI_IN200100UV01[@ITSVersion='XML_1.0']/@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd'/PORR_IN049016UV/r/controlActProcess/@classCode='CACTI'[@moodCode='EVN']/subject/@typeCode='SUBJ'[/investigationEvent/@classCode='INVTG'][@moodCode='EVN']/component/@typeCode='COMP'[/adverseEventAssessment[1]/adverseEventAssessment/@classCode='INVTG'][@moodCode='EVN']/subject1/@typeCode='SBJ'[/primaryRole/@classCode='INVSBJ']/subjectOf2/@typeCode='SBJ'[/organizer/@code='4'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20'][/organizer/@classCode='CATEGORY'][@moodCode='EVN']/component[1]/@typeCode='COMP'[/substanceAdministration[id]/substanceAdministration/@classCode='SBADM'][@moodCode='EVN']/outboundRelationship2/@typeCode='PERT'[/observation/@code='16'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19'][/observation/@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='PQ']/@unit </pre>
h	G.k.7.r	医薬品使用理由 (必要に応じ 繰り返し返す)				繰り返し ノード	<pre> /MCCI_IN200100UV01[@ITSVersion='XML_1.0']/@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd'/PORR_IN049016UV/r/controlActProcess/@classCode='CACTI'[@moodCode='EVN']/subject/@typeCode='SUBJ'[/investigationEvent/@classCode='INVTG'][@moodCode='EVN']/component/@typeCode='COMP'[/adverseEventAssessment[1]/adverseEventAssessment/@classCode='INVTG'][@moodCode='EVN']/subject1/@typeCode='SBJ'[/primaryRole/@classCode='INVSBJ']/subjectOf2/@typeCode='SBJ'[/organizer/@code='4'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20'][/organizer/@classCode='CATEGORY'][@moodCode='EVN']/component[1]/@typeCode='COMP'[/substanceAdministration[id]/substanceAdministration/@classCode='SBADM'][@moodCode='EVN']/inboundRelationship/@typeCode='RSON'[/observation/@code='19'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19'] </pre>
e	G.k.7.r.1	第一次情報源により報告された使用理由	250AN	Coded With Equivalents (CE)	originalText=Encapsulated Data (ED)	値	<pre> /MCCI_IN200100UV01[@ITSVersion='XML_1.0']/@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd'/PORR_IN049016UV/r/controlActProcess/@classCode='CACTI'[@moodCode='EVN']/subject/@typeCode='SUBJ'[/investigationEvent/@classCode='INVTG'][@moodCode='EVN']/component/@typeCode='COMP'[/adverseEventAssessment[1]/adverseEventAssessment/@classCode='INVTG'][@moodCode='EVN']/subject1/@typeCode='SBJ'[/organizer/@code='4'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20'][/organizer/@classCode='CATEGORY'][@moodCode='EVN']/component[1]/@typeCode='COMP'[/substanceAdministration[id]/substanceAdministration/@classCode='SBADM'][@moodCode='EVN']/inboundRelationship/@typeCode='RSON'[/observation/@code='19'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']]/observation/@classCode='OBS'][@moodCode='EVN']/performer[1]/@typeCode='PRF'[/assignedEntity/@classCode='ASSIGNED'][@code='3'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.21']]/value[@xsi:type='CE'][@codeSystem='2.16.840.1.113883.6.163'][/originalText/text] </pre>
e						NullFlavor	<pre> /MCCI_IN200100UV01[@ITSVersion='XML_1.0']/@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd'/PORR_IN049016UV/r/controlActProcess/@classCode='CACTI'[@moodCode='EVN']/subject/@typeCode='SUBJ'[/investigationEvent/@classCode='INVTG'][@moodCode='EVN']/component/@typeCode='COMP'[/adverseEventAssessment[1]/adverseEventAssessment/@classCode='INVTG'][@moodCode='EVN']/subject1/@typeCode='SBJ'[/organizer/@code='4'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20'][/organizer/@classCode='CATEGORY'][@moodCode='EVN']/component[1]/@typeCode='COMP'[/substanceAdministration[id]/substanceAdministration/@classCode='SBADM'][@moodCode='EVN']/inboundRelationship/@typeCode='RSON'[/observation/@code='19'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']]/observation/@classCode='OBS'][@moodCode='EVN']/performer[1]/@typeCode='PRF'[/assignedEntity/@classCode='ASSIGNED'][@code='3'][@codeSystem='2.16.840.1.113883.6.163'][/originalText/@nullFlavor] </pre>

(別添 3)

e	G.k.7.r.2a	使用理由の MedDRA パーシジョン	4AN	Coded With Equivalents (CE)	code=SystemVersion=Character String (ST)	値	<pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/PORR_IN049016UV[1]/controlActProcess[@classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUBJ][1]/investigationEvent[@classCode=INVTG][@moodCode=EVN]/component[@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment[@classCode=INVTG][@moodCode=EVN]/subject[1]/typeCode=SBJ][1]/primaryRole[1]/primaryRole[1]/subject[1]/typeCode=SBJ][1]/organizer[1]/typeCode=EVN][1]/codeSystem=2.16.840.1.113883.3.989.2.1.1.20][1]/organizer[1]/classCode=CATEGORY][@moodCode=EVN]/component[113883.3.989.2.1.1.20][1]/organizer[1]/classCode=CATEGORY][@moodCode=EVN]/component[113883.3.989.2.1.1.19][1]/organizer[1]/classCode=RSO[1]/observation[1]/code=19][@moodCode=EVN]/performance[1]/typeCode=PRF][assignedEntity[1]/value[1]/code=3][@codeSystem=2.16.840.1.113883.3.989.2.1.1.21][1]/value[1]/code=CE][@codeSystem=2.16.840.1.113883.6.163][1]/codeSystemVersion </pre>
e	G.k.7.r.2b	使用理由 (MedDRA コード)	8N	Coded With Equivalents (CE)	code=Character String (ST)	値	<pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/PORR_IN049016UV[1]/controlActProcess[@classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUBJ][1]/investigationEvent[@classCode=INVTG][@moodCode=EVN]/component[@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment[@classCode=INVTG][@moodCode=EVN]/subject[1]/typeCode=SBJ][1]/primaryRole[1]/primaryRole[1]/subject[1]/typeCode=SBJ][1]/organizer[1]/typeCode=EVN][1]/codeSystem=2.16.840.1.113883.3.989.2.1.1.20][1]/organizer[1]/classCode=CATEGORY][@moodCode=EVN]/component[113883.3.989.2.1.1.20][1]/organizer[1]/classCode=CATEGORY][@moodCode=EVN]/component[113883.3.989.2.1.1.19][1]/organizer[1]/classCode=RSO[1]/observation[1]/code=19][@moodCode=EVN]/performance[1]/typeCode=PRF][assignedEntity[1]/value[1]/code=3][@codeSystem=2.16.840.1.113883.3.989.2.1.1.21][1]/value[1]/code=CE][@codeSystem=2.16.840.1.113883.6.163][1]/codeSystemVersion </pre>
e	G.k.8	医薬品に対して取られた処置	1N	Concept Descriptor (CD)	code=Character String (ST)	値	<pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/PORR_IN049016UV[1]/controlActProcess[@classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUBJ][1]/investigationEvent[@classCode=INVTG][@moodCode=EVN]/component[@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment[@classCode=INVTG][@moodCode=EVN]/subject[1]/typeCode=SBJ][1]/primaryRole[1]/primaryRole[1]/subject[1]/typeCode=SBJ][1]/organizer[1]/typeCode=EVN][1]/codeSystem=2.16.840.1.113883.3.989.2.1.1.20][1]/organizer[1]/classCode=CATEGORY][@moodCode=EVN]/component[113883.3.989.2.1.1.20][1]/organizer[1]/classCode=CATEGORY][@moodCode=EVN]/component[113883.3.989.2.1.1.15][1]/act[1]/act[1]/code=CAUS][act[1]/code=EVN][codeSystem=2.16.840.1.113883.3.989.2.1.1.15] </pre>
h	G.k.9.i	医薬品と副作用/有害事象のマトリックス (必要に応じ繰り返し)					
e	G.k.9.i.1	評価対象の副作用/有害事象	N/A				

