

(別添 3)

<p>e</p>		<p>2.E.i.4, E.i.5 及び E.i.6 のすべての項目が表示される場合 データ型 SXPР を伴う最初の comp 項目 HL7 データ型: Parenthetic Set Expression of Point in Time (SXPР<TS>)</p>	<p>2.E.i.4, E.i.5 及び E.i.6 のすべての項目が表示される場合データ型 SXPР を伴う最初の comp 項目 comp/width/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'/PDRR_IN049016UVJ/controlActProcess/@classCode='CACT']/@moodCode='EVN']/subject/@typeCode='SUBJ']/investigationEvent/@classCode='INVTSTG']/@moodCode='EVN']/component/@typeCode='COMP']/adverseEventAssessment[1]/adverseEventAssessment/@classCode='INVTSTG']/@moodCode='EVN']/subject[1]/primaryRole/@classCode='INVSBJ']/subjectOr2/@typeCode='SBJ']/observation[id]/code/@code='29']/@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']/observation/@classCode='OBS']/@moodCode='EVN']/effectiveTime/@xsi:type='SXPР_TS']/comp[@xsi:type='IV_LTS']/width/@unit</pre>
<p>e</p>		<p>3.E.i.4, E.i.5 及び E.i.6 のすべての項目が表示される場合 データ型 SXPР を伴う 2 番目の comp 項目 HL7 データ型: Parenthetic Set Expression of Point in Time (SXPР<TS>)</p>	<p>3.E.i.4, E.i.5 及び E.i.6 のすべての項目が表示される場合データ型 SXPР を伴う 2 番目の comp 項目 comp/width/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'/PDRR_IN049016UVJ/controlActProcess/@classCode='CACT']/@moodCode='EVN']/subject/@typeCode='SUBJ']/investigationEvent/@classCode='INVTSTG']/@moodCode='EVN']/component/@typeCode='COMP']/adverseEventAssessment[1]/adverseEventAssessment/@classCode='INVTSTG']/@moodCode='EVN']/subject[1]/primaryRole/@classCode='INVSBJ']/subjectOr2/@typeCode='SBJ']/observation[id]/code/@code='29']/@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']/observation/@classCode='OBS']/@moodCode='EVN']/effectiveTime/@xsi:type='SXPР_TS']/comp[@xsi:type='IV_LTS']/@operator='A']/width/@unit</pre>
<p>e</p>	<p>E.i.7 最終観察時の副作用/有害事象の転帰</p>	<p>1N</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'/PDRR_IN049016UVJ/controlActProcess/@classCode='CACT']/@moodCode='EVN']/subject/@typeCode='SUBJ']/investigationEvent/@classCode='INVTSTG']/@moodCode='EVN']/component/@typeCode='COMP']/adverseEventAssessment[1]/adverseEventAssessment/@classCode='INVTSTG']/@moodCode='EVN']/subject[1]/primaryRole/@classCode='INVSBJ']/subjectOr2/@typeCode='SBJ']/observation[id]/code/@code='29']/@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']/observation/@classCode='OBS']/@moodCode='EVN']/outboundRelationship2/@typeCode='PERT']/observation/code/@code='27']/@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']/observation/@classCode='OBS']/@moodCode='EVN']/value/@xsi:type='CE']/@codeSystem='2.16.840.1.113883.3.989.2.1.1.11']/@code</pre>
<p>e</p>	<p>E.i.8 医療専門家による医学的確認</p>	<p>ブール型</p>	<p>Boolean (BL)</p>	<p>値</p>	<pre>/MCCI_IN200100UV01[@ITSVersion='XML_1.0']/@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd'/PDRR_IN049016UVJ/controlActProcess/@classCode='CACT']/@moodCode='EVN']/subject/@typeCode='SUBJ']/investigationEvent/@classCode='INVTSTG']/@moodCode='EVN']/component/@typeCode='COMP']/adverseEventAssessment[1]/adverseEventAssessment/@classCode='INVTSTG']/@moodCode='EVN']/subject[1]/primaryRole/@classCode='INVSBJ']/subjectOr2/@typeCode='SBJ']/observation[id]/code/@code='29']/@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']/observation/@classCode='OBS']/@moodCode='EVN']/outboundRelationship2/@typeCode='PERT']/observation/code/@code='24']/@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']/observation/@classCode='OBS']/@moodCode='EVN']/value/@xsi:type='BL']/@value</pre>

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E.I.9	副作用／有害事象が発現した国の識別	2A	Concept Descriptor (CD)	code=Character String (ST)	値	/MCCI_IN200100UV01@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PDRR_IN049016UV1/controlActProcess[@classCode=CACT][@moodCode=EVN]/subject/@typeCode=SUBJ[1]/investigationEvent[@classCode=INVSIG][@moodCode=EVN]/component/@typeCode=COMP[1]adverseEventAssessment[1]adverseEventAssessment[@classCode=INVSIG][@moodCode=EVN]/subject/@typeCode=SBJ[1]/primaryRole/@classCode=INVSIG[2]@typeCode=SBJ[1]observationCode=@code=2][@codeSystem=2.16.840.1.113883.3.989.2.1.1.19][1]observation/@classCode=OBS[1][@moodCode=EVN]/location/@typeCode=LOC[1][@codeSystem=1.0.3166.1.2.2][@codeSystem=1.0.3166.1.2.2][@codeSystem=1.0.3166.1.2.2]
F.r	患者の診断に関連する検査及び処置の結果 (必要に応じて繰り返す)				値	/MCCI_IN200100UV01@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PDRR_IN049016UV1/controlActProcess[@classCode=CACT][@moodCode=EVN]/subject/@typeCode=SUBJ[1]/investigationEvent[@classCode=INVSIG][@moodCode=EVN]/component/@typeCode=COMP[1]adverseEventAssessment[1]adverseEventAssessment[@classCode=INVSIG][@moodCode=EVN]/subject/@typeCode=SBJ[1]/primaryRole/@classCode=INVSIG[2]@typeCode=SBJ[1]observationCode=@code=3][@codeSystem=2.16.840.1.113883.3.989.2.1.1.20][1]organizer/@classCode=CATEGORY[1][@moodCode=EVN]/component/@typeCode=COMP[1]observation/@codeSystem=2.16.840.1.113883.6.163]
F.r.1	日付 (検査)	日付/時間	Point in Time (TS)		値	/MCCI_IN200100UV01@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PDRR_IN049016UV1/controlActProcess[@classCode=CACT][@moodCode=EVN]/subject/@typeCode=SUBJ[1]/investigationEvent[@classCode=INVSIG][@moodCode=EVN]/component/@typeCode=COMP[1]adverseEventAssessment[1]adverseEventAssessment[@classCode=INVSIG][@moodCode=EVN]/subject/@typeCode=SBJ[1]/primaryRole/@classCode=INVSIG[2]@typeCode=SBJ[1]observationCode=@code=3][@codeSystem=2.16.840.1.113883.3.989.2.1.1.20][1]organizer/@classCode=CATEGORY[1][@moodCode=EVN]/component/@typeCode=COMP[1]observation/@codeSystem=2.16.840.1.113883.6.163][r/observation/@classCode=OBS][@moodCode=EVN]/effectiveTime/@value
e					Null Flavor	/MCCI_IN200100UV01@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PDRR_IN049016UV1/controlActProcess[@classCode=CACT][@moodCode=EVN]/subject/@typeCode=SUBJ[1]/investigationEvent[@classCode=INVSIG][@moodCode=EVN]/component/@typeCode=COMP[1]adverseEventAssessment[1]adverseEventAssessment[@classCode=INVSIG][@moodCode=EVN]/subject/@typeCode=SBJ[1]/primaryRole/@classCode=INVSIG[2]@typeCode=SBJ[1]observationCode=@code=3][@codeSystem=2.16.840.1.113883.3.989.2.1.1.20][1]organizer/@classCode=CATEGORY[1][@moodCode=EVN]/component/@typeCode=COMP[1]observation/@codeSystem=2.16.840.1.113883.6.163][r/observation/@classCode=OBS][@moodCode=EVN]/effectiveTime/@nullFlavor
h	検査名				値	/MCCI_IN200100UV01@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PDRR_IN049016UV1/controlActProcess[@classCode=CACT][@moodCode=EVN]/subject/@typeCode=SUBJ[1]/investigationEvent[@classCode=INVSIG][@moodCode=EVN]/component/@typeCode=COMP[1]adverseEventAssessment[1]adverseEventAssessment[@classCode=INVSIG][@moodCode=EVN]/subject/@typeCode=SBJ[1]/primaryRole/@classCode=INVSIG[2]@typeCode=SBJ[1]observationCode=@code=3][@codeSystem=2.16.840.1.113883.3.989.2.1.1.20][1]organizer/@classCode=CATEGORY[1][@moodCode=EVN]/component/@typeCode=COMP[1]observation/@codeSystem=2.16.840.1.113883.6.163][r/observation/@classCode=OBS][@moodCode=EVN]/code/originalText
e	検査名 (自由記載)	250AN	Concept Descriptor (CD)	originalText=Encapsulated Data (ED)	値	/MCCI_IN200100UV01@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PDRR_IN049016UV1/controlActProcess[@classCode=CACT][@moodCode=EVN]/subject/@typeCode=SUBJ[1]/investigationEvent[@classCode=INVSIG][@moodCode=EVN]/component/@typeCode=COMP[1]adverseEventAssessment[1]adverseEventAssessment[@classCode=INVSIG][@moodCode=EVN]/subject/@typeCode=SBJ[1]/primaryRole/@classCode=INVSIG[2]@typeCode=SBJ[1]observationCode=@code=3][@codeSystem=2.16.840.1.113883.3.989.2.1.1.20][1]organizer/@classCode=CATEGORY[1][@moodCode=EVN]/component/@typeCode=COMP[1]observation/@codeSystem=2.16.840.1.113883.6.163][r/observation/@classCode=OBS][@moodCode=EVN]/code/originalText

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e	F.r.2.2a	検査名の MedDRA パージョ ン	4AN	Concept Descriptor (CD)	codeSystemVersion= Character String (ST)	値	/MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=um:h7-org:v3 MCCL_IN200100UV01.xsd]/PORR_IN049016UV01/controlActProcess[@classCode=CACT][@mo dCode=EVN]/subject[@typeCode=SUBJ][1]/investigationEvent[@classCode=INVSTG][@moodCo de=EVN]/component[@typeCode=COMP]/adverseEventAssessment[1]/adverseEventAssessment [1]/classCode=INVSTG[1]/moodCode=EVN]/subject[1][@typeCode=SBJ][1]/primaryRole[1]/classC ode=INVSBJ/subjectO2[2][@typeCode=SBJ]/organizer/code[@code=3][@codeSystem=2.16.840.1 113883.3.989.2.1.1.20][1]/organizer/code[@code=CATEGORY][@moodCode=EVN]/component[@typeCode=COMP]/observation/code[@codeSystem=2.16.840.1.113883.6.163][1]/observation[@classCode=OBS][1][@moodCode=EVN]/code[@code]
e	F.r.2.2b	検査名 (MedDRA コード)	8N	Concept Descriptor (CD)	code=Character String (ST)	値	/MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=um:h7-org:v3 MCCL_IN200100UV01.xsd]/PORR_IN049016UV01/controlActProcess[@classCode=CACT][@mo dCode=EVN]/subject[@typeCode=SUBJ][1]/investigationEvent[@classCode=INVSTG][@moodCo de=EVN]/component[@typeCode=COMP]/adverseEventAssessment[1]/adverseEventAssessment [1]/classCode=INVSTG[1]/moodCode=EVN]/subject[1][@typeCode=SBJ][1]/primaryRole[1]/classC ode=INVSBJ/subjectO2[2][@typeCode=SBJ]/organizer/code[@code=3][@codeSystem=2.16.840.1 113883.3.989.2.1.1.20][1]/organizer/code[@code=CATEGORY][@moodCode=EVN]/component[@typeCode=COMP]/observation/code[@codeSystem=2.16.840.1.113883.6.163][1]/observation[@classCode=OBS][1][@moodCode=EVN]/code[@code]
h	F.r.3	検査結果					
e	F.r.3.1	検査結果 (コード)	1N	Coded With Equivalents (CE)	code=Character String (ST)	値	/MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=um:h7-org:v3 MCCL_IN200100UV01.xsd]/PORR_IN049016UV01/controlActProcess[@classCode=CACT][@mo dCode=EVN]/subject[@typeCode=SUBJ][1]/investigationEvent[@classCode=INVSTG][@moodCo de=EVN]/component[@typeCode=COMP]/adverseEventAssessment[1]/adverseEventAssessment [1]/classCode=INVSTG[1]/moodCode=EVN]/subject[1][@typeCode=SBJ][1]/primaryRole[1]/classC ode=INVSBJ/subjectO2[2][@typeCode=SBJ]/organizer/code[@code=3][@codeSystem=2.16.840.1 113883.3.989.2.1.1.20][1]/organizer/code[@code=CATEGORY][@moodCode=EVN]/component[@typeCode=COMP]/observation/code[@codeSystem=2.16.840.1.113883.6.163][1]/observation[@classCode=OBS][1][@moodCode=EVN]/interpretationCode[@codeSystem=2.16.840.1.113883.3.98 9.2.1.1.12][1]/code
e	F.r.3.2	検査結果 (値/限定子)	50N	Interval of Physical Quantity (IVL<PQ>)	1.EQ center=Physical Quantity (PQ)	値	/MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=um:h7-org:v3 MCCL_IN200100UV01.xsd]/PORR_IN049016UV01/controlActProcess[@classCode=CACT][@mo dCode=EVN]/component[@typeCode=SUBJ][1]/investigationEvent[@classCode=INVSTG][@moodCo de=EVN]/subject[@typeCode=EVN]/subject[1][@typeCode=SBJ][1]/primaryRole[1]/classC ode=INVSBJ/subjectO2[2][@typeCode=SBJ]/organizer/code[@code=3][@codeSystem=2.16.840.1 113883.3.989.2.1.1.20][1]/organizer/code[@code=CATEGORY][@moodCode=EVN]/component[@typeCode=COMP]/observation/code[@codeSystem=2.16.840.1.113883.6.163][1]/observation[@classCode=OBS][1][@moodCode=EVN]/value[@xsi:type=IVL_PQ][1]/center/@value
e					2.GT low=Interval Boundary (IVXB)	値	/MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=um:h7-org:v3 MCCL_IN200100UV01.xsd]/PORR_IN049016UV01/controlActProcess[@classCode=CACT][@mo dCode=EVN]/subject[@typeCode=SUBJ][1]/investigationEvent[@classCode=INVSTG][@moodCo de=EVN]/component[@typeCode=COMP]/adverseEventAssessment[1]/adverseEventAssessment [1]/classCode=INVSTG[1]/moodCode=EVN]/subject[1][@typeCode=SBJ][1]/primaryRole[1]/classC ode=INVSBJ/subjectO2[2][@typeCode=SBJ]/organizer/code[@code=3][@codeSystem=2.16.840.1 113883.3.989.2.1.1.20][1]/organizer/code[@code=CATEGORY][@moodCode=EVN]/component[@typeCode=COMP]/observation/code[@codeSystem=2.16.840.1.113883.6.163][1]/observation[@classCode=OBS][1][@moodCode=EVN]/value[@xsi:type=IVL_PQ][1]/high/@nullFlavor=PINF[1]/low[@inclusive=false][1]/value

