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日米 EU 医薬品規制調和国際会議

ICH E2B 専門家作業部会

個別症例安全性報告 (ICSR) の電子的伝送に
係る実装ガイド

付録 I (G)

技術的情報

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I. 序

本文書では、電子伝送のための有効な ICH ICSR メッセージまたは ICSR 確認応答メッセージの作成を支援するのに必要な技術的情報を示す。本文書の情報はずべて ICH ICSR 実装ガイドと一致しており、技術的ポイントの詳細について概要を示す。

IT 環境の変化又はエラーの特定により変更の必要が生じた場合は、本文書の内容は更新され、ICH E2B (R3) IWG により維持・管理される。

II. 技術的情報

1. ICH データ型、HL7 データ型及び E2B (R3) データ項目の XPath

ICH 及び HL7 におけるデータ型を下表に示す。

HL7 のデータ型の一部は、概念又はデータ値を示すために特定の体系により規定されたコードを使用している。ICH が使用しているコード化された HL7 データ型のうち 3 つは「複合型」として知られるタイプのものである。複合データ型は概念及び値を数字コード及び人間が判読可能なテキストとして表現することができる構成である。ICH が使用している 4 つ目のコード化されたデータ型である CS データ型は複合型ではないが、その代わり、人間が判読可能なテキストを併記せずにコード化された値のみを伝えるものである。さらなる詳細及びコード化されたデータ型のそれぞれの詳細については、HL7 データ型規格を参照のこと。

実装ガイドは、上述のコード化されたデータ型を含め、HL7 データ型に準拠している。複合データ型には *displayName* という任意の構成要素がある。これは人間が判読可能なテキストを送信し、デバッグ又は技術的解析において xml メッセージの解釈を容易にするために使われる。しかし、この *displayName* は E2B (R3) データ項目には対応付けられておらず、そのため任意のものである。実装ガイドでは *displayName* について要求又は記載していないが、*displayName* は HL7 データ型により技術的にサポートされているため、必要に応じて読みやすくするためにメッセージに含めてもよい。手引きについては各地域のガイドを参照のこと。

E2B (R3) のデータ項目を明記するため、XPath も下表に示す。それには、コード及び OID など、ICH ICSR 及び確認応答メッセージの作成に必要なスキーマ項目及び属性が含まれる。ICH の地域間で伝送されるすべてのメッセージは、E2B (R3) のデータ項目を特定する参照インスタンス及び XPath に一致していなければならない。XPath は参照インスタンスに基づいて作成されており、したがって両文書に同じ項目及び属性がなければならないことに留意する。XPath に違いが認められた場合は、参照インスタンス及びスキーマに戻ってオリジナルの XML を確認することが重要である。下表には、E2B (R3) データ項目構造において繰り返しを可能とする E2B (R3) データ項目について、繰り返し可能なセクション (ノード) も示す。XML メッセージ構造には複数の可能なノードが存在するが、ICH ICSR 又は確認応答メッセージでは規定のノードを使用すること。ICH データ型及び対応する HL7 データ型の一覧を表に記載する。