(別添 3)

h	G.k.9.1.2.r 医薬品と副作用／有害事象の因果関係（必要に応じて繰り返す）	60AN	繰り返しのコード	<pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0'][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/PORR_IN049016UV/r/controlActProcess[@classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUBJ]/investigationEvent[@classCode=INVTG][@moodCode=EVN]/component[@typeCode=COMP]/adverseEventAssessment[1]/adverseEventAssessment[@classCode=INVTG][@moodCode=EVN]/component[@typeCode=COMP]/causalityAssessment[1]/causalityAssessment[@code=39][@codeSystem=2.16.840.1.113883.3.989.2.1.1.19][subject[@typeCode=SUBJ]/adverseEffectReference[@classCode=OBS][@moodCode=EVN][id[@root=UUID of k-th reaction]][subject2[@typeCode=SUBJ]/productUseReference[@classCode=SBADM][@moodCode=EVN][id[@root=UUID of k-th drug]]] </pre>
e	G.k.9.1.2.r.1 評価の情報源	60AN	値	<pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0'][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/PORR_IN049016UV/r/controlActProcess[@classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUBJ]/investigationEvent[@classCode=INVTG][@moodCode=EVN]/component[@typeCode=COMP]/adverseEventAssessment[1]/adverseEventAssessment[@classCode=INVTG][@moodCode=EVN]/component[@typeCode=COMP]/causalityAssessment[1]/causalityAssessment[@code=39][@codeSystem=2.16.840.1.113883.3.989.2.1.1.19][subject[@typeCode=SUBJ]/adverseEffectReference[@classCode=OBS][@moodCode=EVN][id[@root=UUID of k-th reaction]][subject2[@typeCode=SUBJ]/productUseReference[@classCode=SBADM][@moodCode=EVN][id[@root=UUID of k-th drug]][author[@typeCode=AUT][1]/assignedEntity[@classCode=ASSIGNED]/code/originalText/text() </pre>
e	G.k.9.1.2.r.2 評価方法	60AN	値	<pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0'][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/PORR_IN049016UV/r/controlActProcess[@classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUBJ]/investigationEvent[@classCode=INVTG][@moodCode=EVN]/component[@typeCode=COMP]/adverseEventAssessment[1]/adverseEventAssessment[@classCode=INVTG][@moodCode=EVN]/component[@typeCode=COMP]/causalityAssessment[1]/causalityAssessment[@code=39][@codeSystem=2.16.840.1.113883.3.989.2.1.1.19][subject[@typeCode=SUBJ]/adverseEffectReference[@classCode=OBS][@moodCode=EVN][id[@root=UUID of k-th reaction]][subject2[@typeCode=SUBJ]/productUseReference[@classCode=SBADM][@moodCode=EVN][id[@root=UUID of k-th drug]][methodCode[1]/originalText/text() </pre>
e	G.k.9.1.2.r.3 評価結果	60AN	値	<pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0'][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/PORR_IN049016UV/r/controlActProcess[@classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUBJ]/investigationEvent[@classCode=INVTG][@moodCode=EVN]/component[@typeCode=COMP]/adverseEventAssessment[1]/adverseEventAssessment[@classCode=INVTG][@moodCode=EVN]/component[@typeCode=COMP]/causalityAssessment[1]/causalityAssessment[@code=39][@codeSystem=2.16.840.1.113883.3.989.2.1.1.19][subject[@typeCode=SUBJ]/adverseEffectReference[@classCode=OBS][@moodCode=EVN][id[@root=UUID of k-th reaction]][subject2[@typeCode=SUBJ]/productUseReference[@classCode=SBADM][@moodCode=EVN][id[@root=UUID of k-th drug]][value[@xsi:type=ST].text() </pre>

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<p>e</p> <p>G.k.9.i.3.1a</p>	<p>医薬品の投与開始から副作用/有害事象発現までの時間間隔 (数)</p> <p>5N</p>	<p>Physical Quantity (PQ)</p>	<p>value=Real Number (REAL)</p>	<p>値</p>	<pre>/MCC1_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3:MCC1_IN200100UV01.xsd']/PORR_IN049016UV1/controlActProcess[@classCode='CACT']/@moodCode=EVN/subject[@typeCode='SUBJ']/investigationEvent[@classCode='INVESTG']/@moodCode=EVN/component[@typeCode='COMP']/adverseEventAssessment[1]/adverseEventAssessment[@classCode='INVESTG']/@moodCode=EVN/subject[1]/primaryRole[@classCode='INVSBJ']/subjectO2[@typeCode='SBJ']/organizer[@classCode='CATEGORY']/@moodCode=EVN/role[@code=4]/@codeSystem=2.16.840.1.113883.3.989.2.1.1.20/1/component/@typeCode=COMP/substanceAdministration[id][k]/substanceAdministration[@classCode='SBADM']/@moodCode=EVN/outboundRelationship[1]/@typeCode='SAS']actReference[@classCode='OBS']/@moodCode=EVN/id[@root=UUID of I-h reaction]/pauseQuantity/@value</pre>
<p>e</p> <p>G.k.9.i.3.1b</p>	<p>医薬品の投与開始から副作用/有害事象発現までの時間間隔 (単位)</p> <p>50AN</p>	<p>Physical Quantity (PQ)</p>	<p>unit=Coded Simple Value (CS)</p>	<p>値</p>	<pre>/MCC1_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3:MCC1_IN200100UV01.xsd']/PORR_IN049016UV1/controlActProcess[@classCode='CACT']/@moodCode=EVN/subject[@typeCode='SUBJ']/investigationEvent[@classCode='INVESTG']/@moodCode=EVN/component[@typeCode='COMP']/adverseEventAssessment[1]/adverseEventAssessment[@classCode='INVESTG']/@moodCode=EVN/subject[1]/primaryRole[@classCode='INVSBJ']/subjectO2[@typeCode='SBJ']/organizer[@classCode='CATEGORY']/@moodCode=EVN/role[@code=4]/@codeSystem=2.16.840.1.113883.3.989.2.1.1.20/1/component/@typeCode=COMP/substanceAdministration[id][k]/substanceAdministration[@classCode='SBADM']/@moodCode=EVN/outboundRelationship[1]/@typeCode='SAS']actReference[@classCode='OBS']/@moodCode=EVN/id[@root=UUID of I-h reaction]/pauseQuantity/@unit</pre>
<p>e</p> <p>G.k.9.i.3.2a</p>	<p>医薬品の最終投与から副作用/有害事象発現までの時間間隔 (数)</p> <p>5N</p>	<p>Physical Quantity (PQ)</p>	<p>value=Real Number (REAL)</p>	<p>値</p>	<pre>/MCC1_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3:MCC1_IN200100UV01.xsd']/PORR_IN049016UV1/controlActProcess[@classCode='CACT']/@moodCode=EVN/subject[@typeCode='SUBJ']/investigationEvent[@classCode='INVESTG']/@moodCode=EVN/component[@typeCode='COMP']/adverseEventAssessment[1]/adverseEventAssessment[@classCode='INVESTG']/@moodCode=EVN/subject[1]/primaryRole[@classCode='INVSBJ']/subjectO2[@typeCode='SBJ']/organizer[@classCode='CATEGORY']/@moodCode=EVN/role[@code=4]/@codeSystem=2.16.840.1.113883.3.989.2.1.1.20/1/component/@typeCode=COMP/substanceAdministration[id][k]/substanceAdministration[@classCode='SBADM']/@moodCode=EVN/outboundRelationship[1]/@typeCode='SAE']actReference[@classCode='OBS']/@moodCode=EVN/id[@root=UUID of I-h reaction]/pauseQuantity/@value</pre>
<p>e</p> <p>G.k.9.i.3.2b</p>	<p>医薬品の最終投与から副作用/有害事象発現までの時間間隔 (単位)</p> <p>50AN</p>	<p>Physical Quantity (PQ)</p>	<p>unit=Coded Simple Value (CS)</p>	<p>値</p>	<pre>/MCC1_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3:MCC1_IN200100UV01.xsd']/PORR_IN049016UV1/controlActProcess[@classCode='CACT']/@moodCode=EVN/subject[@typeCode='SUBJ']/investigationEvent[@classCode='INVESTG']/@moodCode=EVN/component[@typeCode='COMP']/adverseEventAssessment[1]/adverseEventAssessment[@classCode='INVESTG']/@moodCode=EVN/subject[1]/primaryRole[@classCode='INVSBJ']/subjectO2[@typeCode='SBJ']/organizer[@classCode='CATEGORY']/@moodCode=EVN/role[@code=4]/@codeSystem=2.16.840.1.113883.3.989.2.1.1.20/1/component/@typeCode=COMP/substanceAdministration[id][k]/substanceAdministration[@classCode='SBADM']/@moodCode=EVN/outboundRelationship[1]/@typeCode='SAE']actReference[@classCode='OBS']/@moodCode=EVN/id[@root=UUID of I-h reaction]/pauseQuantity/@unit</pre>