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<pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/P/RR_IN049016UV/ControlActProcess[@classCode=CACT][@moodC dCode=EVN]/subject[@typeCode=SUBJ]/InvestigationEvent[@classCode=INVTG][@moodCo de=EVN]/component[@typeCode=COMP]/AdverseEventAssessment[1]/AdverseEventAssessme nt[@classCode=INVTG][@moodCode=EVN]/subject[1]/typeCode=SBJ][1]/primaryRole/@classC ode=INVSBJ/subjectOf2[@typeCode=SBJ]/organizer/code[@code=3][@codeSystem=2.16.840.1 .113883.3.989.2.1.1.20][1]/organizer/@classCode=CATEGORY][@moodCode=EVN]/component[@typeCode=COMP][observation/code/@codeSystem=2.16.840.1.113883.6.163][r/observation/@ classCode=OBS][@moodCode=EVN]/value[@xsi:type=IVL_PQ][1]/low/@nullFlavor </pre>	NullFlavor		
<pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/P/RR_IN049016UV/ControlActProcess[@classCode=CACT][@moodC dCode=EVN]/subject[@typeCode=SUBJ]/InvestigationEvent[@classCode=INVTG][@moodCo de=EVN]/component[@typeCode=COMP]/AdverseEventAssessment[1]/AdverseEventAssessme nt[@classCode=INVTG][@moodCode=EVN]/subject[1]/typeCode=SBJ][1]/primaryRole/@classC ode=INVSBJ/subjectOf2[@typeCode=SBJ]/organizer/code[@code=3][@codeSystem=2.16.840.1 .113883.3.989.2.1.1.20][1]/organizer/@classCode=CATEGORY][@moodCode=EVN]/component[@typeCode=COMP][observation/code/@codeSystem=2.16.840.1.113883.6.163][r/observation/@ classCode=OBS][@moodCode=EVN]/value[@xsi:type=IVL_PQ][1]/high/@nullFlavor </pre>	値	3.GE low=Interval Boundary (IVXB)	
<pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/P/RR_IN049016UV/ControlActProcess[@classCode=CACT][@moodC dCode=EVN]/subject[@typeCode=SUBJ]/InvestigationEvent[@classCode=INVTG][@moodCo de=EVN]/component[@typeCode=COMP]/AdverseEventAssessment[1]/AdverseEventAssessme nt[@classCode=INVTG][@moodCode=EVN]/subject[1]/typeCode=SBJ][1]/primaryRole/@classC ode=INVSBJ/subjectOf2[@typeCode=SBJ]/organizer/code[@code=3][@codeSystem=2.16.840.1 .113883.3.989.2.1.1.20][1]/organizer/@classCode=CATEGORY][@moodCode=EVN]/component[@typeCode=COMP][observation/code/@codeSystem=2.16.840.1.113883.6.163][r/observation/@ classCode=OBS][@moodCode=EVN]/value[@xsi:type=IVL_PQ][1]/low/@nullFlavor </pre>	NullFlavor		
<pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/P/RR_IN049016UV/ControlActProcess[@classCode=CACT][@moodC dCode=EVN]/subject[@typeCode=SUBJ]/InvestigationEvent[@classCode=INVTG][@moodCo de=EVN]/component[@typeCode=COMP]/AdverseEventAssessment[1]/AdverseEventAssessme nt[@classCode=INVTG][@moodCode=EVN]/subject[1]/typeCode=SBJ][1]/primaryRole/@classC ode=INVSBJ/subjectOf2[@typeCode=SBJ]/organizer/code[@code=3][@codeSystem=2.16.840.1 .113883.3.989.2.1.1.20][1]/organizer/@classCode=CATEGORY][@moodCode=EVN]/component[@typeCode=COMP][observation/code/@codeSystem=2.16.840.1.113883.6.163][r/observation/@ classCode=OBS][@moodCode=EVN]/value[@xsi:type=IVL_PQ][1]/high/@nullFlavor </pre>	値	4.LT high=Interval Boundary (IVXB)	
<pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/P/RR_IN049016UV/ControlActProcess[@classCode=CACT][@moodC dCode=EVN]/subject[@typeCode=SUBJ]/InvestigationEvent[@classCode=INVTG][@moodCo de=EVN]/component[@typeCode=COMP]/AdverseEventAssessment[1]/AdverseEventAssessme nt[@classCode=INVTG][@moodCode=EVN]/subject[1]/typeCode=SBJ][1]/primaryRole/@classC ode=INVSBJ/subjectOf2[@typeCode=SBJ]/organizer/code[@code=3][@codeSystem=2.16.840.1 .113883.3.989.2.1.1.20][1]/organizer/@classCode=CATEGORY][@moodCode=EVN]/component[@typeCode=COMP][observation/code/@codeSystem=2.16.840.1.113883.6.163][r/observation/@ classCode=OBS][@moodCode=EVN]/value[@xsi:type=IVL_PQ][1]/high/@nullFlavor </pre>	NullFlavor		

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e		5.LEHigh=Interval Boundary (IVXB)	値	/MCCL_IN200100UV01[@ITSVersion=XML_1.0T][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UVJr/control/ActProcess[@classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUBJ][@investigationEvent/@classCode=INVSTG][@moodCode=EVN]/component[@typeCode=COMP][@adverseEventAssessment[1]/adverseEventAssessment[@classCode=INVSTG][@moodCode=EVN]/subject[1]/typeCode=SBJ][1]/primaryRole[@classCode=INVSBJ]/subjectOf2[1]/typeCode=SBJ][1]/organizer/code[1]/codeSystem=2.16.840.1.113883.3.988.2.1.1.20][1]/organizer/@classCode=CACTORY][@moodCode=EVN]/component[1]/typeCode=COMP][observation/code[1]/codeSystem=2.16.840.1.113883.6.163][r/observation/@classCode=OBS][@moodCode=EVN]/value[@xsi:type=IVL_PQ][low/@nullFlavor=NINF][1]/high/@inclusive=true]/@value
e		NullFlavor	NullFlavor	/MCCL_IN200100UV01[@ITSVersion=XML_1.0T][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UVJr/control/ActProcess[@classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUBJ][1]/investigationEvent/@classCode=INVSTG][@moodCode=EVN]/component[@typeCode=COMP][@adverseEventAssessment[1]/adverseEventAssessment[@classCode=INVSTG][@moodCode=EVN]/subject[1]/typeCode=SBJ][1]/organizer/code[1]/codeSystem=2.16.840.1.113883.3.988.2.1.1.20][1]/organizer/@classCode=CATEGORY][@moodCode=EVN]/component[1]/typeCode=COMP][observation/code[1]/codeSystem=2.16.840.1.113883.6.163][r/observation/@classCode=OBS][@moodCode=EVN]/value[@xsi:type=IVL_PQ][1]/high/@nullFlavor
e	F.r.3.3	Interval of Physical Quantity (VL<PQ>)	値	/MCCL_IN200100UV01[@ITSVersion=XML_1.0T][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UVJr/control/ActProcess[@classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUBJ][1]/investigationEvent/@classCode=INVSTG][@moodCode=EVN]/component[@typeCode=COMP][@adverseEventAssessment[1]/adverseEventAssessment[@classCode=INVSTG][@moodCode=EVN]/subject[1]/typeCode=SBJ][1]/primaryRole[@classCode=INVSBJ]/subjectOf2[1]/typeCode=SBJ][1]/organizer/code[1]/codeSystem=2.16.840.1.113883.3.988.2.1.1.20][1]/organizer/@classCode=CATEGORY][@moodCode=EVN]/component[1]/typeCode=COMP][observation/code[1]/codeSystem=2.16.840.1.113883.6.163][r/observation/@classCode=OBS][@moodCode=EVN]/value[@xsi:type=IVL_PQ][1]/center/@unit
e		2.GT lowValue/unit=Coded Simple Value (CS)	値	/MCCL_IN200100UV01[@ITSVersion=XML_1.0T][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UVJr/control/ActProcess[@classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUBJ][1]/investigationEvent/@classCode=INVSTG][@moodCode=EVN]/component[@typeCode=COMP][@adverseEventAssessment[1]/adverseEventAssessment[@classCode=INVSTG][@moodCode=EVN]/subject[1]/typeCode=SBJ][1]/primaryRole[@classCode=INVSBJ]/subjectOf2[1]/typeCode=SBJ][1]/organizer/code[1]/codeSystem=2.16.840.1.113883.3.988.2.1.1.20][1]/organizer/@classCode=CATEGORY][@moodCode=EVN]/component[1]/typeCode=COMP][observation/code[1]/codeSystem=2.16.840.1.113883.6.163][r/observation/@classCode=OBS][@moodCode=EVN]/value[@xsi:type=IVL_PQ][high/@nullFlavor=PINF][1]/low/@inclusive=false]/@unit
e		3.GE lowValue/unit=Coded Simple Value (CS)	値	/MCCL_IN200100UV01[@ITSVersion=XML_1.0T][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UVJr/control/ActProcess[@classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUBJ][1]/investigationEvent/@classCode=INVSTG][@moodCode=EVN]/component[@typeCode=COMP][@adverseEventAssessment[1]/adverseEventAssessment[@classCode=INVSTG][@moodCode=EVN]/subject[1]/typeCode=SBJ][1]/primaryRole[@classCode=INVSBJ]/subjectOf2[1]/typeCode=SBJ][1]/organizer/code[1]/codeSystem=2.16.840.1.113883.3.988.2.1.1.20][1]/organizer/@classCode=CATEGORY][@moodCode=EVN]/component[1]/typeCode=COMP][observation/code[1]/codeSystem=2.16.840.1.113883.6.163][r/observation/@classCode=OBS][@moodCode=EVN]/value[@xsi:type=IVL_PQ][high/@nullFlavor=PINF][1]/low/@inclusive=true]/@unit

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	<p>4.LT high/value/unit=Code d Simple Value (CS)</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']/@moodCo dCode='EVN']/subject/@typeCode='SUBJ'/investigationEvent/@classCode='INVESTG'/@moodCo de='EVN']/component/@typeCode='COMP'/adverseEventAssessment[1]/adverseEventAssessment [classCode='INVESTG']/moodCode='EVN']/subject[1]/typeCode='SBJ'/primaryRole/@classC ode='INVSBJ'/subject[2]/@typeCode='SBJ'/organizer/@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'[/observation/@ classCode='OBS']/@moodCode='EVN']/value[@xsi:type='VL_PQ']/@unit @inclusive='false'/@unit</pre>
	<p>5.LE high/value/unit=Code d Simple Value (CS)</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']/@moodCo dCode='EVN']/subject/@typeCode='SUBJ'/investigationEvent/@classCode='INVESTG'/@moodCo de='EVN']/component/@typeCode='COMP'/adverseEventAssessment[1]/adverseEventAssessment [classCode='INVESTG']/moodCode='EVN']/subject[1]/typeCode='SBJ'/primaryRole/@classC ode='INVSBJ'/subject[2]/@typeCode='SBJ'/organizer/@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'[/observation/@ classCode='OBS']/@moodCode='EVN']/value[@xsi:type='VL_PQ']/@unit @inclusive='true'/@unit</pre>
<p>F.r.3.4</p>	<p>検査結果に関する非精造化 データ (自由記載)</p>	<p>Encapsulated Data (ED)</p>	<p>2000AN</p>
<p>F.r.4</p>	<p>正常範囲 係値</p>	<p>Physical Quantity (PQ)</p>	<p>50AN</p>

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e	F.r.5	正常範囲 高値	50AN	Physical Quantity (PQ)	value=Real Number (REAL)	値	<pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/PORR_IN049016UVr/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[1]/subjectOriz/@typeCode=SBJ[1]/organizer/code/@code=3[1]/codeSystem=2.16.840.1.113883.3.989.2.1.1.20[1]/organizer/@classCode=CATEGORY[1]/moodCode=EVN/component/@typeCode=COMP[1]/observation/code/@codeSystem=2.16.840.1.113883.6.163[1]/observation/@classCode=OBS[1]/moodCode=EVN/referenceRange/@typeCode=REFV[1]/observationRange/interpretationCode/@code=HT[1]/codeSystem=2.16.840.1.113883.5.83[1][1]/observationRange/interpretationCode=@code=OBS[1][1]/value/@xsi:type=PQ[1]/value </pre>
e	F.r.6	備考	2000AN	Encapsulated Data (ED)		値	<pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/PORR_IN049016UVr/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[1]/subjectOriz/@typeCode=SBJ[1]/organizer/code/@code=3[1]/codeSystem=2.16.840.1.113883.3.989.2.1.1.20[1]/organizer/@classCode=CATEGORY[1]/moodCode=EVN/component/@typeCode=COMP[1]/observation/code/@codeSystem=2.16.840.1.113883.6.163[1]/observation/@classCode=OBS[1]/moodCode=EVN/outboundRelationship2/@typeCode=PERT[1]/observation/code/@code=10[1][1]/codeSystem=2.16.840.1.113883.3.989.2.1.1.19[1]/observation/code=@code=OBS[1][1]/value/@xsi:type=ED[1]/text() </pre>
e	F.r.7	その他の情報	ブール型	Boolean (BL)		値	<pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/PORR_IN049016UVr/controlActProcess[@classCode=CACT][@moodCode=EVN]/component/@typeCode=SUBJ[1]/investigationEvent[@classCode=INVESTG][@moodCode=EVN]/subject/@typeCode=COMP[1]/adverseEventAssessment[1]/adverseEventAssessment[@classCode=INVESTG][@moodCode=EVN]/subject1/@typeCode=SBJ[1]/primaryRole/@classCode=INVSBJ[1]/subjectOriz/@typeCode=SBJ[1]/organizer/code/@code=3[1]/codeSystem=2.16.840.1.113883.3.989.2.1.1.20[1]/organizer/@classCode=CATEGORY[1]/moodCode=EVN/component/@typeCode=COMP[1]/observation/code/@codeSystem=2.16.840.1.113883.6.163[1]/observation/@classCode=OBS[1]/moodCode=EVN/outboundRelationship2/@typeCode=REFR[1]/observation/code/@code=25[1][1]/codeSystem=2.16.840.1.113883.3.989.2.1.1.19[1]/observation/code=@code=OBS[1][1]/value/@xsi:type=BL[1]/value </pre>
h	G.k	医薬品情報 (必要に応じ繰り返し返す)				繰り返し ノード	<pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/PORR_IN049016UVr/controlActProcess[@classCode=CACT][@moodCode=EVN]/component/@typeCode=SUBJ[1]/investigationEvent[@classCode=INVESTG][@moodCode=EVN]/subject/@typeCode=COMP[1]/adverseEventAssessment[1]/adverseEventAssessment[@classCode=INVESTG][@moodCode=EVN]/subject1/@typeCode=SBJ[1]/primaryRole/@classCode=INVSBJ[1]/subjectOriz/@typeCode=SBJ[1]/organizer/code/@code=4[1][1]/codeSystem=2.16.840.1.113883.3.989.2.1.1.20[1]/organizer/@classCode=CATEGORY[1]/moodCode=EVN/component/@typeCode=COMP[1]/substanceAdministration/id </pre>