h:ヘッダ e:エンティ ティ	項目番号	要素名	ICH データ型	HL7データ型	HL7データ型 (下位構成要素)	分類	Xpath
h	N.1	ICH ICSR 伝送識別子 (バッチ ラッパー: BATCH WRAPPER)					
e	N.1.1	バッチ内のメッセージの種 類	11A	Character String with Code (SC)	code=Coded With Equivalents (CE)	値	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/name/@codeSystem=2.16.840.1.113883.3.989.2.1.1.11/@code
e	N.1.2	バッチ番号	100AN	Instance Identifier (II)	extension=Character String (ST)	値	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/id/@root=2.16.840.1.113883.3.989.2.1.3.221/@extension
e	N.1.3	バッチ送信者識別子	60AN	Instance Identifier (II)	extension=Character String (ST)	値	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/sender[@typeCode='SND']/device/@classCode=DEV[@determinerCo de='INSTANCE']/id/@root=2.16.840.1.113883.3.989.2.1.3.1311/@extension
e	N.1.4	バッチ受信者識別子	60AN	Instance Identifier (II)	extension=Character String (ST)	値	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/receiver[@typeCode='RCV']/device/@classCode=DEV[@determinerC ode='INSTANCE']/id/@root=2.16.840.1.113883.3.989.2.1.3.1411/@extension
e	N.1.5	バッチ伝送の日付	日付/ 時間	Point in Time (TS)		値	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/creationTime/@value
h	N.2.r	ICH ICSR メッセージヘッダ (メッセージラッパー) (必 要に応じて繰り返す)				繰り返し ノード	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV
e	N.2.r.1	メッセージ識別子	100AN	Instance Identifier (II)	extension=Character String (ST)	値	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[id]/@root=2.16.840.1.113883.3.989.2.1.3.111/ @extension
e	N.2.r.2	メッセージ送信者識別子	60AN	Instance Identifier (II)	extension=Character String (ST)	値	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[id]/sender[@typeCode='SND']/device/@classCode 'DEV'[@determinerCode='INSTANCE']/id/@root=2.16.840.1.113883.3.989.2.1.3.1111/@extension
e	N.2.r.3	メッセージ受信者識別子	60AN	Instance Identifier (II)	extension=Character String (ST)	値	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[id]/receiver[@typeCode='RCV']/device/@classCode ='DEV'[@determinerCode='INSTANCE']/id/@root=2.16.840.1.113883.3.989.2.1.3.1211/@extension
e	N.2.r.4	メッセージ作成の日付	日付/時間	Point in Time (TS)		値	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[id]/creationTime/@value
h	C.1	症例安全性報告の識別					
e	C.1.1	送信者ごとに固有の (症例) 安全性報告識別子	100AN	Instance Identifier (II)	extension=Character String (ST)	値	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/subject[@typeCode='SUB.1.1']/investigationEvent/@classCode=INVTG[@moodCo de='EVN']/id/@root=2.16.840.1.113883.3.989.2.1.3.1111/@extension

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	作成の日付	日付/時間	Point in Time (TS)	値
e	C.1.2		Point in Time (TS)	/MCCL_IN200100UV01[ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]JPORR_IN049016UV[controlActProcess][@classCode=CACT][@mo dCode=EVN]/effectiveTime/@value
e	C.1.3	報告の種類	Coded With Equivalents (CE)	値 code=Character String (ST)
e	C.1.4	情報源から最初に報告が入 手された日	Interval of Point in Time (IVL<TS>)	値 low=Interval Boundary (VXB)
e	C.1.5	本報告の最新情報入手日	Point in Time (TS)	値
h	C.1.6	送信者が保有している利用 可能なその他の資料		
e	C.1.6.1	利用可能なその他の資料は あるか?	Boolean (BL)	値
h	C.1.6.1.r	送信者が保有している資料 (必要に応じて繰り返し返す)		繰り返し返す ノード
e	C.1.6.1.r.1	送信者が保有している資料	Character String (ST)	値
e	C.1.6.1.r.2	含まれる資料	Encapsulated Data (ED)	値