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e	G.k.9.1.4	再投与で副作用は再発したか？	1N	Coded With Equivalents (CE)	code=Character String (ST)	値	<pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/PDRR_IN049016UV1/controlActProcess[@classCode=CACT][@moo dCode=EVN]/subject[@typeCode=SUBJ][investigationEvent[@classCode=INVESTG][@moodCo de=EVN]/component[@typeCode=COMP][adverseEventAssessment[1]adverseEventAssessme nt[@classCode=INVESTG][@moodCode=EVN]/subject[1][@typeCode=SBJ][1]primaryRole[@classC ode=INVSBJ]/subjectOf2[@typeCode=SBJ]organizer[@classCode=CATEGORY][@moodCode= EVN][code=@code=4][@codeSystem=2.16.840.1.113883.3.989.2.1.1.20][component[1]@typeCo de=COMP][substanceAdministration[id][K]/substanceAdministration[@classCode=SBADM][@moo dCode=EVN]/youtboundRelationship2[@typeCode=PERT][observation/code[@code=31][@codeSy stem=2.16.840.1.113883.3.989.2.1.1.19][observation[@classCode=OBS][@moodCode=EVN][id [@root=UUID reaction][value[@xsi:type=CE][@codeSystem=2.16.840.1.113883.3.989.2.1.1.16][/y@code h </pre>
e	G.k.10.r	医薬品に関するその他の情 報（コード化）（必要に応じ 繰り返す）	2N	Coded With Equivalents (CE)	code=Character String (ST)	値	<pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/PDRR_IN049016UV1/controlActProcess[@classCode=CACT][@moo dCode=EVN]/subject[@typeCode=SUBJ][investigationEvent[@classCode=INVESTG][@moodCo de=EVN]/component[@typeCode=COMP][adverseEventAssessment[1]adverseEventAssessme nt[@classCode=INVESTG][@moodCode=EVN]/subject[1][@typeCode=SBJ][1]primaryRole[@classC ode=INVSBJ]/subjectOf2[@typeCode=SBJ]organizer[@code=4][@codeSystem=2.16.840.1 .113883.3.989.2.1.1.20][organizer[@classCode=CATEGORY][@moodCode=EVN]/component[1]@moodCode=EVN]/youtboundRelationship2[@typeCode=REFR][observation/code[@code=9][@ codeSystem=2.16.840.1.113883.3.989.2.1.1.19][observation[@classCode=OBS][@moodCode= EVN][value[@xsi:type=CE][@codeSystem=2.16.840.1.113883.3.989.2.1.1.17][/y@code </pre>
e						繰り返 し ノ ー ド	<pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/PDRR_IN049016UV1/controlActProcess[@classCode=CACT][@moo dCode=EVN]/subject[@typeCode=SUBJ][investigationEvent[@classCode=INVESTG][@moodCo de=EVN]/component[@typeCode=COMP][adverseEventAssessment[1]adverseEventAssessme nt[@classCode=INVESTG][@moodCode=EVN]/subject[1][@typeCode=SBJ][1]primaryRole[@classC ode=INVSBJ]/subjectOf2[@typeCode=SBJ]organizer[@code=4][@codeSystem=2.16.840.1 .113883.3.989.2.1.1.20][organizer[@classCode=CATEGORY][@moodCode=EVN]/component[1]@moodCode=EVN]/youtboundRelationship2[@typeCode=REFR][observation/code[@code=9][@ codeSystem=2.16.840.1.113883.3.989.2.1.1.19] </pre>
e	G.k.11	医薬品に関するその他の情 報（自由記載）	2000AN	Character String (ST)		値	<pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/PDRR_IN049016UV1/controlActProcess[@classCode=CACT][@moo dCode=EVN]/subject[@typeCode=SUBJ][investigationEvent[@classCode=INVESTG][@moodCo de=EVN]/component[@typeCode=COMP][adverseEventAssessment[1]adverseEventAssessme nt[@classCode=INVESTG][@moodCode=EVN]/subject[1][@typeCode=SBJ][1]primaryRole[@classC ode=INVSBJ]/subjectOf2[@typeCode=SBJ]organizer[@code=4][@codeSystem=2.16.840.1 .113883.3.989.2.1.1.20][organizer[@classCode=CATEGORY][@moodCode=EVN]/component[1]@moodCode=EVN]/youtboundRelationship2[@typeCode=REFR][observation/code[@code=2][@ codeSystem=2.16.840.1.113883.3.989.2.1.1.19][text] </pre>
h	H	症例概要及びその他の情報 の記述					

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e	H.1	臨床経過、治療処置、転帰及びその他の関連情報を含む症例の記述情報	100000AN	Encapsulated Data (ED)	値	/MCCL_IN200100UV01[@ITSVersion='XML_1.0']@xsi:schemaLocation='urn:hl7-org:v3:MCCL_IN200100UV01.xsd'P/PORR_IN049016UV01/controlActProcess[@classCode='CACT']@moodCode='EVN']/subject[@typeCode='SUBJ']/investigationEvent[@classCode='INVESTG']@moodCode='EVN']/text/text()
e	H.2	報告者の意見	20000AN	Encapsulated Data (ED)	値	/MCCL_IN200100UV01[@ITSVersion='XML_1.0']@xsi:schemaLocation='urn:hl7-org:v3:MCCL_IN200100UV01.xsd'P/PORR_IN049016UV01/controlActProcess[@classCode='CACT']@moodCode='EVN']/subject[@typeCode='SUBJ']/investigationEvent[@classCode='INVESTG']@moodCode='EVN']/component[@typeCode='COMP']/adverseEventAssessment[1]/adverseEventAssessment[@classCode='INVESTG']@moodCode='EVN']/component[1]/typeCode='COMP']/observationEvent[code/@code='10']@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']/author[@typeCode='AUT']/signedEntity[@classCode='ASSIGNED']/code[@code='3']@codeSystem='2.16.840.1.113883.3.989.2.1.1.21']/observationEvent[@classCode='OBS']@moodCode='EVN']/value[@xsi:type='ED']/text()
h	H.3.r	送信者による診断名 (必要に応じて繰り返し返す)			繰り返し ノード	/MCCL_IN200100UV01[@ITSVersion='XML_1.0']@xsi:schemaLocation='urn:hl7-org:v3:MCCL_IN200100UV01.xsd'P/PORR_IN049016UV01/controlActProcess[@classCode='CACT']@moodCode='EVN']/subject[@typeCode='SUBJ']/investigationEvent[@classCode='INVESTG']@moodCode='EVN']/component[@typeCode='COMP']/adverseEventAssessment[1]/adverseEventAssessment[@classCode='INVESTG']@moodCode='EVN']/component[1]/typeCode='COMP']/observationEvent[code/@code='15']@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']/author[@typeCode='AUT']/signedEntity[@classCode='ASSIGNED']/code[@code='1']@codeSystem='2.16.840.1.113883.3.989.2.1.1.21']
e	H.3.r.1a	送信者による診断名/症候群及び/又は副作用/有害事象の再分類の MedDRA パーシジョン	4AN	Coded With Equivalents (CE)	値	/MCCL_IN200100UV01[@ITSVersion='XML_1.0']@xsi:schemaLocation='urn:hl7-org:v3:MCCL_IN200100UV01.xsd'P/PORR_IN049016UV01/controlActProcess[@classCode='CACT']@moodCode='EVN']/subject[@typeCode='SUBJ']/investigationEvent[@classCode='INVESTG']@moodCode='EVN']/component[@typeCode='COMP']/adverseEventAssessment[1]/adverseEventAssessment[@classCode='INVESTG']@moodCode='EVN']/component[1]/typeCode='COMP']/observationEvent[code/@code='15']@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']/author[@typeCode='AUT']/signedEntity[@classCode='ASSIGNED']/code[@code='1']@codeSystem='2.16.840.1.113883.3.989.2.1.1.21']/observationEvent[@classCode='OBS']@moodCode='EVN']/value[@xsi:type='CE']@codeSystem='2.16.840.1.113883.3.989.2.1.1.21']
e	H.3.r.1b	送信者による診断名/症候群及び/又は副作用/有害事象の再分類 (MedDRA コード)	8N	Coded With Equivalents (CE)	値	/MCCL_IN200100UV01[@ITSVersion='XML_1.0']@xsi:schemaLocation='urn:hl7-org:v3:MCCL_IN200100UV01.xsd'P/PORR_IN049016UV01/controlActProcess[@classCode='CACT']@moodCode='EVN']/subject[@typeCode='SUBJ']/investigationEvent[@classCode='INVESTG']@moodCode='EVN']/component[@typeCode='COMP']/adverseEventAssessment[1]/adverseEventAssessment[@classCode='INVESTG']@moodCode='EVN']/component[1]/typeCode='COMP']/observationEvent[code/@code='15']@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']/author[@typeCode='AUT']/signedEntity[@classCode='ASSIGNED']/code[@code='1']@codeSystem='2.16.840.1.113883.3.989.2.1.1.21']/observationEvent[@classCode='OBS']@moodCode='EVN']/value[@xsi:type='CE']@codeSystem='2.16.840.1.113883.3.989.2.1.1.21']