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e	G.k.1	医薬品調与の位置付け	1N	Coded With Equivalents (CE)	code=Character String (ST)	値	/MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PQRR_IN049016UVJ/control/ActProcess[@classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUBJ][@investigationEvent/@classCode=INVESTG][@moodCode=EVN]/component[@typeCode=COMP][@adverseEventAssessment/@classCode=COMP][@adverseEventAssessment/@typeCode=COMP][@causalityAssessment/@code=20][@codeSystem=2.16.840.1.113883.3.989.2.1.1.19][@causalityAssessment/@classCode=OBS][@moodCode=EVN]/subject2[@typeCode=SUBJ][@productUseReference/@classCode=SBADM][@moodCode=EVN]/id[@root=UUIID or drug][value[@xsi:type=CE]][@codeSystem=2.16.840.1.113883.3.989.2.1.1.13][@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 MCCI_IN200100UV01.xsd]/PQRR_IN049016UVJ/control/ActProcess[@classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUBJ][@investigationEvent/@classCode=INVESTG][@moodCode=EVN]/component[@typeCode=COMP][@adverseEventAssessment/@classCode=COMP][@adverseEventAssessment/@typeCode=EVN]/subject1[@typeCode=SBJ][@primaryRole/@classCode=INVSBJ][@subjectO2/@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/@classCode=SBADM][@moodCode=EVN]/consumable[@typeCode=CSMT][@instanceOfKind/@classCode=INST][@kindOfProduct/@classCode=MMA][@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 MCCI_IN200100UV01.xsd]/PQRR_IN049016UVJ/control/ActProcess[@classCode=CACT][@moodCode=EVN]/component[@typeCode=COMP][@adverseEventAssessment/@classCode=COMP][@adverseEventAssessment/@typeCode=EVN]/subjectO2[@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/@classCode=SBADM][@moodCode=EVN]/consumable[@typeCode=CSMT][@instanceOfKind/@classCode=INST][@kindOfProduct/@classCode=MMA][@determinerCode=KIND][@code/@codeSystem=TBD-MPID][@code
e	G.k.2.1.2a	PhPID 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 MCCI_IN200100UV01.xsd]/PQRR_IN049016UVJ/control/ActProcess[@classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUBJ][@investigationEvent/@classCode=INVESTG][@moodCode=EVN]/component[@typeCode=COMP][@adverseEventAssessment/@classCode=COMP][@adverseEventAssessment/@typeCode=EVN]/subject1[@typeCode=SBJ][@primaryRole/@classCode=INVSBJ][@subjectO2/@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/@classCode=SBADM][@moodCode=EVN]/consumable[@typeCode=CSMT][@instanceOfKind/@classCode=INST][@kindOfProduct/@classCode=MMA][@determinerCode=KIND][@code/@codeSystem=TBD-PhPID][@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)	値	/MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=um:hl7-org:v3 MCCL_IN200100UV01.xsd]/PDRR_IN049016UVJ/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]/primaryRole[@classC ode=INVSBJ]/subjectO2I[@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]/moodCode=COMP[1]/substanceAdministration[1]/substanceAdministration[@classCode=SBADM][@moodCode=EVN]/consumable[@typeCode=CSM][1]/instanceOfKind[@classCode=INST]/kind OfProduct[@classCode=MMAAT][@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)	値	/MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=um:hl7-org:v3 MCCL_IN200100UV01.xsd]/PDRR_IN049016UVJ/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]/primaryRole[@classC ode=INVSBJ]/subjectO2I[@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]/moodCode=COMP[1]/substanceAdministration[1]/substanceAdministration[@classCode=SBADM][@moodCode=EVN]/consumable[@typeCode=CSM][1]/instanceOfKind[@classCode=INST]/kind OfProduct[@classCode=MMAAT][@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	/MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=um:hl7-org:v3 MCCL_IN200100UV01.xsd]/PDRR_IN049016UVJ/controlActProcess[@classCode=CACT][@moo dCode=EVN]/component[@typeCode=SUBJ]/investigationEvent[@classCode=INVTG][@moodCo de=EVN]/component[@typeCode=COMP]/adverseEventAssessment[1]/adverseEventAssessment [@classCode=INVTG][@moodCode=EVN]/subject[1]/primaryRole[@classC ode=INVSBJ]/subjectO2I[@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]/moodCode=COMP[1]/substanceAdministration[1]/substanceAdministration[@classCode=SBADM][@moodCode=EVN]/consumable[@typeCode=CSM][1]/instanceOfKind[@classCode=INST]/kind OfProduct[@classCode=MMAAT][@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)	値	/MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=um:hl7-org:v3 MCCL_IN200100UV01.xsd]/PDRR_IN049016UVJ/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]/primaryRole[@classC ode=INVSBJ]/subjectO2I[@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]/moodCode=COMP[1]/substanceAdministration[1]/substanceAdministration[@classCode=SBADM][@moodCode=EVN]/consumable[@typeCode=CSM][1]/instanceOfKind[@classCode=INST]/kind OfProduct[@classCode=MMAAT][@determinerCode=KIND]/name[1]/text()

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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 ジョン目付/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]/PORR_IN049016UV1/controlActProcess[@classCode=CACT][@mo dCode=EVN]/subject/@typeCode=SUBJ11/investigationEvent/@classCode=INVESTG11/@moodCo de=EVN/component/@typeCode=COMP11/adverseEventAssessment11/adverseEventAssessment 11/classCode=INVESTG11/@moodCode=EVN/subject11/@typeCode=SBJ11/primaryRole/@classC ode=INVSBJ11/subjectO21/@typeCode=SBJ11/organizer/code/@code=41/@codeSystem=2.16.840.1 113883.3.989.2.1.1.20111/organizer/@classCode=CATEGORY11/@moodCode=EVN/component1 1/@typeCode=COMP11/substanceAdministration11/substanceAdministration/@classCode=SBADM 11/@moodCode=EVN/consumable/@typeCode=CSM111/instanceOfKind/@classCode=INST11/Kind OIP/rodut/@classCode=MMA111/@determinerCode=KIND11/ingredient/@classCode=ACT11/ingre dientSubstance/@classCode=MMA111/@determinerCode=KIND11/code/@codeSystem=TBD-Substa nce11/@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]/PORR_IN049016UV1/controlActProcess[@classCode=CACT][@mo dCode=EVN]/subject/@typeCode=SUBJ111/investigationEvent/@classCode=INVESTG11/@moodCo de=EVN/component/@typeCode=COMP11/adverseEventAssessment11/adverseEventAssessment 11/classCode=INVESTG11/@moodCode=EVN/subject11/@typeCode=SBJ11/primaryRole/@classC ode=INVSBJ11/subjectO21/@typeCode=SBJ11/organizer/code/@code=41/@codeSystem=2.16.840.1 113883.3.989.2.1.1.20111/organizer/@classCode=CATEGORY11/@moodCode=EVN/component1 1/@typeCode=COMP11/substanceAdministration11/substanceAdministration/@classCode=SBADM 11/@moodCode=EVN/consumable/@typeCode=CSM111/instanceOfKind/@classCode=INST11/Kind OIP/rodut/@classCode=MMA111/@determinerCode=KIND11/ingredient/@classCode=ACT11/ingre dientSubstance/@classCode=MMA111/@determinerCode=KIND11/code/@codeSystem=TBD-Substa nce11/@code </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]/PORR_IN049016UV1/controlActProcess[@classCode=CACT][@mo dCode=EVN]/subject/@typeCode=SUBJ111/investigationEvent/@classCode=INVESTG11/@moodCo de=EVN/component/@typeCode=COMP11/adverseEventAssessment11/adverseEventAssessment 11/classCode=INVESTG11/@moodCode=EVN/subject11/@typeCode=SBJ11/primaryRole/@classC ode=INVSBJ11/subjectO21/@typeCode=SBJ11/organizer/code/@code=41/@codeSystem=2.16.840.1 113883.3.989.2.1.1.20111/organizer/@classCode=CATEGORY11/@moodCode=EVN/component1 1/@typeCode=COMP11/substanceAdministration11/substanceAdministration/@classCode=SBADM 11/@moodCode=EVN/consumable/@typeCode=CSM111/instanceOfKind/@classCode=INST11/Kind OIP/rodut/@classCode=MMA111/@determinerCode=KIND11/ingredient/@classCode=ACT11/ingre dientSubstance/@value=11/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]/PORR_IN049016UV1/controlActProcess[@classCode=CACT][@mo dCode=EVN]/subject/@typeCode=SUBJ111/investigationEvent/@classCode=INVESTG11/@moodCo de=EVN/component/@typeCode=COMP11/adverseEventAssessment11/adverseEventAssessment 11/classCode=INVESTG11/@moodCode=EVN/subject11/@typeCode=SBJ11/primaryRole/@classC ode=INVSBJ11/subjectO21/@typeCode=SBJ11/organizer/code/@code=41/@codeSystem=2.16.840.1 113883.3.989.2.1.1.20111/organizer/@classCode=CATEGORY11/@moodCode=EVN/component1 1/@typeCode=COMP11/substanceAdministration11/substanceAdministration/@classCode=SBADM 11/@moodCode=EVN/consumable/@typeCode=CSM111/instanceOfKind/@classCode=INST11/Kind OIP/rodut/@classCode=MMA111/@determinerCode=KIND11/ingredient/@classCode=ACT11/ingre dientSubstance/@value=11/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)	値	/MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=um:hl7-org:v3 MCCL_IN200100UV01.xsd]/P/PORR_IN049016UV[controlActProcess/@classCode=CACT][@moodCode=EVN]/subject/@typeCode=SUBJ[adverseEventAssessment/@classCode=INVESTG][@moodCode=EVN]/component/@typeCode=COMP[adverseEventAssessment[1]/adverseEventAssessment/@classCode=INVESTG][@typeCode=EVN]/subject[1]/primaryRole/@classCode=INVSBJ[subjectOf/@typeCode=SBJ][organizer/code[@code=4]][@codeSystem=2,16,840.1-113883.3,989.2.1.1.20][1]/organizer/@classCode=CATEGORY[1]/moodCode=EVN/component[1]/moodCode=SBADMP[consumable/@typeCode=CSM][1]/instanceOfKind/@classCode=INST[1]/subjectOf/@typeCode=SBJ[productEvent/@classCode=ACT][@moodCode=EVN][code=1][@codeSystem=2,16,840.1,113883.3,989.2.1.1.18]/performer/@typeCode=PRF/assignedEntity/@classCode=ASSIGNED[representedOrganization/@classCode=ORG][@determinerCode=INSTANCE]/addr/country[1]/extd
e	G.k.2.5	治療の資格状況	ブール型	Boolean (BL)		値	/MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=um:hl7-org:v3 MCCL_IN200100UV01.xsd]/P/PORR_IN049016UV[controlActProcess/@classCode=CACT][@moodCode=EVN]/subject/@typeCode=SUBJ[1]/investigationEvent/@classCode=INVESTG][@moodCode=EVN]/component/@typeCode=COMP[adverseEventAssessment[1]/adverseEventAssessment/@classCode=INVESTG][@typeCode=EVN]/subject[1]/primaryRole/@classCode=INVSBJ[subjectOf/@typeCode=SBJ][organizer/code[@code=4]][@codeSystem=2,16,840.1-113883.3,989.2.1.1.20][1]/organizer/@classCode=CATEGORY[1]/moodCode=EVN/component[1]/moodCode=SBADMP[consumable/@typeCode=CSM][1]/instanceOfKind/@classCode=SBADM[1]/@moodCode=EVN[1]/outboundRelationship[2]/@typeCode=PERT[1]/observation/code[@code=6][@codeSystem=2,16,840.1,113883.3,989.2.1.1.19][1]/value
h	G.k.3	医薬品の承認の取得者及び承認/申請番号					/MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=um:hl7-org:v3 MCCL_IN200100UV01.xsd]/P/PORR_IN049016UV[controlActProcess/@classCode=CACT][@moodCode=EVN]/subject/@typeCode=SUBJ[1]/investigationEvent/@classCode=INVESTG][@moodCode=EVN]/component/@typeCode=COMP[adverseEventAssessment[1]/adverseEventAssessment/@classCode=INVESTG][@typeCode=EVN]/subject[1]/primaryRole/@classCode=INVSBJ[subjectOf/@typeCode=SBJ][organizer/code[@code=4]][@codeSystem=2,16,840.1-113883.3,989.2.1.1.20][1]/organizer/@classCode=CATEGORY[1]/moodCode=EVN/component[1]/moodCode=SBADMP[consumable/@typeCode=CSM][1]/instanceOfKind/@classCode=INST[1]/kindOfProduct/@classCode=MMA[1]/determinerCode=KIND[1]/manufacturedProduct/@classCode=MANU[1]/subjectOf/@typeCode=SBJ[1]/approval/@classCode=CNTRCT[1]/moodCode=EVN/jid[1]/root=2,16,840.1,113883.3,989.2.1.3.4][@extension
e	G.k.3.1	承認/申請番号	35AN	Instance Identifier (II)	extension=Character String (ST)	値	

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<p>G.k.3.2</p>	<p>承認/申請国</p>	<p>2A</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]/PDRR_IN049016UV1/controlAciprocess[@classCode=CACT][@moo dCode=EVN]/subject[@typeCode=SUBJ]/investigationEvent[@classCode=INVSCT][@moodCo de=EVN]/component[@typeCode=COMP]/adverseEventAssessment[1]/adverseEventAssessment [@classCode=INVSCT][@moodCode=EVN]/subject[1]/typeCode=SBJ/1/primaryRole[@classC ode=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]/@moodCode=COMP/substanceAdministration[id][k]/substanceAdministration[@classCode=SBADM]/product/@classCode=MMA/1/@determinerCode=KIND/1/asManufacturedProduct/@classCode= MANU/subjectOf/@typeCode=SBJ/1/approval/@classCode=CNTRCT][@moodCode=EVN]/aut hority/@typeCode=AUT/territorialAuthority/@classCode=TERR/territory/@classCode=NAT][@date mlinerCode=INSTANCE]/code/@codeSystem=1,0,3,166,1.2,2][@code </pre>
<p>G.k.3.3</p>	<p>承認の取得者/申請者の名 称</p>	<p>80AN</p>	<p>Organization Name (ON)</p>	<p>name=Entity Name Part (ENXP)</p>	<p>値</p>	<pre> /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PDRR_IN049016UV1/controlAciprocess[@classCode=CACT][@moo dCode=EVN]/subject[@typeCode=SUBJ]/investigationEvent[@classCode=INVSCT][@moodCo de=EVN]/component[@typeCode=COMP]/adverseEventAssessment[1]/adverseEventAssessment [@classCode=INVSCT][@moodCode=EVN]/subject[1]/typeCode=SBJ/1/primaryRole[@classC ode=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]/@moodCode=COMP/substanceAdministration[id][k]/substanceAdministration[@classCode=SBADM]/product/@classCode=MMA/1/@determinerCode=KIND/1/asManufacturedProduct/@classCode= MANU/subjectOf/@typeCode=SBJ/1/approval/@classCode=CNTRCT][@moodCode=EVN]/hot linerCode=HLDT/1/role/@classCode=HLDT/playingOrganization/@classCode=ORG][@date mlinerCode=INSTANCE]/name/text() </pre>
<p>G.k.4.r</p>	<p>投与量及び関連情報 (必要に 応じ繰り返す)</p>	<p></p>	<p></p>	<p></p>	<p>繰り返し ノード</p>	<pre> /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PDRR_IN049016UV1/controlAciprocess[@classCode=CACT][@moo dCode=EVN]/subject[@typeCode=SUBJ]/investigationEvent[@classCode=INVSCT][@moodCo de=EVN]/component[@typeCode=COMP]/adverseEventAssessment[1]/adverseEventAssessment [@classCode=INVSCT][@moodCode=EVN]/subject[1]/typeCode=SBJ/1/primaryRole[@classC ode=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]/@moodCode=COMP/substanceAdministration[id][k]/substanceAdministration[@classCode=SBADM]/product/@classCode=EVN/1/outboundRelationship2[@typeCode=COMP]/substanceAdministration] </pre>
<p>G.k.4.r.1a</p>	<p>投与量 (数)</p>	<p>8N</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]/PDRR_IN049016UV1/controlAciprocess[@classCode=CACT][@moo dCode=EVN]/subject[@typeCode=SUBJ]/investigationEvent[@classCode=INVSCT][@moodCo de=EVN]/component[@typeCode=COMP]/adverseEventAssessment[1]/adverseEventAssessment [@classCode=INVSCT][@moodCode=EVN]/subject[1]/typeCode=SBJ/1/primaryRole[@classC ode=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]/@moodCode=COMP/substanceAdministration[id][k]/substanceAdministration[@classCode=SBADM]/product/@classCode=EVN/1/outboundRelationship2[@typeCode=COMP]/substanceAdministration] </pre>