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e	C.1.7	本症例は当該国の緊急報告の基準を満たすか？	ブール型	Boolean (BL)	値	/MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3MCCL_IN200100UV01.xsd]/PDRR_IN049016UVr/controlActProcess[@classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUB][1]/investigationEvent[@classCode=INVTG][@moodCode=EVN]/component[@typeCode=COMP][observationEvent[@code=23][@codeSystem=2.16.840.1.113883.3.989.2.1.1.19]][1]/observationEvent[@classCode=OBS][@moodCode=EVN]/value[@xsi:type=BL][@value]
e					NullFlavor	/MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3MCCL_IN200100UV01.xsd]/PDRR_IN049016UVr/controlActProcess[@classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUB][1]/investigationEvent[@classCode=INVTG][@moodCode=EVN]/component[@typeCode=COMP][observationEvent[@code=23][@codeSystem=2.16.840.1.113883.3.989.2.1.1.19]][1]/observationEvent[@classCode=OBS][@moodCode=EVN]/value[@xsi:type=BL][@nullFlavor]
h	C.1.8	世界的に固有の症例識別子				
e	C.1.8.1	世界的に固有の症例識別子	100AN	Instance Identifier (I)	extension=Character String (ST)	/MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3MCCL_IN200100UV01.xsd]/PDRR_IN049016UVr/controlActProcess[@classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUB][1]/investigationEvent[@classCode=INVTG][@moodCode=EVN]/id[@root=2.16.840.1.113883.3.989.2.1.3.2][1][@extension]
e	C.1.8.2	本症例の第一送信者	1N	Coded With Equivalents (CE)	code=Character String (ST)	/MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3MCCL_IN200100UV01.xsd]/PDRR_IN049016UVr/controlActProcess[@classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUB][1]/investigationEvent[@classCode=INVTG][@moodCode=EVN]/outboundRelationship[@typeCode=SPRT][relatedInvestigationEvent[@code=1][@codeSystem=2.16.840.1.113883.3.989.2.1.2.2]][1]/relatedInvestigationEvent[@classCode=INVTG][@moodCode=EVN]/subjectOr2[@typeCode=SUB][1]/controlActEvent[@classCode=CACT][@moodCode=EVN]/author[@typeCode=AUT][assignedEntity[@classCode=ASSIGNED][code[@codeSystem=2.16.840.1.113883.3.989.2.1.3.3][@code]
h	C.1.9	その他の症例識別子				
e	C.1.9.1	過去の伝送で記録されたその他の症例識別子はあるか？	ブール型	Boolean (BL)	値	/MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3MCCL_IN200100UV01.xsd]/PDRR_IN049016UVr/controlActProcess[@classCode=CACT][@moodCode=EVN]/subjectOr2[@typeCode=SUB][1]/investigationEvent[@classCode=INVTG][@moodCode=EVN]/subjectOr2[@typeCode=SUB][1.23][1][1]/investigationCharacteristic[@code=2][@codeSystem=2.16.840.1.113883.3.989.2.1.1.23][1][1]/investigationCharacteristic[@classCode=OBS][@moodCode=EVN]/value[@xsi:type=BL][@value]
e					NullFlavor	/MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3MCCL_IN200100UV01.xsd]/PDRR_IN049016UVr/controlActProcess[@classCode=CACT][@moodCode=EVN]/subjectOr2[@typeCode=SUB][1]/investigationEvent[@classCode=INVTG][@moodCode=EVN]/subjectOr2[@typeCode=SUB][1.23][1][1]/investigationCharacteristic[@code=2][@codeSystem=2.16.840.1.113883.3.989.2.1.1.23][1][1]/investigationCharacteristic[@classCode=OBS][@moodCode=EVN]/value[@xsi:type=BL][@nullFlavor]
h	C.1.9.1.r	症例識別子の情報源 (必要に応じて繰り返す)			繰り返し ノード	/MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3MCCL_IN200100UV01.xsd]/PDRR_IN049016UVr/controlActProcess[@classCode=CACT][@moodCode=EVN]/subjectOr1[@typeCode=SUB][1][1]/controlActEvent[id]
e	C.1.9.1.r.1	症例識別子の情報源	100AN	Instance Identifier (I)	値	/MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3MCCL_IN200100UV01.xsd]/PDRR_IN049016UVr/controlActProcess[@classCode=CACT][@moodCode=EVN]/subjectOr1[@typeCode=SUB][1][1]/investigationEvent[id][@root=2.16.840.1.113883.3.989.2.1.3.3][1][1]/assigningAuthorityName