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e	H.4	送信者の意見	20000AN	Encapsulated Data (ED)	値	<pre> /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PDRR_IN049016UV/p/controlActProcess[@classCode=CACTI][@moo dCode=EVN]/subject[@typeCode=SUBJ][1]/investigationEvent[@classCode=INVTG][@moodCo de=EVN]/component[@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment [@classCode=INVTG][@moodCode=EVN]/component[1][@typeCode=COMP][observationEvent[code][@code=1][@codeSystem=2.16.840.1.113883.3.989.2.1.1.19][author[@typeCode=AUT][as signedEntity[@classCode=ASSIGNED][code=1][@codeSystem=2.16.840.1.113883.3.989. 2.1.1.21][1]/observationEvent[@classCode=OBS][@moodCode=EVN][value[@xsi:type=ED]/text 0 </pre>
h	H.5.r	母国語で記載された症例概要及び報告者の意見(必要に応じて繰り返し送す)			繰り返し ノード	<pre> /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PDRR_IN049016UV/p/controlActProcess[@classCode=CACTI][@moo dCode=EVN]/subject[@typeCode=SUBJ][1]/investigationEvent[@classCode=INVTG][@moodCo de=EVN]/component[@typeCode=COMP][observationEvent[code][@code=36][@codeSystem=2. 16.840.1.113883.3.989.2.1.1.19][author[@typeCode=AUT][assignedEntity[@classCode=ASSIGN ED][code][@code=2][@codeSystem=2.16.840.1.113883.3.989.2.1.1.21]]] </pre>
e	H.5.r.1a	症例概要及び報告者の意見に関する記述情報	100000AN	Encapsulated Data (ED)	値	<pre> /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PDRR_IN049016UV/p/controlActProcess[@classCode=CACTI][@moo dCode=EVN]/subject[@typeCode=SUBJ][1]/investigationEvent[@classCode=INVTG][@moodCo de=EVN]/component[@typeCode=COMP][observationEvent[code][@code=36][@codeSystem=2. 16.840.1.113883.3.989.2.1.1.19][author[@typeCode=AUT][assignedEntity[@classCode=ASSIGN ED][code][@code=2][@codeSystem=2.16.840.1.113883.3.989.2.1.1.21][1]/observationEvent[cl assCode=OBS][@moodCode=EVN][value[@xsi:type=ED]/text() </pre>
e	H.5.r.1b	症例概要及び報告者の意見の記載言語	3A	Encapsulated Data (ED)	値	<pre> /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PDRR_IN049016UV/p/controlActProcess[@classCode=CACTI][@moo dCode=EVN]/subject[@typeCode=SUBJ][1]/investigationEvent[@classCode=INVTG][@moodCo de=EVN]/component[@typeCode=COMP][observationEvent[code][@code=36][@codeSystem=2. 16.840.1.113883.3.989.2.1.1.19][author[@typeCode=AUT][assignedEntity[@classCode=ASSIGN ED][code][@code=2][@codeSystem=2.16.840.1.113883.3.989.2.1.1.21][1]/observationEvent[cl assCode=OBS][@moodCode=EVN][value[@xsi:type=ED]/@language </pre>

ヘッダ e:エン タイプ	ファイルド 番号	ファイルド名	ICSRメッ セージにおけ るファイルド 番号	ICHデー タ型	HL7データ型 (下位構成要素)	分類	Xpath
h	ACK.M/A	ICH ICSRバッチ確認 応答					
e	ACK.M.1	確認応答バッチ番号		100AN	extension=Character String (ST)	値	/MCCL_IN200101UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCL_IN200101UV01.xsd']/id[@root='2.16.840.1.113883.3.989.2.1.3.20']@extension
e	ACK.M.2	確認応答バッチ送信 者識別子	N.1.4	60AN	extension=Character String (ST)	値	/MCCL_IN200101UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCL_IN200101UV01.xsd']/sender[@typeCode='SND']/device[@classCode='DEV'][@determiner Code='INSTANCE']/id[@root='2.16.840.1.113883.3.989.2.1.3.17']@extension
e	ACK.M.3	確認応答バッチ受信 者識別子	N.1.3	60AN	extension=Character String (ST)	値	/MCCL_IN200101UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCL_IN200101UV01.xsd']/receiver[@typeCode='RCV']/device[@classCode='DEV'][@determiner Code='INSTANCE']/id[@root='2.16.840.1.113883.3.989.2.1.3.18']@extension
e	ACK.M.4	バッチ伝送の確認応 答日		日付/時 間	Point in Time (TS)	値	/MCCL_IN200101UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCL_IN200101UV01.xsd']/creationTime/@value
e	ACK.A.1	ICSRバッチ番号	N.1.2	100AN	extension=Character String (ST)	値	/MCCL_IN200101UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCL_IN200101UV01.xsd']/acknowledgement[@typeCode]/targetBatchId/@root='2.16.840.1.113 883.3.989.2.1.3.22']@extension
e	ACK.A.2	確認応答地域メッ セージ番号		100AN	extension=Character String (ST)	値	/MCCL_IN200101UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCL_IN200101UV01.xsd']/attentionLineKeyWordText[@code='2'][@codeSystem='2.16.840.1.11 3883.3.989.2.1.1.24']@value[@xsi:type='I']@root='2.16.840.1.113883.3.989.2.1.3.21']@extens ion
e	ACK.A.3	ICSRバッチ伝送日	N.1.5	日付/時 間	Point in Time (TS)	値	/MCCL_IN200101UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCL_IN200101UV01.xsd']/attentionLineKeyWordText[@code='3'][@codeSystem='2.16.840.1.11 3883.3.989.2.1.1.24']@value[@xsi:type='TS']@value