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<p>e</p>		<p>B.4.k.4.r.3 の単位が 合計の場合： Physical Quantity (PQ)</p>	<p>値</p>	<p>value=Real Number (REAL)</p>	<pre> /MCCL_IN200100UV01/@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd/YPORR_IN049016UV/ControlActProcess/@classCode=CACT][@moo dCode=EVN]/subject/@typeCode=SUBJ][/investigationEvent/@classCode=INVSTG][@moodCo de=EVN]/component/@typeCode=COMP][adverseEventAssessment][/adverseEventAssessment /@classCode=INVSTG][@moodCode=EVN]/subject[/@typeCode=SBJ][/primaryRole/@classC ode=INVSBJ]/subjectOr[/@typeCode=SBJ]/organizer/code[/@code=4][/@codeSystem=2.16.840.1 13883.3.989.2.1.1.20][/organizer/@classCode=CATEGORY][@moodCode=EVN]/component[/@typeCode=COMP]/substanceAdministration[/@classCode=SBADM][@moodCode=EVN]/outboundRelationship2[/@typeCode=COMP]/substanceAdministration[/@sub stanceAdministration/@classCode=SBADM][@moodCode=EVN]/doseCheckQuantity[/@sub stanceAdministration/@classCode=SBADM][@numerator/@xsi:type=PQ]/@value </pre>
<p>e</p>	<p>G.k.4.r.1b</p>	<p>投与量 (単位)</p>	<p>50AN</p>	<p>unit=Coded Simple Value (CS)</p>	<pre> /MCCL_IN200100UV01/@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd/YPORR_IN049016UV/ControlActProcess/@classCode=CACT][@moo dCode=EVN]/subject/@typeCode=SUBJ][/investigationEvent/@classCode=INVSTG][@moodCo de=EVN]/component/@typeCode=COMP][adverseEventAssessment][/adverseEventAssessment /@classCode=INVSTG][@moodCode=EVN]/subject[/@typeCode=SBJ][/primaryRole/@classC ode=INVSBJ]/subjectOr[/@typeCode=SBJ]/organizer/code[/@code=4][/@codeSystem=2.16.840.1 13883.3.989.2.1.1.20][/organizer/@classCode=CATEGORY][@moodCode=EVN]/component[/@typeCode=COMP]/substanceAdministration[/@classCode=SBADM][@moodCode=EVN]/outboundRelationship2[/@typeCode=COMP]/substanceAdministration[/@sub stanceAdministration/@classCode=SBADM][@numerator/@xsi:type=PQ]/@value </pre>
<p>e</p>		<p>B.4.k.4.r.3 の単位が 合計の場合： Physical Quantity (PQ)</p>	<p>値</p>	<p>unit=Coded Simple Value (CS)</p>	<pre> /MCCL_IN200100UV01/@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd/YPORR_IN049016UV/ControlActProcess/@classCode=CACT][@moo dCode=EVN]/subject/@typeCode=SUBJ][/investigationEvent/@classCode=INVSTG][@moodCo de=EVN]/component/@typeCode=COMP][adverseEventAssessment][/adverseEventAssessment /@classCode=INVSTG][@moodCode=EVN]/subject[/@typeCode=SBJ][/primaryRole/@classC ode=INVSBJ]/subjectOr[/@typeCode=SBJ]/organizer/code[/@code=4][/@codeSystem=2.16.840.1 13883.3.989.2.1.1.20][/organizer/@classCode=CATEGORY][@moodCode=EVN]/component[/@typeCode=COMP]/substanceAdministration[/@classCode=SBADM][@moodCode=EVN]/outboundRelationship2[/@typeCode=COMP]/substanceAdministration[/@sub stanceAdministration/@classCode=SBADM][@numerator/@xsi:type=PQ]/@unit </pre>

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<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> <p>1) G.k.4.r.2, G.k.4.r.3</p> <p>2) G.k.4.r.4</p> <p>3) G.k.4.r.5</p> <p>4) G.k.4.r.6a, G.k.4.r.6b</p> <p>データ型 SXPX を伴う最初の comp 項目</p> <p>Parenthetic Set Expression of Time (SXPX_TS) [Periodic Interval of Time (P1VL_TS)]</p>	<p>値</p> <p>periodValue=Real Number (REAL)</p>	<pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]P_ORR_IN049016UV[controlActProcess]@classCode=CACT][@moo dCode=EVN]/subject[@typeCode=SUBJ][investigationEvent]{@classCode=INVTG}[@moodCo de=EVN]/component[@typeCode=COMP][adverseEventAssessment][1]adverseEventAssessment [@classCode=INVSTG][@moodCode=EVN]/subject1[@typeCode=SBJ][primaryRole]{@classC ode=INVSBJ}/subjectOf2[@typeCode=SBJ][organizerCode=4][@codeSystem=2.16.840.1 .113883.3.989.2.1.1.20][1]organizer[@classCode=CATEGORY][@moodCode=EVN]/component [@typeCode=COMP][substanceAdministration][k]substanceAdministration[@classCode=SBADM][@moodCode=EVN]/outboundRelationship2[@typeCode=COMP][substanceAdministration][j]sub stanceAdministration[@classCode=SBADM][@moodCode=EVN]/effectiveTime[@xsi:type=SXPX_ TS]/comp[@xsi:type=P1VL_TS]/period/@value </pre>
<p>G.k.4.r.2</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> <p>1) G.k.4.r.2, G.k.4.r.3</p> <p>2) G.k.4.r.4</p> <p>3) G.k.4.r.5</p> <p>4) G.k.4.r.6a, G.k.4.r.6b</p> <p>データ型 SXPX を伴う2番目の comp 項目</p> <p>Parenthetic Set Expression of Time (SXPX_TS) [Periodic Interval of Time (P1VL_TS)]</p>	<p>値</p>	<pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]P_ORR_IN049016UV[controlActProcess]@classCode=CACT][@moo dCode=EVN]/subject[@typeCode=SUBJ][investigationEvent]{@classCode=INVTG}[@moodCo de=EVN]/component[@typeCode=COMP][adverseEventAssessment][1]adverseEventAssessment [@classCode=INVSTG][@moodCode=EVN]/subject1[@typeCode=SBJ][primaryRole]{@classC ode=INVSBJ}/subjectOf2[@typeCode=SBJ][organizerCode=4][@codeSystem=2.16.840.1 .113883.3.989.2.1.1.20][1]organizer[@classCode=CATEGORY][@moodCode=EVN]/component [@typeCode=COMP][substanceAdministration][k]substanceAdministration[@classCode=SBADM][@moodCode=EVN]/outboundRelationship2[@typeCode=COMP][substanceAdministration][j]sub stanceAdministration[@classCode=SBADM][@moodCode=EVN]/effectiveTime[@xsi:type=SXPX_ TS]/comp[@xsi:type=P1VL_TS][operator=A]/period/@value </pre>

(別添 3)

		<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> <p>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> <p>Periodic Interval of Time (PVL_TS)</p>	<p>値</p> <p>period/value=Real Number (REAL)</p>	<pre> /MCCL_IN200100UV01@ITSVersion=XML_1.0][@xmlns:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/PARR_IN049016UV01/controlActProcess[@classCode=CACT][@mo dCode=EVN]/subject/@typeCode=SUBJ[1]/investigationEvent/@classCode=INVEST[1]/moodCo de=EVN/component/@typeCode=COMP[1]/adverseEventAssessment/@classCode=INVEST[1]/moodCo de=EVN/component/@typeCode=COMP[1]/adverseEventAssessment[1]/adverseEventAssessment [1]/classCode=INVEST[1]/moodCode=EVN/subject[1]/typeCode=SBJ[1]/primaryRole/@classC ode=INVSBJ[1]/subjectO2/@typeCode=SBJ[1]/organizer/code/@code=4][@codesSystem=2.16.840.1 113883.3.988.2.1.1.20][1]organizer/@classCode=CATEGORY[1]/moodCode=EVN/component[1]/typeCode=COMP[1]/substanceAdministration[id]/substanceAdministration/@classCode=SBADM [1]/moodCode=EVN/youboundRelationship2/@typeCode=COMP[1]/substanceAdministration[1]/sub stanceAdministration/@classCode=SBADM[1]/moodCode=EVN/youboundRelationship2/@typeCode=SBADM [1]/substanceAdministration/@classCode=SBADM[1]/moodCode=EVN/youboundRelationship2/@typeCode=SBADM[1] S]/period/@value </pre>
		<p>1. 以下のデータ項目の2つの値が表示される場合</p> <p>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> <p>50AN</p> <p>投与間隔の定数</p>	<p>値</p> <p>period/unit=Coded Simple Value (CS)</p>	<pre> /MCCL_IN200100UV01@ITSVersion=XML_1.0][@xmlns:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/PARR_IN049016UV01/controlActProcess[@classCode=CACT][@mo dCode=EVN]/subject/@typeCode=SUBJ[1]/investigationEvent/@classCode=INVEST[1]/moodCo de=EVN/component/@typeCode=COMP[1]/adverseEventAssessment/@classCode=INVEST[1]/moodCo de=EVN/component/@typeCode=COMP[1]/adverseEventAssessment[1]/adverseEventAssessment [1]/classCode=INVEST[1]/moodCode=EVN/subject[1]/typeCode=SBJ[1]/primaryRole/@classC ode=INVSBJ[1]/subjectO2/@typeCode=SBJ[1]/organizer/code/@code=4][@codesSystem=2.16.840.1 113883.3.988.2.1.1.20][1]organizer/@classCode=CATEGORY[1]/moodCode=EVN/component[1]/typeCode=COMP[1]/substanceAdministration[id]/substanceAdministration/@classCode=SBADM [1]/moodCode=EVN/youboundRelationship2/@typeCode=COMP[1]/substanceAdministration[1]/sub stanceAdministration/@classCode=SBADM[1]/moodCode=EVN/youboundRelationship2/@typeCode=SBADM [1]/substanceAdministration/@classCode=SBADM[1] TS]/comp[@xmlns:type=PVL_TS]/period/@unit </pre>
		<p>G.k.4.r.3</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"> 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 2 番目の comp 項目</p> <p>Parenthetic Set Expression of Time (SXPР_TS) Periodic Interval of Time (PIVL_TS)</p>	<p>値</p>	<pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]PARR_IN049016UV[r]/controlActProcess[@classCode=CACT][@moodCode=EVN]/subject/@typeCode=SUBJ[r]/investigationEvent[@classCode=INVTG][@moodCode=EVN]/component/@typeCode=COMP[r]/adverseEventAssessment[1]/adverseEventAssessment[@classCode=INVTG][@moodCode=EVN]/subject1/@typeCode=SBJ[r]/primaryRole/@classCode=INVSBJ[subject12]/@typeCode=SBJ[r]/organizer/code/@code=4][@codeSystem=2.16.840.1.113883.3.989.2.1.1.20][r]/organizer/@classCode=CATEGORY[r]/moodCode=EVN]/component[1]/@typeCode=COMP[r]/substanceAdministration[r]/substanceAdministration[@classCode=SBADM][@moodCode=EVN]/effectiveTime[@xsi:type=SXPР_TS]/comp/@xsi:type=PIVL_TS][@operator=A]/period/@unit </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>Periodic Interval of Time (PIVL_TS)</p>	<p>値</p>	<pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]PARR_IN049016UV[r]/controlActProcess[@classCode=CACT][@moodCode=EVN]/subject/@typeCode=SUBJ[r]/investigationEvent[@classCode=INVTG][@moodCode=EVN]/component/@typeCode=COMP[r]/adverseEventAssessment[1]/adverseEventAssessment[@classCode=INVTG][@moodCode=EVN]/subject1/@typeCode=SBJ[r]/primaryRole/@classCode=INVSBJ[subject12]/@typeCode=SBJ[r]/organizer/code/@code=4][@codeSystem=2.16.840.1.113883.3.989.2.1.1.20][r]/organizer/@classCode=CATEGORY[r]/moodCode=EVN]/component[1]/@typeCode=COMP[r]/substanceAdministration[r]/substanceAdministration[@classCode=SBADM][@moodCode=EVN]/effectiveTime[@xsi:type=PIVL_TS]/period/@unit </pre>

<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 SXPX を伴う最初の comp 項目</p> <p>Parenthetic Set Expression of Time (SXPX_TS) [Intervale of Point in Time (IV_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']/PORR_IN049016UV/r/controlActProcess[@classCode='CACT']/@mo dCode=EVN']/subject/@typeCode=SUBJ[1]/investigationEvent[@classCode='INVSTG']/@moodCo de=EVN']/component/@typeCode=COMP[1]/adverseEventAssessment[1]/adverseEventAssessme nt[@classCode='INVSTG']/@moodCode=EVN']/subject1/@typeCode='SBJ[1]/primaryRole/@classC ode='INVSBJ']/subjectOf2/@typeCode='SBJ'[organizationCode='4']/@codeSystem='2.16.840.1 .113883.3.989.2.1.1.20'[1]/organizer[@classCode='CATEGORY']/@moodCode=EVN']/component [@typeCode=COMP][substanceAdministration[id]/k/substanceAdministration[@classCode='SBADM ']/@moodCode=EVN']/youthoundRelationship2/@typeCode=COMP[1]/substanceAdministration[1]/sub stanceAdministration[@classCode='SBADM']/@moodCode=EVN']/effectiveTime[@xsi:type='SXPX_ TS']/comp[@xsi:type='IV_TS']/low/@value </pre>
<p>e</p>			<p>Null/Flavor</p>	<pre> /MCCL_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCL_IN200100UV01.xsd']/PORR_IN049016UV/r/controlActProcess[@classCode='CACT']/@mo dCode=EVN']/subject/@typeCode=SUBJ[1]/investigationEvent[@classCode='INVSTG']/@moodCo de=EVN']/component/@typeCode=COMP[1]/adverseEventAssessment[1]/adverseEventAssessme nt[@classCode='INVSTG']/@moodCode=EVN']/subject1/@typeCode='SBJ[1]/primaryRole/@classC ode='INVSBJ']/subjectOf2/@typeCode='SBJ'[organizationCode='4']/@codeSystem='2.16.840.1 .113883.3.989.2.1.1.20'[1]/organizer[@classCode='CATEGORY']/@moodCode=EVN']/component [@typeCode=COMP][substanceAdministration[id]/k/substanceAdministration[@classCode='SBADM ']/@moodCode=EVN']/youthoundRelationship2/@typeCode=COMP[1]/substanceAdministration[1]/sub stanceAdministration[@classCode='SBADM']/@moodCode=EVN']/effectiveTime[@xsi:type='SXPX_ TS']/comp[@xsi:type='IV_TS']/low/@nullFlavor </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 SXPР を伴う 2 番目の comp 項目</p> <p>Parenthetic Set Expression of Time (SXPР_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_IN049016UV1/controlActProcess/@classCode=CACTI[@moodCode=EVN]/subject/@typeCode=SUBJ1[investigationEvent/@classCode=INVTG]/@moodCode=EVN/component/@typeCode=COMP1[adverseEventAssessment1]/adverseEventAssessment/@classCode=INVTG/@moodCode=EVN/subject1/@typeCode=SBJ1[primaryRole]/classCode=INVSBJ/subjectOf2/@typeCode=SBJ1[organizerCode=4]/@codeSystem=2.16.840.1.113883.3.889.2.1.1.2011[organizer/@classCode=CATEGORY]/@moodCode=EVN/component1/@typeCode=COMP1[substanceAdministration]/@classCode=SBADM1[substanceAdministrationRelationship2]/@typeCode=COMP1[substanceAdministration]/@classCode=EVN/outboundRelationship2/@typeCode=SBADM1[substanceAdministration]/@classCode=SBADM1[operator='A']/flow/@value </pre>
	<p>NullFlavor</p>	<pre> /MCCI_IN200100UV01[@ITSVersion='XML_1.0']/@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd'/pORR_IN049016UV1/controlActProcess/@classCode=CACTI[@moodCode=EVN]/subject/@typeCode=SUBJ1[investigationEvent/@classCode=INVTG]/@moodCode=EVN/component/@typeCode=COMP1[adverseEventAssessment1]/adverseEventAssessment/@classCode=INVTG/@moodCode=EVN/subject1/@typeCode=SBJ1[primaryRole]/classCode=INVSBJ/subjectOf2/@typeCode=SBJ1[organizerCode=4]/@codeSystem=2.16.840.1.113883.3.889.2.1.1.2011[organizer/@classCode=CATEGORY]/@moodCode=EVN/component1/@typeCode=COMP1[substanceAdministration]/@classCode=SBADM1[substanceAdministrationRelationship2]/@typeCode=COMP1[substanceAdministration]/@classCode=EVN/outboundRelationship2/@typeCode=SBADM1[operator='A']/flow/@nullFlavor </pre>