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Code	Section	Case Category	Instance Identifier (II)	extension=Character String (ST)	Value
e	C.1.9.1.r.2	症例識別子	100AN	extension=Character String (ST)	/MCCl_IN200100UV01[ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCl_IN200100UV01.xsd]PDRR_IN049016UVJ[controlActProcess/@classCode=CACT][@moodCode=EVN]/subject/@typeCode=SUBJ[relatedInvestigationEvent/@classCode=INVSIG][@moodCode=EVN]/subjectOf2/@typeCode=SUBJ[controlActEvent/@classCode=CACT][@moodCode=EVN]/subjectOf2/@typeCode=SUBJ[controlActEvent/@classCode=CACT][@moodCode=EVN]/subjectOf2/@typeCode=SUBJ[relatedInvestigationCode/@nullFlavor=NA][relatedInvestigation/@classCode=INVSIG][@moodCode=EVN]/subjectOf2/@typeCode=SUBJ[controlActEvent/@classCode=CACT][@moodCode=EVN][@root=2.16.840.1.113883.3.989.2.1.3.2][extension]
e	C.1.10.r	本報告と関連する報告の識別子 (必要に応じて繰り返し返す)	100AN	extension=Character String (ST)	/MCCl_IN200100UV01[ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCl_IN200100UV01.xsd]PDRR_IN049016UVJ[controlActProcess/@classCode=CACT][@moodCode=EVN]/subject/@typeCode=SUBJ[relatedInvestigationEvent/@classCode=INVSIG][@moodCode=EVN]/outboundRelationship/@typeCode=SPRT[relatedInvestigationCode/@nullFlavor=NA][relatedInvestigation/@classCode=INVSIG][@moodCode=EVN]/subjectOf2/@typeCode=SUBJ[controlActEvent/@classCode=CACT][@moodCode=EVN][@root=2.16.840.1.113883.3.989.2.1.3.2][extension]
h	C.1.11	報告破棄/修正			
e	C.1.11.1	報告破棄/修正	1N	code=Character String (ST)	/MCCl_IN200100UV01[ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCl_IN200100UV01.xsd]PDRR_IN049016UVJ[controlActProcess/@classCode=CACT][@moodCode=EVN]/subject/@typeCode=SUBJ[relatedInvestigationEvent/@classCode=INVSIG][@moodCode=EVN]/subjectOf2/@typeCode=SUBJ[relatedInvestigationCharacteristic/@code=3][@codeSystem=2.16.840.1.113883.3.989.2.1.1.23][relatedInvestigationCharacteristic/@classCode=OBS][@moodCode=EVN][value/@xsi:type=CE][@codeSystem=2.16.840.1.113883.3.989.2.1.1.57][code]
e	C.1.11.2	報告破棄/修正理由	2000AN	originalText = Encapsulated Data (ED)	/MCCl_IN200100UV01[ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCl_IN200100UV01.xsd]PDRR_IN049016UVJ[controlActProcess/@classCode=CACT][@moodCode=EVN]/subjectOf2/@typeCode=SUBJ[relatedInvestigationEvent/@classCode=INVSIG][@moodCode=EVN]/subjectOf2/@typeCode=SUBJ[relatedInvestigationCharacteristic/@code=4][@codeSystem=2.16.840.1.113883.3.989.2.1.1.23][relatedInvestigationCharacteristic/@classCode=OBS][@moodCode=EVN][value/@xsi:type=CE][originalText]
h	C.2.r	第一次情報源 (必要に応じて繰り返し返す)			繰り返し返すノード
h	C.2.r.1	報告者の氏名			
e	C.2.r.1.1	報告者の職名	50AN	prefix=Entity Name Part (ENXP)	/MCCl_IN200100UV01[ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCl_IN200100UV01.xsd]PDRR_IN049016UVJ[controlActProcess/@classCode=CACT][@moodCode=EVN]/outboundRelationship/@typeCode=SPRT[relatedInvestigationCode/@code=2][@codeSystem=2.16.840.1.113883.3.989.2.1.1.22][relatedInvestigation/@classCode=INVSIG][@moodCode=EVN]/author/@typeCode=AUT[assignedEntity/@classCode=ASSIGNED]/assignedPerson/@classCode=PSN[instanceName/@prefix1/text]
e					NullFlavor