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e	ACK.A.4	伝送確認応答コード	2A	Coded Value (CS)	値	/MCCI_IN200101UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200101UV01.xsd']/acknowledgement/@typeCode
e	ACK.A.5	パッチバリデーションエラー	250AN	Encapsulated Data (ED)	値	/MCCI_IN200101UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200101UV01.xsd']/acknowledgement/@typeCode/acknowledgementDetail[1]/text/text()
h	ACK.B.r	ICH ICSRメッセージ確認応答			繰り返しのノード	/MCCI_IN200101UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200101UV01.xsd']/MCCI_IN000002UV01
e	ACK.B.r.1	ICSRメッセージ番号	100AN N.2.r.1 C.1.1	Instance Identifier (II)	値 extension=Character String (ST)	/MCCI_IN200101UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200101UV01.xsd']/MCCI_IN000002UV01[receiver/@typeCode[1]]/targetMessage/id[@root=2.16.840.1.113883.3.989.2.1.3.1]/@extension
e	ACK.B.r.2	地域報告番号	100AN	Instance Identifier (II)	値 extension=Character String (ST)	/MCCI_IN200101UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200101UV01.xsd']/MCCI_IN000002UV01[receiver/@typeCode[1]]/targetMessage/id[@root=2.16.840.1.113883.3.989.2.1.3.19]/@extension
e	ACK.B.r.3	ICSRメッセージ確認応答受信者	60AN N.2.r.2	Instance Identifier (II)	値 extension=Character String (ST)	/MCCI_IN200101UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200101UV01.xsd']/MCCI_IN000002UV01[receiver/@typeCode=RCV]/device/@classCode=DEV[1]/@determinerCode=INSTANCE[id/@root=2.16.840.1.113883.3.989.2.1.3.16]/@extension
e	ACK.B.r.4	ICSRメッセージ確認応答送信者	60AN N.2.r.3	Instance Identifier (II)	値 extension=Character String (ST)	/MCCI_IN200101UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200101UV01.xsd']/MCCI_IN000002UV01[sender/@typeCode=SND]/device/@classCode=DEV[1]/@determinerCode=INSTANCE[id/@root=2.16.840.1.113883.3.989.2.1.3.15]/@extension
e	ACK.B.r.5	ICSRメッセージ作成日	日付/時間	Point in Time (TS)	値	/MCCI_IN200101UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200101UV01.xsd']/MCCI_IN000002UV01[attentionLine/keyWordText/@code=1][codeSystem=2.16.840.1.113883.3.989.2.1.1.24][value/@xsi:type=TS]/@value
e	ACK.B.r.6	ICSRメッセージの確認応答コード	2A	Coded Value (CS)	値	/MCCI_IN200101UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200101UV01.xsd']/MCCI_IN000002UV01[acknowledgement[1]]/@typeCode

(別添 3)

e	ACK.B.r.7	エラーメッセージ又は意見	250AN	Encapsulated Data (ED)	値	<pre> /MCC_IN200101UV01[@ITSVersion=XML_1.0]@xsi:schemaLocation=um:hl7-org:v3 MCC_IN200101UV01.xsd /MCC_IN00002UV01[rj/acknowledgement[@typeCode[1]acknowledge gmentDetail[1]/text/text() </pre>
---	-----------	--------------	-------	------------------------	---	--

1 2. 複数の XML 表現に関する XML 断片

2 ICSR メッセージにおいて、大部分の E2R (R3) データ項目では XML の 1 つの記述方
 3 法がスキーマにより定義されているが、一部のデータ項目では複数の記述方法が示され
 4 ている。ISO/HL7 ICSR モデルにおいて E2R (R3) データ項目の値又は組み合わせをサ
 5 ポートするため、複数の XML コード化の方法が存在し、このばらつきに対応している。
 6 スキーマにおいては最適なデータ型及び属性を使用しなければならない。例えば、投与
 7 量項目の時間間隔の単位 (G.k.4.r.3) には、「cyclical (周期的)」、「as necessary (必
 8 要時)」及び「total (合計)」に対して UCUM 及び非 UCUM コードの値がある。G.k.4.r.3
 9 の値が「total (合計)」又はその他の値の場合、投与量 (数) (G.k.4.r.1a) 及び投与量
 10 (単位) (G.k.4.r.1b) の XML は異なる。データ項目の組み合わせに関するもう 1 つの
 11 例として、発現日 (E.i.4)、終了日 (E.i.5) 及び持続期間 (E.i.6) がある。3 つのデー
 12 タ項目のすべてが表示されている場合又は開始日と持続期間のみが使用されている場
 13 合、異なる HL7 データ型及び属性がスキーマにより定義される。本項にはこれらの例
 14 に対する XML 断片を示す。

15 2.1 開始日、終了日及び持続期間

16 実装ガイド 3.4 項の実務ルールの記述に従って、3 つのデータ項目のうち 2 つに入力する
 17 方がよい。

18 2.1.1. E.i.4 「発現日」及び E.i.5 「終了日」に入力するが、E.i.6 「持続期間」は入力しない

```

19 <observation classCode="OBS" moodCode="EVN">
20 <id root="154eb889-958b-45f2-a02f-42d4d6f4657f"/>
21 <code code="29" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" displayName="reaction"/>
22 <effectiveTime xsi:type="IVL_TS">
23 <low value="20090101"/>
24 <!-- E.i.4 Date of Start of Reaction / Event -->
25 <high value="20090102"/>
26 <!-- E.i.5: Date of End of Reaction / Event -->
27 </effectiveTime>
28 <value xsi:type="CE" code="E.i.2.1b" codeSystem="2.16.840.1.113883.6.163"
29 codeSystemVersion="E.i.2.1a">
30 <!-- E.i.2.1a: MedDRA Version for Reaction / Event -->
31 <!-- E.i.2.1b: Reaction / Event in MedDRA Terminology-->
32 <originalText language="E.i.1.1b">E.i.1.1a</originalText>
33 <!-- E.i.1a: Reaction / Event as Reported by the Primary Source in Native Language -->
34 </value>

```

35 2.1.2. E.i.4 「発現日」 (又は E.i.5 「終了日」) 及び E.i.6 「持続期間」に入力する

```

36 <observation classCode="OBS" moodCode="EVN">
37 <id root="154eb889-958b-45f2-a02f-42d4d6f4657f"/>
38 <code code="29" codeSystem="2.16.840.1.113883.3.989.2.1.1.19"

```

```

39   displayName="reaction"/>
40       <effectiveTime xsi:type="IVL_TS">
41           <low value="20090101"/>
42           <!-- E.i.4 Date of Start of Reaction / Event -->
43           <width value="24" unit="E.i.6b"/>
44           <!-- E.i.6a: Duration of Reaction / Event -->
45           <!-- E.i.6b: Duration of Reaction / Event (Duration Unit) -->
46       </effectiveTime>
47       <value xsi:type="CE" code="E.i.2.1b" codeSystem="2.16.840.1.113883.6.163"
48   codeSystemVersion="E.i.2.1a">
49           <!-- E.i.2.1a: MedDRA Version for Reaction / Event -->
50           <!-- E.i.2.1b: Reaction / Event in MedDRA Terminology-->
51           <originalText>E.i.0.a</originalText>
52           <originalText language="E.i.1.1b">E.i.1.1a</originalText>
53           <!-- E.i.1a: Reaction / Event as Reported by the Primary Source in Native Language
54   -->
55       </value>
56   2.1.3.   E.i.4 「発現日」、E.i.5 「終了日」、及び E.i.6 「持続期間」に入力する
57       <observation classCode="OBS" moodCode="EVN">
58           <id root="154eb889-958b-45f2-a02f-42d4d6f4657f"/>
59           <code code="29" codeSystem="2.16.840.1.113883.3.989.2.1.1.19"
60   displayName="reaction"/>
61           <effectiveTime xsi:type="SXPR_TS">
62               <comp xsi:type="IVL_TS">
63                   <low value="20090101"/>
64                   <!-- E.i.4 Date of Start of Reaction / Event -->
65                   <high value="20090102"/>
66                   <!-- E.i.5: Date of End of Reaction / Event -->
67               </comp>
68               <comp xsi:type="IVL_TS" operator="A">
69                   <width value="24" unit="h"/>
70                   <!-- E.i.6a: Duration of Reaction / Event -->
71                   <!-- E.i.6b: Duration of Reaction / Event (Duration Unit) -->
72               </comp>
73           </effectiveTime>
74           <value xsi:type="CE" code="E.i.2.1b" codeSystem="2.16.840.1.113883.6.163"
75   codeSystemVersion="E.i.2.1a">
76           <!-- E.i.2.1a: MedDRA Version for Reaction / Event -->