(別添3)

<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"> 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>Interval of Point in Time (IVL_TS)</p>	<p>値</p>	<p>low=Interval Boundary (IVXB)</p>	<p>AMCCL_IN200100UV01[ITSVersion=XML_1.0][Xsi:schemaLocation=um:hl7-org:v3 MCCI_IN200100UV01.xsd/PORR_IN049016UV1/ControlActProcess/@classCode=CAC][@moodCode=EVN]/subject/@typeCode=SUBJ[1]/investigationEvent/@classCode=INVTG[1][@moodCode=EVN]/component/@typeCode=COMP[1]/adverseEventAssessment[1]/adverseEventAssessment/@classCode=INVTG[1][@moodCode=EVN]/subject[1]/typeCode=SBJ[1]/primaryRole/@classCode=INVSBJ[1]/subjectOz/@typeCode=SBJ[1]/organizer/@code=4][@codeSystem=2.16.840.1.113883.3.989.2.1.1.20][1]/organizer/@classCode=CATEGORY[1][@moodCode=EVN]/component/@typeCode=COMP[1]/substanceAdministration[1][@moodCode=EVN]/component/@typeCode=SBADM[1]/outboundRelationship2/@typeCode=COMP[1]/substanceAdministration[1]/substanceAdministration/@classCode=SBADM[1][@moodCode=EVN]/effectiveTime/@xsi:type=IVL_TS][low/@value</p>
<p>Interval of Point in Time (IVL_TS)</p>	<p>NullFlavor</p>		<p>AMCCL_IN200100UV01[ITSVersion=XML_1.0][Xsi:schemaLocation=um:hl7-org:v3 MCCI_IN200100UV01.xsd/PORR_IN049016UV1/ControlActProcess/@classCode=CAC][@moodCode=EVN]/subject/@typeCode=SUBJ[1]/investigationEvent/@classCode=INVTG[1][@moodCode=EVN]/component/@typeCode=COMP[1]/adverseEventAssessment[1]/adverseEventAssessment/@classCode=INVTG[1][@moodCode=EVN]/subject[1]/typeCode=SBJ[1]/primaryRole/@classCode=INVSBJ[1]/subjectOz/@typeCode=SBJ[1]/organizer/@code=4][@codeSystem=2.16.840.1.113883.3.989.2.1.1.20][1]/organizer/@classCode=CATEGORY[1][@moodCode=EVN]/component/@typeCode=COMP[1]/substanceAdministration[1][@moodCode=EVN]/component/@typeCode=SBADM[1]/outboundRelationship2/@typeCode=COMP[1]/substanceAdministration[1]/substanceAdministration/@classCode=SBADM[1][@moodCode=EVN]/effectiveTime/@xsi:type=IVL_TS][low/@nullFlavor</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 SXPB を伴う最初の comp 項目</p> <p>Parenthetic Set Expression of Time (SXPB_TS)</p> <p>Interval of Point in Time (IVL_TS)</p>	<p>値</p>	<p>high=Interval Boundary (IVXB)</p>	<p>AMCCL_IN200100UV01[ITSVersion=XML_1.0][Xsi:schemaLocation=um:hl7-org:v3 MCCI_IN200100UV01.xsd/PORR_IN049016UV1/ControlActProcess/@classCode=CAC][@moodCode=EVN]/subject/@typeCode=SUBJ[1]/investigationEvent/@classCode=INVTG[1][@moodCode=EVN]/component/@typeCode=COMP[1]/adverseEventAssessment[1]/adverseEventAssessment/@classCode=INVTG[1][@moodCode=EVN]/subject[1]/typeCode=SBJ[1]/primaryRole/@classCode=INVSBJ[1]/subjectOz/@typeCode=SBJ[1]/organizer/@code=4][@codeSystem=2.16.840.1.113883.3.989.2.1.1.20][1]/organizer/@classCode=CATEGORY[1][@moodCode=EVN]/component/@typeCode=COMP[1]/substanceAdministration[1][@moodCode=EVN]/component/@typeCode=SBADM[1]/outboundRelationship2/@typeCode=COMP[1]/substanceAdministration[1]/substanceAdministration/@classCode=SBADM[1][@moodCode=EVN]/effectiveTime/@xsi:type=SXPB_TS][comp/@xsi:type=IVL_TS]/high/@value</p>

(別添 3)

<p>/MCCI_IN200100UV01/@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hi7-org:v3 MCCI_IN200100UV01.xsd]/P/RR_IN049016UVI/controlActProcess/@classCode=CACT][@mo dCode=EVN]/subject/@typeCode=SUBJ][1]/investigationEvent/@classCode=INVSIG][@moodCo de=EVN]/component/@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment /@classCode=INVSIG][@moodCode=EVN]/subject/@typeCode=SBJ][1]/primaryRole/@classC ode=INVSBJ]/subjectOf2/@typeCode=SBJ][organizer/code/@code=4][@codeSystem=2.16.840.1 .113883.3.989.2.1.1.20][1]/organizer/@classCode=CATEGORY][@moodCode=EVN]/component[/@typeCode=COMP][substanceAdministration[id]/substanceAdministration/@classCode=SBADM][@moodCode=EVN]/outboundRelationship2/@typeCode=COMP][substanceAdministration]/sub stanceAdministration/@classCode=SBADM][@moodCode=EVN]/effectiveTime/@xsi:type=SXP R_ TS]/comp/@xsi:type=IVL_TS]/high/@nullFlavor</p>	<p>NullFlavor</p>		
<p>/MCCI_IN200100UV01/@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hi7-org:v3 MCCI_IN200100UV01.xsd]/P/RR_IN049016UVI/controlActProcess/@classCode=CACT][@mo dCode=EVN]/subject/@typeCode=SUBJ][1]/investigationEvent/@classCode=INVSIG][@moodCo de=EVN]/component/@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment /@classCode=INVSIG][@moodCode=EVN]/subject/@typeCode=SBJ][1]/primaryRole/@classC ode=INVSBJ]/subjectOf2/@typeCode=SBJ][organizer/code/@code=4][@codeSystem=2.16.840.1 .113883.3.989.2.1.1.20][1]/organizer/@classCode=CATEGORY][@moodCode=EVN]/component[/@typeCode=COMP][substanceAdministration[id]/substanceAdministration/@classCode=SBADM][@moodCode=EVN]/outboundRelationship2/@typeCode=COMP][substanceAdministration]/sub stanceAdministration/@classCode=SBADM][@moodCode=EVN]/effectiveTime/@xsi:type=SXP R_ TS]/comp/@xsi:type=IVL_TS][@operator=A]/high/@value</p>	<p>値</p>		
<p>/MCCI_IN200100UV01/@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hi7-org:v3 MCCI_IN200100UV01.xsd]/P/RR_IN049016UVI/controlActProcess/@classCode=CACT][@mo dCode=EVN]/subject/@typeCode=SUBJ][1]/investigationEvent/@classCode=INVSIG][@moodCo de=EVN]/component/@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment /@classCode=INVSIG][@moodCode=EVN]/subject/@typeCode=SBJ][1]/primaryRole/@classC ode=INVSBJ]/subjectOf2/@typeCode=SBJ][organizer/code/@code=4][@codeSystem=2.16.840.1 .113883.3.989.2.1.1.20][1]/organizer/@classCode=CATEGORY][@moodCode=EVN]/component[/@typeCode=COMP][substanceAdministration[id]/substanceAdministration/@classCode=SBADM][@moodCode=EVN]/outboundRelationship2/@typeCode=COMP][substanceAdministration]/sub stanceAdministration/@classCode=SBADM][@moodCode=EVN]/effectiveTime/@xsi:type=SXP R_ TS]/comp/@xsi:type=IVL_TS][@operator=A]/high/@nullFlavor</p>	<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 SXP
を伴
う 2 番目の comp
目
Parenthetic Set
Expression of Time
(SXP_TS)
[Intervale of Point in
Time (IVL_TS)]

(別添3)

e			<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> <p>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> <p>Interval of Point in Time (IVL_TS)</p>	<p>high=Interval Boundary (VXB)</p>	<p>値</p>	<pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/PORR_IN049016JV[controlActProcess/@classCode=CACT][@moo dCode=EVN]/subject/@typeCode=SUBJ[1]/investigationEvent/@classCode=INVESTG[1]/moo dCode=EVN/component/@typeCode=COMP[1]/adverseEventAssessment[1]/adverseEventAssessm ent/@classCode=INVESTG[1]/subject/@typeCode=SBJ[1]/primaryRole/@classC ode=INVSBJ[1]/subjectO2/@typeCode=SBJ[1]/organizer/code/@code=4][@codeSystem=2.16.840.1 .113883.3.989.2.1.1.20][1]/organizer/@classCode=CATEGORY[1]/moodCode=EVN/component[1]/@typeCode=COMP[1]/substanceAdministration[1]/@classCode=SBADM [1]/@moodCode=EVN[1]/outboundRelationship2/@typeCode=COMP[1]/substanceAdministration[1]/sub stanceAdministration[1]/@classCode=SBADM[1][@moodCode=EVN]/effectiveTime/@xsi:type=IVL_TS "/high/@value </pre>
e				<p>NullFlavor</p>	<p>NullFlavor</p>	<pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/PORR_IN049016JV[controlActProcess/@classCode=CACT][@moo dCode=EVN]/subject/@typeCode=SUBJ[1]/investigationEvent/@classCode=INVESTG[1]/moo dCode=EVN/component/@typeCode=COMP[1]/adverseEventAssessment[1]/adverseEventAssessm ent/@classCode=INVESTG[1]/subject/@typeCode=SBJ[1]/primaryRole/@classC ode=INVSBJ[1]/subjectO2/@typeCode=SBJ[1]/organizer/code/@code=4][@codeSystem=2.16.840.1 .113883.3.989.2.1.1.20][1]/organizer/@classCode=CATEGORY[1]/moodCode=EVN/component[1]/@typeCode=COMP[1]/substanceAdministration[1]/@classCode=SBADM [1]/@moodCode=EVN[1]/outboundRelationship2/@typeCode=COMP[1]/substanceAdministration[1]/sub stanceAdministration[1]/@classCode=SBADM[1][@moodCode=EVN]/effectiveTime/@xsi:type=IVL_TS "/high/@nullFlavor </pre>
e	G.k.4.r.6a	医薬品投与期間 (数)	<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> <p>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> <p>データ型 SXPR を伴う最初の comp 項目</p> <p>Parenthetic Set Expression of Time (SXPR_TS) [Interval of Point in Time (IVL_TS)]</p>	<p>width=Real Number (REAL)</p>	<p>値</p>	<pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/PORR_IN049016JV[controlActProcess/@classCode=CACT][@moo dCode=EVN]/subject/@typeCode=SUBJ[1]/investigationEvent/@classCode=INVESTG[1]/moo dCode=EVN/component/@typeCode=COMP[1]/adverseEventAssessment[1]/adverseEventAssessm ent/@classCode=INVESTG[1]/subject/@typeCode=SBJ[1]/primaryRole/@classC ode=INVSBJ[1]/subjectO2/@typeCode=SBJ[1]/organizer/code/@code=4][@codeSystem=2.16.840.1 .113883.3.989.2.1.1.20][1]/organizer/@classCode=CATEGORY[1]/moodCode=EVN/component[1]/@typeCode=COMP[1]/substanceAdministration[1]/@classCode=SBADM [1]/@moodCode=EVN[1]/outboundRelationship2/@typeCode=COMP[1]/substanceAdministration[1]/sub stanceAdministration[1]/@classCode=SBADM[1][@moodCode=EVN]/effectiveTime/@xsi:type=IXPR_ TS]/comp/@xsi:type=IVL_TS]/width/@value </pre>

(別添 3)

	<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 SXPR を併用 2 番目の comp 項目</p> <p>Parenthetic Set Expression of Time (SXPR_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'/PARR_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/@typeCode='SBJ']/organizer/code/@code='4']/@codeSystem='2.16.840.1.113883.3.988.2.1.1.20']/@typeCode='SBAD']/@moodCode='EVN']/component[1]/@typeCode='COMP']/substanceAdministration[id]/substanceAdministration/@classCode='SBADM']/@moodCode='EVN']/outboundRelationship2/@typeCode='SBAD']/@moodCode='EVN']/effectiveTime/@xsi:type='SXPR_TS']/comp/@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>	<pre> /MCCL_IN200100UV01[@ITSVersion='XML_1.0']/@xsi:schemaLocation='urn:hl7-org:v3 MCCL_IN200100UV01.xsd'/PARR_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/@typeCode='SBJ']/organizer/code/@code='4']/@codeSystem='2.16.840.1.113883.3.988.2.1.1.20']/@typeCode='SBAD']/@moodCode='EVN']/component[1]/@typeCode='COMP']/substanceAdministration[id]/substanceAdministration/@classCode='SBADM']/@moodCode='EVN']/outboundRelationship2/@typeCode='SBAD']/@moodCode='EVN']/effectiveTime/@xsi:type='IVL_TS']/width/@value </pre> <p>width/value=Real Number (REAL)</p>