```

```

77         <!-- E.i.2.1b: Reaction / Event in MedDRA Terminology-->
78         <originalText language="E.i.1.1b">E.i.1.1a</originalText>
79         <!-- E.i.1.1a: Reaction / Event as Reported by the Primary Source in Native
80 Language -->
81         <!-- E.i.1.1b: Reaction / Event as Reported by the Primary Source Language
82 -->
83         </value>
84
85 2.1.4. G.k.4.r.4 「開始日」及び G.k.4.r.5 「終了日」に入力するが、G.k.4.r.6 には入力しない
86 <substanceAdministration classCode="SBADM" moodCode="EVN">
87 <text>G.k.4.r.8</text>
88 <!-- G.k.4.r.8: Dosage Text -->
89 <effectiveTime xsi:type="SXPR_TS">
90 <comp xsi:type="PIVL_TS">
91 <period value="10" unit="G.k.4.r.3"/>
92 <!-- G.k.4.r.2: Number of Units in the Interval -->
93 <!-- G.k.4.r.3: Definition of the Time Interval Unit -->
94 </comp>
95 <comp xsi:type="IVL_TS" operator="A">
96 <low value="20090101"/>
97 <!-- G.k.4.r.4: Date and Time of Start of Drug-->
98 <high value="20090101"/>
99 <!-- G.k.4.r.5: Date and Time of Last Administration-->
100 </comp>
101 </effectiveTime>
102 2.1.5. G.k.4.r.4 「開始日」(又は G.k.4.r.5 「終了日」)及び G.k.4.r.6 に入力する
103 <substanceAdministration classCode="SBADM" moodCode="EVN">
104 <text>G.k.4.r.8</text>
105 <!-- G.k.4.r.8: Dosage Text -->
106 <effectiveTime xsi:type="SXPR_TS">
107 <comp xsi:type="PIVL_TS">
108 <period value="10" unit="G.k.4.r.3"/>
109 <!-- G.k.4.r.2: Number of Units in the Interval -->
110 <!-- G.k.4.r.3: Definition of the Time Interval Unit -->
111 </comp>
112 <comp xsi:type="IVL_TS" operator="A">

```

```

113         <low value="20090101"/>
114         <!-- G.k.4.r.4: Date and Time of Start of Drug -->
115         <width value ="4" unit ="G.k.4.6b"/>
116         <!-- G.k.4.6a: Duration of Drug Administration (number) -->
117         <!-- G.k.4.6b: Duration of Drug Administration (unit) -->
118     </comp>
119 </effectiveTime>

120 2.1.6. G.k.4.r.2 及び G.k.4.r.3 には入力しないが、G.k.4.r.5、G.k.4.7 又は G.k.4.r.6 のいずれ
121 かに入力する

122 この場合、スキーマエラーを避けるため、データ型はIVL_TS又はPIVL_TSでなければならない。
123 SXPR_TSは許可されない。

124 IVL_TSの例：
125     <substanceAdministration classCode="SBADM" moodCode="EVN">
126         <text>G.k.4.r.8</text>
127         <!-- G.k.4.r.8: Dosage Text -->
128         <effectiveTime xsi:type="IVL_TS">
129             <low value="20090101"/>
130             <!-- G.k.4.r.4: Date and Time of Start of Drug -->
131             <width value ="4" unit ="G.k.4.6b"/>
132             <!-- G.k.4.r.6a: Duration of Drug Administration (number) -->
133             <!-- G.k.4.r.6b: Duration of Drug Administration (unit) -->
134         </effectiveTime>

135 PIVL_TSのもう1つの例：
136     <substanceAdministration classCode="SBADM" moodCode="EVN">
137         <text>G.k.4.r.9</text>
138         <!-- G.k.4.r.9: Dosage Text -->
139         <effectiveTime xsi:type="PIVL_TS">
140             <period value="10" unit="G.k.4.r.4"/>
141             <!-- G.k.4.r.3: Number of Units in the Interval -->
142             <!-- G.k.4.r.4: Definition of the Time Interval Unit -->
143         </effectiveTime>

144 2.1.7. G.k.4.r.4「開始日」、G.k.4.r.5「終了日」、及びG.k.4.r.8「持続期間」に入力する
145     <substanceAdministration classCode="SBADM" moodCode="EVN">
146         <text>G.k.4.r.8</text>
147         <!-- G.k.4.r.8: Dosage Text -->

```

```

148     <effectiveTime xsi:type="SXPR_TS">
149         <comp xsi:type="PIVL_TS">
150             <period value="10" unit="G.k.4.r.3"/>
151             <!-- G.k.4.r.2: Number of Units in the Interval -->
152             <!-- G.k.4.r.3: Definition of the Time Interval Unit -->
153         </comp>
154         <comp xsi:type="IVL_TS" operator="A">
155             <low value="20090101"/>
156             <!-- G.k.4.r.4: Date and Time of Start of Drug-->
157             <high value="20090101"/>
158             <!-- G.k.4.r.5: Date and Time of Last Administration -->
159         </comp>
160         <comp xsi:type="IVL_TS" operator="A">
161             <width value="24" unit="h"/>
162             <!-- G.k.4.r.6a: Duration of Drug Administration (number) -->
163             <!-- G.k.4.r.6b: Duration of Drug Administration (unit) -->
164         </comp>
165     </effectiveTime>

```

166 2.2. F 検査結果

167 2.2.1. F.r.3.2 値及び限定子

168 2.2.1.1. 値 (例: "10 mg/dL")

169 この場合、HL7 の"value"項目は1つの"center"項目で構成される。

```

170     <value xsi:type="IVL_PQ" >
171         <center value="10" unit="mg/dl" />
172     </value>

```

173 2.2.1.2. 値より大きい (例: "> 10 mg/dL")

174 この場合、HL7 の"value"項目は"low"値及び"high"値の範囲で構成される。限定子「より
175 大きい」場合は、正の無限の高値により示される (すなわち、null flavor"PINF"を使用)。
176 属性"inclusive"は、限定子が厳密 (すなわち、同等) であることを示すため"false"に設定
177 される。

```

178     <value xsi:type="IVL_PQ" >
179         <low value="10" unit="mg/dl" inclusive="false"/>
180         <high nullFlavor="PINF"/>
181     </value>

```

182 2.2.1.3. 値より小さい (例: "< 10 mg/dL")

183 この場合、HL7 の"value"項目は"low"値及び"high"値の範囲で構成される。限定子「より
184 小さい」場合は、負の無限の低値により示される (すなわち、null flavor"NINF"を使用)。
185 属性"inclusive"は、限定子が厳密 (すなわち、同等) であることを示すため"false"に設定
186 される。

```
187     <value xsi:type="IVL_PQ" >
188         <low nullFlavor="NINF"/>
189         <high value="10" unit="mg/dl" inclusive="false"/>
190     </value>
```

191 2.2.1.4. 値以上 (例: ">= 10 mg/dL")

192 この場合、HL7 の"value"項目は"low"値及び"high"値の範囲で構成される。限定子「以上」
193 の場合は、正の無限の高値により示される (すなわち、null flavor"PINF"を使用)。属
194 性"inclusive"は、同等であることを示すため"true"に設定される。

```
195     <value xsi:type="IVL_PQ" >
196         <low value="10" unit="mg/dl" inclusive="true"/>
197         <high nullFlavor="PINF"/>
198     </value>
```

199 2.2.1.5. 値以下 (例: "<= 10 mg/dL")

200 この場合、HL7 の"value"項目は"low"値及び"high"値の範囲で構成される。限定子「より
201 小さい」場合は、負の無限の低値により示される (すなわち、null flavor"NINF"を使用)。
202 属性"inclusive"は、同等であることを示すため"true"に設定される。

```
203     <value xsi:type="IVL_PQ" >
204         <low nullFlavor="NINF"/>
205         <high value="10" unit="mg/dl" inclusive="true"/>
206     </value>
```

207 2.2.2 F.r.3.2 及び F.r.3.3

```
208     <observation moodCode="EVN" classCode="OBS">
209         <code code="F.r.2.2b" codeSystem="2.16.840.1.113883.6.163"
210         codeSystemVersion="F.r.2.2a">
211             <!-- F.r.2.2a: Test Name (MedDRA version) -->
212             <!-- F.r.2.1b: Test Name (MedDRA code) -->
213             <originalText>F.r.2.1</originalText>
214             <!-- F.r.2.1: Test Name (free text) -->
215             </code>
216             <effectiveTime value="20090101"/>
```

```

217      <!-- F.r.1: Test Date -->
218      <value xsi:type="IVL_PQ">
219      <center value="10" unit="mg/dl"/>
220      <!-- F.r.3.2: Test Result (Value) -->
221      <!-- F.r.3.3: Unit -->
222      </value>
223  2.2.3.   F.r.3.1
224      <observation classCode="OBS" moodCode="EVN">
225      <code code="F.r.2.2b" codeSystem="2.16.840.1.113883.6.163" codeSystemVersion="F.r.2.2a">
226      <originalText>F.r.2</originalText>
227      </code>
228      <effectiveTime value="20090101"/>
229      <!-- F.r.1: Test Date -->
230      <interpretationCode code="Positive" codeSystem="2.16.840.1.113883.3.989.2.1.1.12"/>
231      <!-- F.r.3.1: Test Result (Code) -->
232  2.2.4.   F.r.3.4
233      <observation classCode="OBS" moodCode="EVN">
234      <code code="F.r.2.2b" codeSystem="2.16.840.1.113883.6.163" codeSystemVersion="F.r.2.2a">
235      <originalText>F.r.2</originalText>
236      </code>
237      <effectiveTime value="20090101"/>
238      <!-- F.r.1: Test Date -->
239      <value xsi:type="ED">F.r.3.4</value>
240      <!-- F.r.3.4: Result Unstructured Data (free text) -->
241  2.3. G.k.4 投与量の例
242  2.3.1.   1日当たり1/回
243      <outboundRelationship2 typeCode="COMP">
244      <substanceAdministration classCode="SBADM" moodCode="EVN">
245      <text>1 per day</text>
246      <effectiveTime xsi:type="SXPR_TS">
247      <comp xsi:type="PIVL_TS">
248      <period value="1" unit="d"/>
249      </comp>
250      </effectiveTime>
251      </substanceAdministration>

```

```

252     </outboundRelationship2>
253 2.3.2.   1日当たり1錠/回
254     <outboundRelationship2 typeCode="COMP">
255         <substanceAdministration classCode="SBADM" moodCode="EVN">
256             <text>1 tablet per day </text>
257             <effectiveTime xsi:type="SXPR_TS">
258                 <comp xsi:type="PIVL_TS">
259                     <period value="1" unit="d"/>
260                 </comp>
261             </effectiveTime>
262             <doseQuantity value="1" unit="{DF}"/>
263             <consumable typeCode="CSM">
264                 <instanceOfKind classCode="INST">
265                     <kindOfProduct classCode="MMAT" determinerCode="KIND">
266                         <formCode>
267                             <originalText>Tablet</originalText>
268                         </formCode>
269                     </kindOfProduct>
270                 </instanceOfKind>
271             </consumable>
272         </substanceAdministration>
273     </outboundRelationship2>
274 2.3.3.   1日1回、1/4錠/回
275     <outboundRelationship2 typeCode="COMP">
276         <substanceAdministration classCode="SBADM" moodCode="EVN">
277             <effectiveTime xsi:type="SXPR_TS">
278                 <comp xsi:type="PIVL_TS">
279                     <period value="1" unit="d"/>
280                 </comp>
281             </effectiveTime>
282             <doseQuantity value="0.25" unit="{DF}"/>
283             <consumable typeCode="CSM">
284                 <instanceOfKind classCode="INST">
285                     <kindOfProduct classCode="MMAT" determinerCode="KIND">
286                         <formCode>
287                             <originalText>Tablet</originalText>

```


(別添3)

```
288         </formCode>
289     </kindOfProduct>
290 </instanceOfKind>
291 </consumable>
292 </substanceAdministration>
293 </outboundRelationship2>
294
295 2.3.4. 週1回、6錠/回
296 <outboundRelationship2 typeCode="COMP">
297     <substanceAdministration classCode="SBADM" moodCode="EVN">
298         <effectiveTime xsi:type="SXPR_TS">
299             <comp xsi:type="PIVL_TS">
300                 <period value="1" unit="w"/>
301             </comp>
302         </effectiveTime>
303         <doseQuantity value="6" unit="{DF}"/>
304         <consumable typeCode="CSM">
305             <instanceOfKind classCode="INST">
306                 <kindOfProduct classCode="MMAT" determinerCode="KIND">
307                     <formCode>
308                         <originalText>Tablet</originalText>
309                     </formCode>
310                 </kindOfProduct>
311             </instanceOfKind>
312         </consumable>
313     </substanceAdministration>
314 </outboundRelationship2>
315 2.3.5. 1日2回、1錠/回
316 例1
317 <outboundRelationship2 typeCode="COMP">
318     <substanceAdministration classCode="SBADM" moodCode="EVN">
319         <effectiveTime xsi:type="SXPR_TS">
320             <comp xsi:type="PIVL_TS">
321                 <period value="12" unit="h"/>
322             </comp>
323         </effectiveTime>
```

```

324         <doseQuantity value="1" unit="{DF}"/>
325         <consumable typeCode="CSM">
326             <instanceOfKind classCode="INST">
327                 <kindOfProduct classCode="MMAT" determinerCode="KIND">
328                     <formCode>
329                         <originalText>Tablet</originalText>
330                     </formCode>
331                 </kindOfProduct>
332             </instanceOfKind>
333         </consumable>
334     </substanceAdministration>
335 </outboundRelationship2>
336

```

例2

```

337 <outboundRelationship2 typeCode="COMP">
338     <substanceAdministration classCode="SBADM" moodCode="EVN">
339         <effectiveTime xsi:type="SXPR_TS">
340             <comp xsi:type="PIVL_TS">
341                 <period value="1" unit="d"/>
342             </comp>
343         </effectiveTime>
344         <doseQuantity value="2" unit="{DF}"/>
345         <consumable typeCode="CSM">
346             <instanceOfKind classCode="INST">
347                 <kindOfProduct classCode="MMAT" determinerCode="KIND">
348                     <formCode>
349                         <originalText>Tablet</originalText>
350                     </formCode>
351                 </kindOfProduct>
352             </instanceOfKind>
353         </consumable>
354     </substanceAdministration>
355 </outboundRelationship2>
356

```

357

2.3.6. 1日4回、7.5 mg/回

例1

```

360 <outboundRelationship2 typeCode="COMP">
361     <substanceAdministration classCode="SBADM" moodCode="EVN">

```

```

362         <effectiveTime xsi:type="SXPR_TS">
363             <comp xsi:type="PIVL_TS">
364                 <period value="6" unit="h"/>
365             </comp>
366         </effectiveTime>
367         <doseQuantity value="7.5" unit="mg"/>
368     </substanceAdministration>
369 </outboundRelationship2>

```

370 例2

```

371 <outboundRelationship2 typeCode="COMP">
372     <substanceAdministration classCode="SBADM" moodCode="EVN">
373         <effectiveTime xsi:type="SXPR_TS">
374             <comp xsi:type="PIVL_TS">
375                 <period value="1" unit="d"/>
376             </comp>
377         </effectiveTime>
378         <doseQuantity value="30" unit="mg"/>
379     </substanceAdministration>
380 </outboundRelationship2>

```

381 2.3.7. 1日1回、15 mL/回

```

382 <outboundRelationship2 typeCode="COMP">
383     <substanceAdministration classCode="SBADM" moodCode="EVN">
384         <effectiveTime xsi:type="SXPR_TS">
385             <comp xsi:type="PIVL_TS">
386                 <period value="1" unit="d"/>
387             </comp>
388         </effectiveTime>
389         <doseQuantity value="15" unit="mL"/>
390     </substanceAdministration>
391 </outboundRelationship2>

```

392 2.3.8. 2日に1回、1錠/回

```

393 <outboundRelationship2 typeCode="COMP">
394     <substanceAdministration classCode="SBADM" moodCode="EVN">
395         <effectiveTime xsi:type="SXPR_TS">
396             <comp xsi:type="PIVL_TS">
397                 <period value="2" unit="d"/>
398             </comp>
399         </effectiveTime>

```

```

400         <doseQuantity value="1" unit="{DF}"/>
401         <consumable typeCode="CSM">
402             <instanceOfKind classCode="INST">
403                 <kindOfProduct classCode="MMAT" determinerCode="KIND">
404                     <formCode>
405                         <originalText>Tablet</originalText>
406                     </formCode>
407                 </kindOfProduct>
408             </instanceOfKind>
409         </consumable>
410     </substanceAdministration>
411 </outboundRelationship2>
412

```

413 2.3.9. 頓用、1錠/回、開始日、終了日

```

414     <outboundRelationship2 typeCode="COMP">
415         <substanceAdministration classCode="SBADM" moodCode="EVN">
416             <effectiveTime xsi:type="SXPR_TS">
417                 <comp xsi:type="PIVL_TS">
418                     <periodunit="{as necessary}"/>
419                 </comp>
420                 <comp xsi:type="IVL_TS" operator="A">
421                     <low value="200906"/>
422                     <high value="200908"/>
423                 </comp>
424             </effectiveTime>
425             <doseQuantity value="1" unit="{DF}"/>
426