<p>G.k.4.r.6b</p>	<p>医薬品投与期間 (単位)</p> <p>50AN</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: 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 SXPР を伴う最初の comp 項目 Parenthetic Set Expression of Time (SXPР_TS) [Interval of Point in Time (IVL_TS)]</p>	<p>width/unit=Coded Simple Value (CS)</p> <p>値</p> <pre> /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xmlns:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UV/r/control/ActProcess[@classCode=CACT][@moodCode=EVN]/subject/@typeCode=SUBJ[1]/investigationEvent[1]/adverseEventAssessment[1]/adverseEventAssessment[1]/component/@typeCode=COMP[1]/adverseEventAssessment[1]/adverseEventAssessment[1]/classCode=INVSBJ[1]/subjectO2/@typeCode=EVN[1]/subject1/@typeCode=SBJ[1]/primaryRole/@classCode=INVSBJ[1]/subjectO2/@typeCode=EVN[1]/organizer/code/@code=4[1]/codeSystem=2,16,840,1113883.3,989.2,1.1,20[1]/organizer/@classCode=CATEGORY[1]/moodCode=EVN[1]/component/@typeCode=COMP[1]/substanceAdministration[id]/substanceAdministration/@classCode=SBADM[1]/moodCode=EVN[1]/outboundRelationship2/@typeCode=COMP[1]/substanceAdministration[id]/substanceAdministration/@classCode=SBADM[1]/moodCode=EVN[1]/effectiveTime/@xsi:type=SXPР_TS[1]/comp/@xsi:type=IVL_TS[1]/width@unit </pre>
<p>e</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: 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 SXPР を伴う2番目の comp 項目 Parenthetic Set Expression of Time (SXPР_TS)[Interval of Point in Time (IVL_TS)]</p>	<p>値</p> <pre> /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xmlns:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UV/r/control/ActProcess[@classCode=CACT][@moodCode=EVN]/subject/@typeCode=SUBJ[1]/investigationEvent[1]/adverseEventAssessment[1]/adverseEventAssessment[1]/component/@typeCode=COMP[1]/adverseEventAssessment[1]/adverseEventAssessment[1]/classCode=INVSBJ[1]/subjectO2/@typeCode=EVN[1]/subject1/@typeCode=SBJ[1]/primaryRole/@classCode=INVSBJ[1]/subjectO2/@typeCode=EVN[1]/organizer/code/@code=4[1]/codeSystem=2,16,840,1113883.3,989.2,1.1,20[1]/organizer/@classCode=CATEGORY[1]/moodCode=EVN[1]/component/@typeCode=COMP[1]/substanceAdministration[id]/substanceAdministration/@classCode=SBADM[1]/moodCode=EVN[1]/outboundRelationship2/@typeCode=COMP[1]/substanceAdministration[id]/substanceAdministration/@classCode=SBADM[1]/moodCode=EVN[1]/effectiveTime/@xsi:type=SXPР_TS[1]/comp/@xsi:type=IVL_TS[1]/operator=Aywidth@unit </pre>

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		<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> <p>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> <p>Interval of Point in Time (IVL_TS)</p>	<p>width/units=Coded Simple Value (CS)</p>	<p>値</p>	<pre>/MCCI_IN200100UV01[@ITSVersion='XML_1.0']/@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UV[/controlActProcess/@classCode=CACTI][@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[subjectO2/@typeCode=SBJ]/organizer/code/@code=4][@codeSystem=2.16.840.1.113883.3.989.2.1.1.20][1]/organizer/@classCode=CATEGORY[1][@moodCode=EVN]/component/@typeCode=COMP[1]/substanceAdministration[id]/substanceAdministration/@classCode=SBADM[1][@moodCode=EVN]/outboundRelationship2/@typeCode=COMP[1]/substanceAdministration/@classCode=SBADM][@width/@unit]</pre>
G.k.4.r.7	<p>パッチ/ロット番号</p>	<p>35AN</p>	<p>値</p>	<p>値</p>	<pre>/MCCI_IN200100UV01[@ITSVersion='XML_1.0']/@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UV[/controlActProcess/@classCode=CACTI][@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[subjectO2/@typeCode=SBJ]/organizer/code/@code=4][@codeSystem=2.16.840.1.113883.3.989.2.1.1.20][1]/organizer/@classCode=CATEGORY[1][@moodCode=EVN]/component/@typeCode=COMP[1]/substanceAdministration[id]/substanceAdministration/@classCode=SBADM[1][@moodCode=EVN]/outboundRelationship2/@typeCode=COMP[1]/substanceAdministration/@classCode=SBADM][@instanceOfKind/@classCode=INST]/productInstance/@classCode=MMAAT[1][@determineRCode=INSTANCE]/@number/text()</pre>
G.k.4.r.8	<p>投与量を表す記述情報</p>	<p>2000AN</p>	<p>値</p>	<p>値</p>	<pre>/MCCI_IN200100UV01[@ITSVersion='XML_1.0']/@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UV[/controlActProcess/@classCode=CACTI][@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[subjectO2/@typeCode=SBJ]/organizer/code/@code=4][@codeSystem=2.16.840.1.113883.3.989.2.1.1.20][1]/organizer/@classCode=CATEGORY[1][@moodCode=EVN]/component/@typeCode=COMP[1]/substanceAdministration[id]/substanceAdministration/@classCode=SBADM[1][@moodCode=EVN]/outboundRelationship2/@typeCode=COMP[1]/substanceAdministration/@classCode=SBADM][@text/text()</pre>
G.k.4.r.9	<p>医薬品精形</p>				

(別添 3)

e	G.k.4.r.9.1	医薬品利形 (自由記載)	60AN	Coded With Equivalents (CE)	originalText=Encapsulated Data (ED)	値	/MCCL_IN200100UV01/@ITSVersion=XML_1.0T/@xsis:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd/PPORR_IN049016UVJ/controlActProcess/@classCode=CACTI/@moodCode=EVN/subject/@typeCode=SUBJ/1/investigationEvent/@classCode=INVESTG/@moodCode=EVN/component/@typeCode=COMP/1/adverseEventAssessment/1/adverseEventAssessment/@classCode=INVESTG/@moodCode=EVN/subject/1/primaryRole/@classCode=INVSBJ/subject/2/1.1.20/1/organizer/@code=4/1/@codeSystem=2.16.840.1.113883.3.989.2.1.1.20/1/organizer/@classCode=CATEGORY/@moodCode=EVN/component/@typeCode=COMP/1/substanceAdministration/@classCode=SBADM/1/@moodCode=EVN/youboundRelationship/2/@typeCode=COMP/1/substanceAdministration/@classCode=SBADM/1/instanceOfKind/@classCode=INST/1/KindOfProduct/@classCode=MMA/1/@determinerCode=KI/ND/1/ormCode/@codeSystem=TBD-DoseForm/1/originalText/text
e	G.k.4.r.9.2a	医薬品利形の ID バージョン 目付/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_1.0T/@xsis:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd/PPORR_IN049016UVJ/controlActProcess/@classCode=CACTI/@moodCode=EVN/subject/@typeCode=SUBJ/1/investigationEvent/@classCode=INVESTG/@moodCode=EVN/component/@typeCode=COMP/1/adverseEventAssessment/1/adverseEventAssessment/@classCode=INVESTG/@moodCode=EVN/subject/1/primaryRole/@classCode=INVSBJ/subject/2/1.1.20/1/organizer/@code=4/1/@codeSystem=2.16.840.1.113883.3.989.2.1.1.20/1/organizer/@classCode=CATEGORY/@moodCode=EVN/component/@typeCode=COMP/1/substanceAdministration/@classCode=SBADM/1/@moodCode=EVN/youboundRelationship/2/@typeCode=COMP/1/substanceAdministration/@classCode=SBADM/1/instanceOfKind/@classCode=INST/1/KindOfProduct/@classCode=MMA/1/@determinerCode=KI/ND/1/ormCode/@codeSystem=TBD-DoseForm/1/originalText/
e	G.k.4.r.9.2b	医薬品利形の ID	M5 ガイド ラインを参 照	Coded With Equivalents (CE)	code=Character String (ST)	値	/MCCL_IN200100UV01/@ITSVersion=XML_1.0T/@xsis:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd/PPORR_IN049016UVJ/controlActProcess/@classCode=CACTI/@moodCode=EVN/subject/@typeCode=SUBJ/1/investigationEvent/@classCode=INVESTG/@moodCode=EVN/component/@typeCode=COMP/1/adverseEventAssessment/1/adverseEventAssessment/@classCode=INVESTG/@moodCode=EVN/subject/1/primaryRole/@classCode=INVSBJ/subject/2/1.1.20/1/organizer/@code=4/1/@codeSystem=2.16.840.1.113883.3.989.2.1.1.20/1/organizer/@classCode=CATEGORY/@moodCode=EVN/component/@typeCode=COMP/1/substanceAdministration/@classCode=SBADM/1/@moodCode=EVN/youboundRelationship/2/@typeCode=COMP/1/substanceAdministration/@classCode=SBADM/1/instanceOfKind/@classCode=INST/1/KindOfProduct/@classCode=MMA/1/@determinerCode=KI/ND/1/ormCode/@codeSystem=TBD-DoseForm/1/@codeSystemVersion
h	G.k.4.r.10	投与経路					/MCCL_IN200100UV01/@ITSVersion=XML_1.0T/@xsis:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd/PPORR_IN049016UVJ/controlActProcess/@classCode=CACTI/@moodCode=EVN/subject/@typeCode=SUBJ/1/investigationEvent/@classCode=INVESTG/@moodCode=EVN/component/@typeCode=COMP/1/adverseEventAssessment/1/adverseEventAssessment/@classCode=INVESTG/@moodCode=EVN/subject/1/primaryRole/@classCode=INVSBJ/subject/2/1.1.20/1/organizer/@code=4/1/@codeSystem=2.16.840.1.113883.3.989.2.1.1.20/1/organizer/@classCode=CATEGORY/@moodCode=EVN/component/@typeCode=COMP/1/substanceAdministration/@classCode=SBADM/1/@moodCode=EVN/youboundRelationship/2/@typeCode=COMP/1/substanceAdministration/@classCode=SBADM/1/instanceOfKind/@classCode=INST/1/KindOfProduct/@classCode=MMA/1/@determinerCode=KI/ND/1/ormCode/@codeSystem=TBD-DoseForm/1/@code

(別添 3)

<p>G.k.4.r.10.1</p>	<p>投与経路 (自由記載)</p>	<p>80AN</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]/PORR_IN049016UV7/controlActProcess/@classCode=CACT][@moodCode=EVN]/subject/@typeCode=SUB][1]/InvestigationEvent/@classCode=INVTG][@moodCode=EVN]/component/@typeCode=COMP[adverseEventAssessment[1]/adverseEventAssessment/@classCode=INVTG][@moodCode=EVN]/subject1/@typeCode=SBJ][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[id]/substanceAdministration/@classCode=SBADM][@moodCode=EVN]/youtboundRelationship2/@typeCode=COMP][substanceAdministration[id]/substanceAdministration/@classCode=SBADM][@moodCode=EVN]/routeCode/@codeSystem=2.16.840.1.113883.3.989.2.1.1.14][originalText/@nullFlavor]</pre>
<p>G.k.4.r.10.2a</p>	<p>投与経路の ID パーティション付ノ番号</p>	<p>M5 ガイドラインを参照</p>	<p>codeSystemVersion=Character String (ST)</p>	<p>NullFlavor</p>	<pre>/MCCI_IN200100UV01/@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UV7/controlActProcess/@classCode=CACT][@moodCode=EVN]/subject/@typeCode=SUB][1]/InvestigationEvent/@classCode=INVTG][@moodCode=EVN]/component/@typeCode=COMP[adverseEventAssessment[1]/adverseEventAssessment/@classCode=INVTG][@moodCode=EVN]/subject1/@typeCode=SBJ][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[id]/substanceAdministration/@classCode=SBADM][@moodCode=EVN]/youtboundRelationship2/@typeCode=COMP][substanceAdministration[id]/substanceAdministration/@classCode=SBADM][@moodCode=EVN]/routeCode/@codeSystem=2.16.840.1.113883.3.989.2.1.1.14][originalText/@nullFlavor]</pre>
<p>G.k.4.r.10.2b</p>	<p>投与経路の ID</p>	<p>M5 ガイドライン(3N)を参照</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]/PORR_IN049016UV7/controlActProcess/@classCode=CACT][@moodCode=EVN]/subject/@typeCode=SUB][1]/InvestigationEvent/@classCode=INVTG][@moodCode=EVN]/component/@typeCode=COMP[adverseEventAssessment[1]/adverseEventAssessment/@classCode=INVTG][@moodCode=EVN]/subject1/@typeCode=SBJ][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[id]/substanceAdministration/@classCode=SBADM][@moodCode=EVN]/youtboundRelationship2/@typeCode=COMP][substanceAdministration[id]/substanceAdministration/@classCode=SBADM][@moodCode=EVN]/routeCode/@codeSystem=2.16.840.1.113883.3.989.2.1.1.14][@codeSystemVersion]</pre>
<p>G.k.4.r.11</p>	<p>薬への投与経路 (薬一子ノ胎児報告の場合)</p>				<pre>/MCCI_IN200100UV01/@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UV7/controlActProcess/@classCode=CACT][@moodCode=EVN]/subject/@typeCode=SUB][1]/InvestigationEvent/@classCode=INVTG][@moodCode=EVN]/component/@typeCode=COMP[adverseEventAssessment[1]/adverseEventAssessment/@classCode=INVTG][@moodCode=EVN]/subject1/@typeCode=SBJ][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[id]/substanceAdministration/@classCode=SBADM][@moodCode=EVN]/youtboundRelationship2/@typeCode=COMP][substanceAdministration[id]/substanceAdministration/@classCode=SBADM][@moodCode=EVN]/routeCode/@codeSystem=2.16.840.1.113883.3.989.2.1.1.14][@code]</pre>

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<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_1.0T]@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd/y/PORR_IN049016UVI/control/ActProcess[@classCode=CACT]@moodCode=EVN/y/subject/@typeCode=SUBJ/y/InvestigationEvent[@classCode=INVESTG]@moodCode=EVN/y/component/@typeCode=COMP/y/adverseEventAssessment/y/adverseEventAssessment[@classCode=INVESTG]@moodCode=EVN/y/subject1/@typeCode=SBJ/y/primaryRole/@classCode=INVSBJ/y/subjectOf/@typeCode=SBJ/y/organizer/code/@code=4/@codeSystem=2.16.840.1.113883.3.989.2.1.1.20/y/organizer/@classCode=CATEGORY/y/moodCode=EVN/y/component/@typeCode=COMP/y/substanceAdministration/y/substanceAdministration[@classCode=SBADM]@moodCode=EVN/y/relationship2/@typeCode=COMP/y/substanceAdministration/y/substanceAdministration[@classCode=SBADM]@moodCode=EVN/y/relationship2/@typeCode=EVN/y/relationship2/@typeCode=REFR/y/observation/code/@code=28/@codeSystem=2.16.840.1.113883.3.989.2.1.1.19/y/observation/@classCode=OBS/@moodCode=EVN/y/value/@xsi:type=CE/@codeSystem=2.16.840.1.113883.3.989.2.1.1.14/y/originalText/text </pre>	<p>NullFlavor</p>	<pre> /MCCI_IN200100UV01[@ITSVersion=XML_1.0T]@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd/y/PORR_IN049016UVI/control/ActProcess[@classCode=CACT]@moodCode=EVN/y/subject/@typeCode=SUBJ/y/InvestigationEvent[@classCode=INVESTG]@moodCode=EVN/y/component/@typeCode=COMP/y/adverseEventAssessment/y/adverseEventAssessment[@classCode=INVESTG]@moodCode=EVN/y/subject1/@typeCode=SBJ/y/primaryRole/@classCode=INVSBJ/y/subjectOf/@typeCode=SBJ/y/organizer/code/@code=4/@codeSystem=2.16.840.1.113883.3.989.2.1.1.20/y/organizer/@classCode=CATEGORY/y/moodCode=EVN/y/component/@typeCode=COMP/y/substanceAdministration/y/substanceAdministration[@classCode=SBADM]@moodCode=EVN/y/relationship2/@typeCode=COMP/y/substanceAdministration/y/substanceAdministration[@classCode=SBADM]@moodCode=EVN/y/relationship2/@typeCode=EVN/y/relationship2/@typeCode=REFR/y/observation/code/@code=28/@codeSystem=2.16.840.1.113883.3.989.2.1.1.19/y/observation/@classCode=OBS/@moodCode=EVN/y/value/@xsi:type=CE/@codeSystem=2.16.840.1.113883.3.989.2.1.1.14/y/originalText/text </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>
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(別添 3)

<p>e</p>	<p>G.k.4.r.11.2b</p>	<p>親への疫与経路の ID</p>	<p>M5 ガイド ライン (3N) を参 照</p>	<p>Coded With Equivalents (CE)</p>	<p>code=Character String (ST)</p>	<p>値</p> <pre> /MCCL_IN200100UV01/@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/P/RR_IN049016UV/p/controlActProcess/@classCode=CACT][@moo dCode=EVN]/subject/@typeCode=SUBJ][1]/investigationEvent/@classCode=INVESTG][@moodCo de=EVN]/component/@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment /@classCode=INVESTG][@moodCode=EVN]/subject/@typeCode=SBJ][1]/primaryRole/@classC ode=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[id][K]/substanceAdministration/@classCode=SBADM][@moodCode=EVN]/outboundRelationship2/@typeCode=COMP][substanceAdministration]/sub stanceAdministration/@classCode=SBADM][@moodCode=EVN]/inboundRelationship/@typeCode =REFR][observation/@code=28][@codeSystem=2.16.840.1.1.13883.3.989.2.1.1.19][1]/obse rvation/@classCode=OBS][@moodCode=EVN]/value/@xsi:type=CE][@codeSystem=2.16.840.1. 113883.3.989.2.1.1.14][1]/@code </pre>
<p>e</p>	<p>G.k.5a</p>	<p>副作用／有害事象発現まで の累積総投与量 (数)</p>	<p>10N</p>	<p>Physical Quantity (PQ)</p>	<p>value=Real Number (REAL)</p>	<p>値</p> <pre> /MCCL_IN200100UV01/@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/P/RR_IN049016UV/p/controlActProcess/@classCode=CACT][@moo dCode=EVN]/subject/@typeCode=SUBJ][1]/investigationEvent/@classCode=INVESTG][@moodCo de=EVN]/component/@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment /@classCode=INVESTG][@moodCode=EVN]/subject/@typeCode=SBJ][1]/primaryRole/@classC ode=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[id][K]/substanceAdministration/@classCode=SBADM][@moodCode=EVN]/outboundRelationship2/@typeCode=SUMM][observation/@code=14][@codeSystem=2.16.840.1.113883.3.989.2.1.1.19][1]/observation/@classCode=OBS][@moodCod e=EVN]/value/@xsi:type=PQ][1]/@value </pre>
<p>e</p>	<p>G.k.5b</p>	<p>副作用／有害事象発現まで の累積総投与量 (単位)</p>	<p>50AN</p>	<p>Physical Quantity (PQ)</p>	<p>unit=Coded Simple Value (CS)</p>	<p>値</p> <pre> /MCCL_IN200100UV01/@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/P/RR_IN049016UV/p/controlActProcess/@classCode=CACT][@moo dCode=EVN]/subject/@typeCode=SUBJ][1]/investigationEvent/@classCode=INVESTG][@moodCo de=EVN]/component/@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment /@classCode=INVESTG][@moodCode=EVN]/subject/@typeCode=SBJ][1]/primaryRole/@classC ode=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[id][K]/substanceAdministration/@classCode=SBADM][@moodCode=EVN]/outboundRelationship2/@typeCode=SUMM][observation/@code=14][@codeSystem=2.16.840.1.113883.3.989.2.1.1.19][1]/observation/@classCode=OBS][@moodCod e=EVN]/value/@xsi:type=PQ][1]/@unit </pre>
<p>e</p>	<p>G.k.6a</p>	<p>曝露時の妊婦期間 (数)</p>	<p>3N</p>	<p>Physical Quantity (PQ)</p>	<p>value=Real Number (REAL)</p>	<p>値</p> <pre> /MCCL_IN200100UV01/@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/P/RR_IN049016UV/p/controlActProcess/@classCode=CACT][@moo dCode=EVN]/subject/@typeCode=SUBJ][1]/investigationEvent/@classCode=INVESTG][@moodCo de=EVN]/component/@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment /@classCode=INVESTG][@moodCode=EVN]/subject/@typeCode=SBJ][1]/primaryRole/@classC ode=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[id][K]/substanceAdministration/@classCode=SBADM][@moodCode=EVN]/outboundRelationship2/@typeCode=PERT][observation/@code=16][@codeSystem=2.16.840.1.113883.3.989.2.1.1.19][1]/observation/@classCode=OBS][@moodCod e=EVN]/value/@xsi:type=PQ][1]/@value </pre>

(別添 3)

e	G.k.6.b	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_IN049016UVf/controlActProcess[@classCode=CACT][@mo dCode=EVN]/subject[@typeCode=SUBJ][@investigationEvent/@classCode=INVSTG][@moodCo de=EVN]/component[@typeCode=COMP][adverseEventAssessment][adverseEventAssessment /@classCode=INVSTG][@moodCode=EVN]/subject1[@typeCode=SBJ][@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 /@typeCode=COMP][substanceAdministration][k/substanceAdministration/@classCode=SBADM][@moodCode=EVN]/boundRelationship2[@typeCode=PERT][observation/@code=19][@c odeSystem=2.16.840.1.113883.3.989.2.1.1.19][observation/@classCode=OBS][@moodCod e=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)				繰り返し ノード	<pre> /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UVf/controlActProcess[@classCode=CACT][@mo dCode=EVN]/subject[@typeCode=SUBJ][@investigationEvent/@classCode=INVSTG][@moodCo de=EVN]/component[@typeCode=COMP][adverseEventAssessment][adverseEventAssessment /@classCode=INVSTG][@moodCode=EVN]/subject1[@typeCode=SBJ][@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 /@typeCode=COMP][substanceAdministration][k/substanceAdministration/@classCode=SBADM][@moodCode=EVN]/boundRelationship[@typeCode=RSO][observation/@code=19][@c odeSystem=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=Encapsu lated Data (ED)	値	<pre> /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UVf/controlActProcess[@classCode=CACT][@mo dCode=EVN]/subject[@typeCode=SUBJ][@investigationEvent/@classCode=INVSTG][@moodCo de=EVN]/component[@typeCode=COMP][adverseEventAssessment][adverseEventAssessment /@classCode=INVSTG][@moodCode=EVN]/subject1[@typeCode=SBJ][@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 /@typeCode=COMP][substanceAdministration][k/substanceAdministration/@classCode=SBADM][@moodCode=EVN]/boundRelationship[@typeCode=RSO][observation/@code=19][@c odeSystem=2.16.840.1.113883.3.989.2.1.1.19][originalText/text() </pre>
e						NullFlavor	<pre> /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UVf/controlActProcess[@classCode=CACT][@mo dCode=EVN]/subject[@typeCode=SUBJ][@investigationEvent/@classCode=INVSTG][@moodCo de=EVN]/component[@typeCode=COMP][adverseEventAssessment][adverseEventAssessment /@classCode=INVSTG][@moodCode=EVN]/subject1[@typeCode=SBJ][@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 /@typeCode=COMP][substanceAdministration][k/substanceAdministration/@classCode=SBADM][@moodCode=EVN]/boundRelationship[@typeCode=RSO][observation/@code=19][@c odeSystem=2.16.840.1.113883.3.989.2.1.1.19][originalText/@nullFlavor </pre>

(別添 3)

<p>e</p> <p>G.k.7.r.2a</p> <p>使用理由の MedDRA パー ジョン</p>	<p>4AN</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'/PDRR_IN049016UV1/controlActProcess[@classCode='CACTI']/@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']/subjectC02[@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'/inboundRelationship[@typeCode='RSON']/observation/code[@code='19']/@c odeSystem='2.16.840.1.13883.3.989.2.1.1.19'[@typeCode='RSON']/observation/@classCode='OBS'[@moodCode= EVN']/performer[@typeCode='PRF']/assignedEntity[@classCode='ASSIGNED']/code[@code='3']/@c odeSystem='2.16.840.1.13883.3.989.2.1.1.21'[@value][1]/value[@xsi:type='CE']/@codeSystem='2.16.840. 1.13883.3.989.2.1.1.15'[@codeSystemVersion]</pre>
<p>e</p> <p>G.k.7.r.2b</p> <p>使用理由 (MedDRA コード)</p>	<p>8N</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'/PDRR_IN049016UV1/controlActProcess[@classCode='CACTI']/@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']/subjectC02[@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'/inboundRelationship[@typeCode='RSON']/observation/code[@code='19']/@c odeSystem='2.16.840.1.13883.3.989.2.1.1.19'[@typeCode='RSON']/observation/@classCode='OBS'[@moodCode= EVN']/performer[@typeCode='PRF']/assignedEntity[@classCode='ASSIGNED']/code[@code='3']/@c odeSystem='2.16.840.1.13883.3.989.2.1.1.21'[@value][1]/value[@xsi:type='CE']/@codeSystem='2.16.840. 1.13883.3.989.2.1.1.15'[@codeSystemVersion]</pre>
<p>e</p> <p>G.k.8</p> <p>医薬品に対して取られた処 置</p>	<p>1N</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'/PDRR_IN049016UV1/controlActProcess[@classCode='CACTI']/@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']/subjectC02[@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'/inboundRelationship[@typeCode='RSON']/observation/code[@code='19']/@c odeSystem='2.16.840.1.13883.3.989.2.1.1.19'[@typeCode='RSON']/observation/@classCode='OBS'[@moodCode= EVN']/performer[@typeCode='PRF']/assignedEntity[@classCode='ASSIGNED']/code[@code='3']/@c odeSystem='2.16.840.1.13883.3.989.2.1.1.21'[@value][1]/value[@xsi:type='CE']/@codeSystem='2.16.840. 1.13883.3.989.2.1.1.15'[@codeSystemVersion]</pre>
<p>h</p> <p>G.k.9.i</p> <p>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)</p>				
<p>e</p> <p>G.k.9.l.1</p> <p>評価対象の副作用/有害事 象</p>	<p>N/A</p>		<p>値</p>	

(別添 3)

e	G.k.9.i.3.1a	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)	5N	Physical Quantity (PQ)	value=Real Number (REAL)	値	/MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/PORR_IN049016UVJr/controlAct/process[@classCode=CACT][@moo dCode=EVN]/subject/@typeCode=SUBJ[1]/investigationEvent[@classCode=INVSTG][@moodCo de=EVN]/component/@typeCode=COMP[1]/adverseEventAssessment[1]/adverseEventAssessment [@classCode=INVSTG][@moodCode=EVN]/subject[1]/typeCode=SBJ[1]/primaryRole[@classC ode=INVSBJ]/subjectO2/@typeCode=SBJ/organizer[@classCode=CATEGORY][@moodCode= EVN][code[@code=4]][@codeSystem=2.16.840.1.113883.3.989.2.1.1.20][1]/component/@typeCo de=COMP[1]/substanceAdministration[id][k]/substanceAdministration[@classCode=SBADM][@moo dCode=EVN]/outboundRelationship[1][@typeCode=SAS][actReference[@classCode=OBS][@moo dCode=EVN]/id[@root=UJID of I-h reaction]]/pauseQuantity/@value
e	G.k.9.i.3.1b	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)	50AN	Physical Quantity (PQ)	unit=Coded Simple Value (CS)	値	/MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/PORR_IN049016UVJr/controlAct/process[@classCode=CACT][@moo dCode=EVN]/subject/@typeCode=SUBJ[1]/investigationEvent[@classCode=INVSTG][@moodCo de=EVN]/component/@typeCode=COMP[1]/adverseEventAssessment[1]/adverseEventAssessment [@classCode=INVSTG][@moodCode=EVN]/subject[1]/typeCode=SBJ[1]/primaryRole[@classC ode=INVSBJ]/subjectO2/@typeCode=SBJ/organizer[@classCode=CATEGORY][@moodCode= EVN][code[@code=4]][@codeSystem=2.16.840.1.113883.3.989.2.1.1.20][1]/component/@typeCo de=COMP[1]/substanceAdministration[id][k]/substanceAdministration[@classCode=SBADM][@moo dCode=EVN]/outboundRelationship[1][@typeCode=SAS][actReference[@classCode=OBS][@moo dCode=EVN]/id[@root=UJID of I-h reaction]]/pauseQuantity/@unit
e	G.k.9.i.3.2a	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)	5N	Physical Quantity (PQ)	value=Real Number (REAL)	値	/MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/PORR_IN049016UVJr/controlAct/process[@classCode=CACT][@moo dCode=EVN]/subject/@typeCode=SUBJ[1]/investigationEvent[@classCode=INVSTG][@moodCo de=EVN]/component/@typeCode=COMP[1]/adverseEventAssessment[1]/adverseEventAssessment [@classCode=INVSTG][@moodCode=EVN]/subject[1]/typeCode=SBJ[1]/primaryRole[@classC ode=INVSBJ]/subjectO2/@typeCode=SBJ/organizer[@classCode=CATEGORY][@moodCode= EVN][code[@code=4]][@codeSystem=2.16.840.1.113883.3.989.2.1.1.20][1]/component/@typeCo de=COMP[1]/substanceAdministration[id][k]/substanceAdministration[@classCode=SBADM][@moo dCode=EVN]/outboundRelationship[1][@typeCode=SAE][actReference[@classCode=OBS][@moo dCode=EVN]/id[@root=UJID of I-h reaction]]/pauseQuantity/@value
e	G.k.9.i.3.2b	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)	50AN	Physical Quantity (PQ)	unit=Coded Simple Value (CS)	値	/MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/PORR_IN049016UVJr/controlAct/process[@classCode=CACT][@moo dCode=EVN]/subject/@typeCode=SUBJ[1]/investigationEvent[@classCode=INVSTG][@moodCo de=EVN]/component/@typeCode=COMP[1]/adverseEventAssessment[1]/adverseEventAssessment [@classCode=INVSTG][@moodCode=EVN]/subject[1]/typeCode=SBJ[1]/primaryRole[@classC ode=INVSBJ]/subjectO2/@typeCode=SBJ/organizer[@classCode=CATEGORY][@moodCode= EVN][code[@code=4]][@codeSystem=2.16.840.1.113883.3.989.2.1.1.20][1]/component/@typeCo de=COMP[1]/substanceAdministration[id][k]/substanceAdministration[@classCode=SBADM][@moo dCode=EVN]/outboundRelationship[1][@typeCode=SAE][actReference[@classCode=OBS][@moo dCode=EVN]/id[@root=UJID of I-h reaction]]/pauseQuantity/@unit