```

427 2.3.10. 頓用、20 mg/回

```

428     <outboundRelationship2 typeCode="COMP">
429         <substanceAdministration classCode="SBADM" moodCode="EVN">
430             <effectiveTime xsi:type="PIVL_TS">
431                 <periodunit="{as necessary}"/>
432             </effectiveTime>
433             <doseQuantity value="20" unit="mg"/>
434

```

435 2.3.11. 周期的、500 mg/回、開始日、終了日

```

436     <outboundRelationship2 typeCode="COMP">
437         <substanceAdministration classCode="SBADM" moodCode="EVN">
438             <effectiveTime xsi:type="SXPR_TS">
439                 <comp xsi:type="PIVL_TS">
440                     <periodunit="{cyclical}"/>
441                 </comp>
442                 <comp xsi:type="IVL_TS" operator="A">
443                     <low value="200906"/>
444                     <high value="200908"/>
445                 </comp>
446             </effectiveTime>
447         <doseQuantity value="500" unit="mg"/>

```

448 2.3.12. 周期的、500 mg/回

```

449     <outboundRelationship2 typeCode="COMP">
450         <substanceAdministration classCode="SBADM" moodCode="EVN">
451             <effectiveTime xsi:type="PIVL_TS">
452                 <periodunit="{cyclical}"/>
453             </effectiveTime>
454         <doseQuantity value="500" unit="mg"/>

```

455 2.3.13. 総投与量 20,000 mg、開始日、終了日

```

456     <substanceAdministration classCode="SBADM" moodCode="EVN">
457         <effectiveTime xsi:type="SXPR_TS">
458             <comp xsi:type="PIVL_TS">
459                 <periodunit="{total}"/>
460             </comp>
461             <comp xsi:type="IVL_TS" operator="A">
462                 <low value="200906"/>
463                 <high value="201005"/>
464             </comp>
465         </effectiveTime>
466         <doseCheckQuantity>
467             <numerator xsi:type="PQ" value="20000" unit="mg"/>
468             <denominator xsi:type="PQ" nullFlavor="UNK"/>
469         </doseCheckQuantity>

```

470 2.4. 電話、Fax、電子メール (C.3.4.6、C.3.4.7、及び C.3.4.8)

471 HL7 telecom データ型の構文 –

```
472         <telecom value="tel:C.3.4.6"/>
473         <!-- C.3.4.6: Sender's Telephone -->
474         <telecom value="fax:C.3.4.7"/>
475         <!-- C.3.4.7: Sender's Fax -->
476         <telecom value="mailto:C.3.4.8"/>
477         <!-- C.3.4.8 : Sender's E-mail Address -->
```

478 2.5. 報告者の電話番号に対して"Privacy"を示す (C.2.r.2.7)

479 "Privacy"を示すため、ICH E2B では送信者に対し telecom スキームの後に null
480 flavor=MSK の使用を推奨している。

481 例 –

```
482         <telecom value="tel:" nullFlavor="MSK"/>
483         <!--C.2.r.2.7: Reporter's Telephone is Masked for Privacy -->
```

484 これは標準のHL7のnull flavorではないことに留意する。

485 2.6. トライメスターを使用した妊娠期間 (D.2.2.1b)

```
486         <subjectOf2 typeCode="SBJ">
487             <observation moodCode="EVN" classCode="OBS">
488                 <code code="16" codeSystem="2.16.840.1.113883.3.989.2.1.1.19"
489                 displayName="gestationPeriod"/>
490                 <value xsi:type="PQ" value="1" unit="{trimester}"/>
491             </observation>
492         </subjectOf2>
```

493 2.7. 値がないが、スキーマが null flavor を求めている場合の (成分/特定成分名) の例
494 (G.k.2.3.r.1)

```
495         <ingredient classCode="ACTI">
496             <quantity>
497                 <numerator value="10" unit="mg"/>
498                 <denominator value="1"/>
499             </quantity>
500             <ingredientSubstance classCode="MMAT" determinerCode="KIND">
501                 <name nullFlavor="UNK"/>
502             </ingredientSubstance>
```

503 </ingredient>

504 2.8. 各副作用に関する因果関係情報の例

505 <component typeCode="COMP">

506 <causalityAssessment classCode="OBS" moodCode="EVN">

507 <code code="39" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" displayName="causality"/>

508 <value xsi:type="ST">G.k.9.i.2.r.3</value>

509 <methodCode>

510 <originalText>G.k.9.i.2.r.2</originalText>

511 </methodCode>

512 <author typeCode="AUT">

513 <assignedEntity classCode="ASSIGNED">

514 <code>

515 <originalText>G.k.9.i.2.r.1</originalText>

516 </code>

517 </assignedEntity>

518 </author>

519 <subject1 typeCode="SUBJ">

520 <adverseEffectReference classCode="OBS" moodCode="EVN">

521 <id root="154eb889-958b-45f2-a02f-42d4d6f4657f"/>

522 </adverseEffectReference>

523 </subject1>

524 <subject2 typeCode="SUBJ">

525 <productUseReference classCode="SBADM" moodCode="EVN">

526 <id root="3c91b4d5-e039-4a7a-9c30-67671b0ef9e4"/>

527 </productUseReference>

528 </subject2>

529 </causalityAssessment>

530 </component>

531

532 III. 参照インスタンスについての注意事項

- 533 • 参照インスタンスでは、各データ項目の XML における記述方法を示すため、実際の値
534 の代わりに E2B (R3) の各データ項目の項目番号が示されている。各データ項目の名称
535 は XML 中にコメントとして示されている。
- 536 • コードが数値である場合、そのコードのテキスト (ラベル) を人間が判読可能なように
537 *display name* に示す。
- 538 • 参照インスタンスと関連する XPath は付録 I (D) と相互参照されている。
- 539 • 項目のデータ型が"PQ"である場合、HL7 PQ データ型のルールによりその値の単位は参
540 考例に示されない。有効な ICH 単位については、付録 I (F) の ICH E2B コードリスト
541 25 及び 26 を参照のこと。
- 542 • 患者及び親の投与経路 (G.k.4.r.11) の関連性は、医薬品情報のオーガナイザクション
543 内の繰り返しの入れ子構造 (インバウンド及びアウトバンドの関係) を用いて入力する。
544 親の投与経路は入れ子になった'inboundRelationship'として入力し、観察コード及びコー
545 ド化された情報と自由記述の両方をサポートするオブザベーションコードと値の組合せ
546 を用いて表す。

547 例 :

```
548 <outboundRelationship2typeCode="COMP">
549   <substanceAdministrationclassCode="SBADM"moodCode="EVN">
550     <inboundRelationshiptypeCode="REFR">
551       <observationclassCode="OBS"moodCode="EVN">
552         <code code="parentRouteOfAdministration"
553           codeSystem="2.16.840.1.113883.3.989.2.1.1.19"/>
554         <valuexsi:type="CE" code="G.k.4.r.11.2b"
555           codeSystem="2.16.840.1.113883.3.989.2.1.1.14"
556           codeSystemVersion="G.k.4.r.11.2a">
557           <!-- G.k.4.r.11.2a: Parent Route of Administration TermID Version Date / Number
558             #1-1 -->
559           <!-- G.k.4.r.11.2b: Parent Route of Administration TermID #1-1 -->
560           <originalText>G.k.4.r.11.1</originalText>
561           <!-- G.k.4.r.11.1: Parent Route of Administration (free text) #1-1 -->
562           </value>
563         </observation>
564       </inboundRelationship>
565     </substanceAdministration>
566   </outboundRelationship2>
```


567 **IV. 参考**

568 **ICSR メッセージにおける E2B (R3) データ項目構造**

569 エクセルファイルは、ICSR メッセージにおける E2B (R3) データ項目の構成について
570 説明している。参照インスタンスの XML タグは E2B (R3) データ項目毎にグループ化
571 されており、これにより利用者はデータ項目の繰り返しブロック及び階層構造を確認す
572 ることができる。本文書の目的は HL7 に基づく XML メッセージに詳しくない利用者
573 に対して参照インスタンスの解釈を容易にすることであるため、本文書は初回の公表以降
574 は更新されない可能性があることに留意する。