(別添 3)

e	G.k.9.i.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> /MCCI_IN200100UV01[@ITSVersion=XML_1.0T]@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd/y/PORR_IN049016UVf/control/ActProcess[@classCode=CACT]@moodCode=EVN/y/subject/@typeCode=SUBJ/y/investigationEvent/@classCode=INVESTG/@moodCode=EVN/y/component/@typeCode=COMP/y/adverseEventAssessment[1]/adverseEventAssessment[@classCode=INVESTG]@moodCode=EVN/y/subject1/@typeCode=SBJ/y/primaryRole/@classCode=INVSBJ/y/subjectOr2/@typeCode=SBJ/y/organizer/@classCode=CATEGORY/@moodCode=EVN/y/code/@code=4/@codeSystem=2.16.840.1.113883.3.989.2.1.1.20/y/component/@typeCode=COMP/y/substanceAdministration[id]/y/substanceAdministration[@classCode=SBADM]@moodCode=EVN/y/outboundRelationship2/@typeCode=PERT/y/observation/code/@code=31/@codeSystem=2.16.840.1.113883.3.989.2.1.1.19/y/observation/@classCode=OBS/@moodCode=EVN/y/outboundRelationship1/@typeCode=REFR/y/actReference/@classCode=OBS/@moodCode=EVN/y/id/@root=UUID of reaction/y/value/@xsi:type=CE/@codeSystem=2.16.840.1.113883.3.989.2.1.1.16/y/@code </pre>
e	G.k.10.r	医薬品に関するその他の情報 (コード化) (必要に応じて繰り返す)	2N	Coded With Equivalents (CE)	code=Character String (ST)	値	<pre> /MCCI_IN200100UV01[@ITSVersion=XML_1.0T]@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd/y/PORR_IN049016UVf/control/ActProcess[@classCode=CACT]@moodCode=EVN/y/subject/@typeCode=SUBJ/y/investigationEvent/@classCode=INVESTG/@moodCode=EVN/y/component/@typeCode=COMP/y/adverseEventAssessment[1]/adverseEventAssessment[@classCode=INVESTG]@moodCode=EVN/y/subject1/@typeCode=SBJ/y/primaryRole/@classCode=INVSBJ/y/subjectOr2/@typeCode=SBJ/y/organizer/@classCode=CATEGORY/@moodCode=EVN/y/code/@code=4/@codeSystem=2.16.840.1.113883.3.989.2.1.1.20/y/organizer/@classCode=CATEGORY/@moodCode=EVN/y/component/@typeCode=COMP/y/substanceAdministration[id]/y/substanceAdministration[@classCode=SBADM]@moodCode=EVN/y/outboundRelationship2/@typeCode=REFR/y/observation/code/@code=9/@codeSystem=2.16.840.1.113883.3.989.2.1.1.19/y/observation/@classCode=OBS/@moodCode=EVN/y/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> /MCCI_IN200100UV01[@ITSVersion=XML_1.0T]@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd/y/PORR_IN049016UVf/control/ActProcess[@classCode=CACT]@moodCode=EVN/y/subject/@typeCode=SUBJ/y/investigationEvent/@classCode=INVESTG/@moodCode=EVN/y/component/@typeCode=COMP/y/adverseEventAssessment[1]/adverseEventAssessment[@classCode=INVESTG]@moodCode=EVN/y/subject1/@typeCode=SBJ/y/primaryRole/@classCode=INVSBJ/y/subjectOr2/@typeCode=SBJ/y/organizer/@classCode=CATEGORY/@moodCode=EVN/y/code/@code=4/@codeSystem=2.16.840.1.113883.3.989.2.1.1.20/y/organizer/@classCode=CATEGORY/@moodCode=EVN/y/component/@typeCode=COMP/y/substanceAdministration[id]/y/substanceAdministration[@classCode=SBADM]@moodCode=EVN/y/outboundRelationship2/@typeCode=REFR/y/observation/code/@code=9/@codeSystem=2.16.840.1.113883.3.989.2.1.1.19/y/observation/@classCode=OBS/@code=9/@codeSystem=2.16.840.1.113883.3.989.2.1.1.17/y/@code </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> /MCCI_IN200100UV01[@ITSVersion=XML_1.0T]@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd/y/PORR_IN049016UVf/control/ActProcess[@classCode=CACT]@moodCode=EVN/y/subject/@typeCode=SUBJ/y/investigationEvent/@classCode=INVESTG/@moodCode=EVN/y/component/@typeCode=COMP/y/adverseEventAssessment[1]/adverseEventAssessment[@classCode=INVESTG]@moodCode=EVN/y/subject1/@typeCode=SBJ/y/primaryRole/@classCode=INVSBJ/y/subjectOr2/@typeCode=SBJ/y/organizer/@classCode=CATEGORY/@moodCode=EVN/y/code/@code=4/@codeSystem=2.16.840.1.113883.3.989.2.1.1.20/y/organizer/@classCode=CATEGORY/@moodCode=EVN/y/component/@typeCode=COMP/y/substanceAdministration[id]/y/substanceAdministration[@classCode=SBADM]@moodCode=EVN/y/outboundRelationship2/@typeCode=REFR/y/observation/code/@code=2/@codeSystem=2.16.840.1.113883.3.989.2.1.1.19/y/observation/@classCode=OBS/@code=2/@codeSystem=2.16.840.1.113883.3.989.2.1.1.19/y/text </pre>
h	H	症例概要及びその他の情報の記述					

(別添 3)

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	<pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/PDRR_IN049016UV1/controlActIProcess[@classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUBJ1]/investigationEvent[@classCode=INVESTG1][@moodCode=EVN]/text/text() </pre>
e	H.2	報告者の意見	20000AN	Encapsulated Data (ED)	値	<pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/PDRR_IN049016UV1/controlActIProcess[@classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUBJ1]/investigationEvent[@classCode=INVESTG1][@moodCode=EVN]/component[@typeCode=COMP1]/adverseEventAssessment[1]/adverseEventAssessment[@classCode=INVESTG1][@moodCode=EVN]/component1[@typeCode=COMP1]/observationEvent[code=@code=10][@codeSystem=2.16.840.1.113883.3.989.2.1.1.19][author/@typeCode=AUT]/asSignedEntity[@classCode=ASSIGNED]/code[@code=37][@codeSystem=2.16.840.1.113883.3.989.2.1.1.21][1]/observationEvent[@classCode=OBS1][@moodCode=EVN]/value[@xsi:type=ED]/text </pre>
h	H.3.r	送信者による診断名 (必要に応じ繰り返し)			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/controlActIProcess[@classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUBJ1]/investigationEvent[@classCode=INVESTG1][@moodCode=EVN]/component[@typeCode=COMP1]/adverseEventAssessment[1]/adverseEventAssessment[@classCode=INVESTG1][@moodCode=EVN]/component1[@typeCode=COMP1]/observationEvent[code=@code=15][@codeSystem=2.16.840.1.113883.3.989.2.1.1.19][author/@typeCode=AUT]/asSignedEntity[@classCode=ASSIGNED]/code[@code=1][@codeSystem=2.16.840.1.113883.3.989.2.1.1.21] </pre>
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 パージョン	4AN	Coded With Equivalents (CE)	値	<pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/PDRR_IN049016UV1/controlActIProcess[@classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUBJ1]/investigationEvent[@classCode=INVESTG1][@moodCode=EVN]/component[@typeCode=COMP1]/adverseEventAssessment[1]/adverseEventAssessment[@classCode=INVESTG1][@moodCode=EVN]/component1[@typeCode=COMP1]/observationEvent[code=@code=15][@codeSystem=2.16.840.1.113883.3.989.2.1.1.19][author/@typeCode=AUT]/asSignedEntity[@classCode=ASSIGNED]/code[@code=1][@codeSystem=2.16.840.1.113883.3.989.2.1.1.21][1]/observationEvent[@classCode=OBS1][@moodCode=EVN]/value[@xsi:type=CE][@codeSystem=2.16.840.1.113883.6.1637]/codeSystemVersion </pre>
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	<pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/PDRR_IN049016UV1/controlActIProcess[@classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUBJ1]/investigationEvent[@classCode=INVESTG1][@moodCode=EVN]/component[@typeCode=COMP1]/adverseEventAssessment[1]/adverseEventAssessment[@classCode=INVESTG1][@moodCode=EVN]/component1[@typeCode=COMP1]/observationEvent[code=@code=15][@codeSystem=2.16.840.1.113883.3.989.2.1.1.19][author/@typeCode=AUT]/asSignedEntity[@classCode=ASSIGNED]/code[@code=1][@codeSystem=2.16.840.1.113883.3.989.2.1.1.21][1]/observationEvent[@classCode=OBS1][@moodCode=EVN]/value[@xsi:type=CE][@codeSystem=2.16.840.1.113883.6.1637]/code </pre>

(別添 3)

e	H.4	送付者の意見	20000AN	Encapsulated Data (ED)	値	<pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/PORR_IN049016JVF/controlActProcess[@classCode=CACT][@moodCo dCode=EVN]/subject/@typeCode=SUBJ][investigationEvent[@classCode=INVESTG][@moodCo dCode=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][as signedEntity/@classCode=ASSIGNED][code=@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(必要に応じ繰り返し送す)			繰り返し送すノード	<pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/PORR_IN049016JVF/controlActProcess[@classCode=CACT][@moodCo dCode=EVN]/subject/@typeCode=SUBJ][investigationEvent[@classCode=INVESTG][@moodCo dCode=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> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/PORR_IN049016JVF/controlActProcess[@classCode=CACT][@moodCo dCode=EVN]/subject/@typeCode=SUBJ][investigationEvent[@classCode=INVESTG][@moodCo dCode=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]][/observationEvent[@d 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)	language=Coded Simple Value (CS)	<pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/PORR_IN049016JVF/controlActProcess[@classCode=CACT][@moodCo dCode=EVN]/subject/@typeCode=SUBJ][investigationEvent[@classCode=INVESTG][@moodCo dCode=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]][/observationEvent[@d assCode=OBS][@moodCode=EVN][value[@xsi:type=ED][@language </pre>

ヘッダ エン ディ	フィールド 番号	フィールド名	ICSR メッ セージにおけ るフィールド 番号	ICH デー タ型	HL7 データ型 (下位構成要素)	分類	Xpath
	ACK.M/A	ICH ICSR バッチ確認 応答					
	ACK.M.1	確認応答バッチ番号		100AN	extension=Character String (ST)	値	/MCCCL_IN200101UV01[@ITSVersion=XML_1.0][@xmlns:schemaLocation=urn:hl7-org:v3 MCCCL_IN200101UV01.xsd]/id/@root=2.16.840.1.113883.3.989.2.1.3.20/@extension
	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	/MCCCL_IN200101UV01[@ITSVersion=XML_1.0][@xmlns:schemaLocation=urn:hl7-org:v3 MCCCL_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
	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	/MCCCL_IN200101UV01[@ITSVersion=XML_1.0][@xmlns:schemaLocation=urn:hl7-org:v3 MCCCL_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
	ACK.M.4	バッチ伝送の確認応 答日		日付/時 間	Point in Time (TS)	値	/MCCCL_IN200101UV01[@ITSVersion=XML_1.0][@xmlns:schemaLocation=urn:hl7-org:v3 MCCCL_IN200101UV01.xsd]/creationTime/@value
	ACK.A.1	ICSR バッチ番号	N.1.2	100AN	extension=Character String (ST)	値	/MCCCL_IN200101UV01[@ITSVersion=XML_1.0][@xmlns:schemaLocation=urn:hl7-org:v3 MCCCL_IN200101UV01.xsd]/acknowledgement/@typeCode/targetBatchId/@root=2.16.840.1.113 883.3.989.2.1.3.22/@extension
	ACK.A.2	確認応答地域メッ セージ番号		100AN	extension=Character String (ST)	値	/MCCCL_IN200101UV01[@ITSVersion=XML_1.0][@xmlns:schemaLocation=urn:hl7-org:v3 MCCCL_IN200101UV01.xsd]/attentionLine[keyWordText=@code=2][@codeSystem=2.16.840.1.11 3883.3.989.2.1.1.24][@value][@xmlns:schemaLocation=urn:hl7-org:v3 MCCCL_IN200101UV01.xsd]/value/@root=2.16.840.1.113883.3.989.2.1.3.21/@extens ion
	ACK.A.3	ICSR バッチ伝送日	N.1.5	日付/時 間	Point in Time (TS)	値	/MCCCL_IN200101UV01[@ITSVersion=XML_1.0][@xmlns:schemaLocation=urn:hl7-org:v3 MCCCL_IN200101UV01.xsd]/attentionLine[keyWordText=@code=3][@codeSystem=2.16.840.1.11 3883.3.989.2.1.1.24][@value][@xmlns:schemaLocation=urn:hl7-org:v3 MCCCL_IN200101UV01.xsd]/value/@root=2.16.840.1.113883.3.989.2.1.3.21/@extens ion

(別添 3)

e	ACK.A.4	伝送確認応答コード	2A	Coded Value (CS)	値	/MCCCL_IN200101UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=um:hl7-org:v3 MCCCL_IN200101UV01.xsd]/acknowledgement/@typeCode
e	ACK.A.5	バッヂバリデーションエラー	250AN	Encapsulated Data (ED)	値	/MCCCL_IN200101UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=um:hl7-org:v3 MCCCL_IN200101UV01.xsd]/acknowledgementDetail[1]/text/text()
h	ACK.B.r	ICH ICSR メッセージ確認応答			繰り返し ノード	/MCCCL_IN200101UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=um:hl7-org:v3 MCCCL_IN200101UV01.xsd]/MCCCL_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)	/MCCCL_IN200101UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=um:hl7-org:v3 MCCCL_IN200101UV01.xsd]/MCCCL_IN000002UV01[1]/acknowledgement[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)	/MCCCL_IN200101UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=um:hl7-org:v3 MCCCL_IN200101UV01.xsd]/MCCCL_IN000002UV01[1]/id[@root=2,16,840,1,113883,3,989,2,1,3,1]/@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)	/MCCCL_IN200101UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=um:hl7-org:v3 MCCCL_IN200101UV01.xsd]/MCCCL_IN000002UV01[1]/receiver[1]/device/@classCode=DEV][@determinerCode=INSTANCE]/id[@root=2,16,840,1,113883,3,989,2,1,3,15]/@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)	/MCCCL_IN200101UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=um:hl7-org:v3 MCCCL_IN200101UV01.xsd]/MCCCL_IN000002UV01[1]/sender[1]/device/@classCode=DEV][@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 成日	日付/時 間 N.2.r.4 C.1.2	Point in Time (TS)	値	/MCCCL_IN200101UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=um:hl7-org:v3 MCCCL_IN200101UV01.xsd]/MCCCL_IN000002UV01[1]/attentionLine[keyWordText@codes=1][@codeSystem=2,16,840,1,113883,3,989,2,1,1,24][1]/value[1]/@xsi:type=TS
e	ACK.B.r.6	ICSR メッセージの 確認応答コード	2A	Coded Value (CS)	値	/MCCCL_IN200101UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=um:hl7-org:v3 MCCCL_IN200101UV01.xsd]/MCCCL_IN000002UV01[1]/acknowledgement[1]/@typeCode

(別添 3)

ACK.B.r.7	エラー／警告メッセージ又は意見	250AN	Encapsulated Data (ED)	値	/MCC_IN200101UV01[(@ITSVersion=XML_1.0)]@axischemaLocation=um:h17-org:v3 MCC_IN200101UV01.xsd/MCC_IN00002UV01r/acknowledgement[@typeCode][1]acknowledgementDetail[1]/text/text()
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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 SXPRTS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="SXPRTS">
149         <comp xsi:type="PIVLTST">
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="IVLTST" 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="IVLTST" 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="IVLPQ" >
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="IVLPQ" >
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>

```

```

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

```

337 例2

```

338     <outboundRelationship2 typeCode="COMP">
339         <substanceAdministration classCode="SBADM" moodCode="EVN">
340             <effectiveTime xsi:type="SXPR_TS">
341                 <comp xsi:type="PIVL_TS">
342                     <period value="1" unit="d"/>
343                 </comp>
344             </effectiveTime>
345             <doseQuantity value="2" unit="{DF}"/>
346             <consumable typeCode="CSM">
347                 <instanceOfKind classCode="INST">
348                     <kindOfProduct classCode="MMAT" determinerCode="KIND">
349                         <formCode>
350                             <originalText>Tablet</originalText>
351                         </formCode>
352                     </kindOfProduct>
353                 </instanceOfKind>
354             </consumable>
355         </substanceAdministration>
356     </outboundRelationship2>
357

```

358 2.3.6. 1日4回、7.5 mg/回

359 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>

```

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         </substanceAdministration>

```

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         </substanceAdministration>

```

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-9c30-67671b0e9e4"/>

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ー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。