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e	C.2.r.1.2	報告者の名前	60AN	Person Name (PN)	given=Entity Name Part (ENXP)	値	/MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hi7-org:v3 MCCI_IN200100UV01.xsd]/PARR_IN049016UVJ/controlActProcess[@classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUBJ][relatedInvestigation/@code=2][@code de=EVN]/outboundRelationship[@typeCode=SPRT][relatedInvestigation/@code=2][@code System=2.16.840.1.113883.3.989.2.1.1.22][relatedInvestigation/@classCode=INVSTG][@mood Code=EVN]/subjectOf2[@typeCode=SUBJ]/controlActEvent[@classCode=CACT][@moodCode=EVN]/author[@typeCode=AUT]/assignedEntity[@classCode=ASSIGNED]/assignedPerson[@class Code=PSN][@determinerCode=INSTANCE]/name/given[1]/text()
e						NullFlavor	/MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hi7-org:v3 MCCI_IN200100UV01.xsd]/PARR_IN049016UVJ/controlActProcess[@classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUBJ][relatedInvestigation/@code=2][@code de=EVN]/outboundRelationship[@typeCode=SPRT][relatedInvestigation/@code=2][@code System=2.16.840.1.113883.3.989.2.1.1.22][relatedInvestigation/@classCode=INVSTG][@mood Code=EVN]/subjectOf2[@typeCode=SUBJ]/controlActEvent[@classCode=CACT][@moodCode=EVN]/author[@typeCode=AUT]/assignedEntity[@classCode=ASSIGNED]/assignedPerson[@class Code=PSN][@determinerCode=INSTANCE]/name/given[1]/text()
e	C.2.r.1.3	報告者の中間名	60AN	Person Name (PN)	given=Entity Name Part (ENXP)	値	/MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hi7-org:v3 MCCI_IN200100UV01.xsd]/PARR_IN049016UVJ/controlActProcess[@classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUBJ][relatedInvestigation/@code=2][@code de=EVN]/outboundRelationship[@typeCode=SPRT][relatedInvestigation/@code=2][@code System=2.16.840.1.113883.3.989.2.1.1.22][relatedInvestigation/@classCode=INVSTG][@mood Code=EVN]/subjectOf2[@typeCode=SUBJ]/controlActEvent[@classCode=CACT][@moodCode=EVN]/author[@typeCode=AUT]/assignedEntity[@classCode=ASSIGNED]/assignedPerson[@class Code=PSN][@determinerCode=INSTANCE]/name/given[2]/text()
e						NullFlavor	/MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hi7-org:v3 MCCI_IN200100UV01.xsd]/PARR_IN049016UVJ/controlActProcess[@classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUBJ][relatedInvestigation/@code=2][@code de=EVN]/outboundRelationship[@typeCode=SPRT][relatedInvestigation/@code=2][@code System=2.16.840.1.113883.3.989.2.1.1.22][relatedInvestigation/@classCode=INVSTG][@mood Code=EVN]/subjectOf2[@typeCode=SUBJ]/controlActEvent[@classCode=CACT][@moodCode=EVN]/author[@typeCode=AUT]/assignedEntity[@classCode=ASSIGNED]/assignedPerson[@class Code=PSN][@determinerCode=INSTANCE]/name/given[2]/text()
e	C.2.r.1.4	報告者の姓	60AN	Person Name (PN)	family=Entity Name Part (ENXP)	値	/MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hi7-org:v3 MCCI_IN200100UV01.xsd]/PARR_IN049016UVJ/controlActProcess[@classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUBJ][relatedInvestigation/@code=2][@code de=EVN]/outboundRelationship[@typeCode=SPRT][relatedInvestigation/@code=2][@code System=2.16.840.1.113883.3.989.2.1.1.22][relatedInvestigation/@classCode=INVSTG][@mood Code=EVN]/subjectOf2[@typeCode=SUBJ]/controlActEvent[@classCode=CACT][@moodCode=EVN]/author[@typeCode=AUT]/assignedEntity[@classCode=ASSIGNED]/assignedPerson[@class Code=PSN][@determinerCode=INSTANCE]/name/family[1]/text()
e						NullFlavor	/MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hi7-org:v3 MCCI_IN200100UV01.xsd]/PARR_IN049016UVJ/controlActProcess[@classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUBJ][relatedInvestigation/@code=2][@code de=EVN]/outboundRelationship[@typeCode=SPRT][relatedInvestigation/@code=2][@code System=2.16.840.1.113883.3.989.2.1.1.22][relatedInvestigation/@classCode=INVSTG][@mood Code=EVN]/subjectOf2[@typeCode=SUBJ]/controlActEvent[@classCode=CACT][@moodCode=EVN]/author[@typeCode=AUT]/assignedEntity[@classCode=ASSIGNED]/assignedPerson[@class Code=PSN][@determinerCode=INSTANCE]/name/family[1]/text()
h	C.2.r.2	報告者の住所及び電話番号					

(別添 3)

e	C.2.r.2.1	報告者の組織	60AN	Organization Name (ON)	name=Entity Name Part (ENXP)	値	/MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORG_IN049016UV[1]/controlActProcess[@classCode=CACT][@mood Code=EVTN]/subject[@typeCode=SUBJ][1]/investigationEvent[1][@classCode=INVTG][@moodCo de=EVTN]/outboundRelationship[1][@typeCode=SPRT][relatedInvestigation/code/@code=2][@code System=2,16,840,1,113883,3,989,2,1,1,22][1]/relatedInvestigation[1][@classCode=INVTG][@mood Code=EVTN]/subjectOf2[@typeCode=SUBJ][controlActEvent[1][@classCode=CACT][@moodCode= EVTN]/author[1][@typeCode=AUT][assignedEntity[1][@classCode=ASIGNED]/representedOrganization [1][@classCode=ORG][1][@determinerCode=INSTANCE]/assignedEntity[1][@classCode=ASIGNED]/r epresentedOrganization[1][@classCode=ORG][1][@determinerCode=INSTANCE]/name/text()
e						NullFlavor	/MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORG_IN049016UV[1]/controlActProcess[@classCode=CACT][@mood Code=EVTN]/subject[@typeCode=SUBJ][1]/investigationEvent[1][@classCode=INVTG][@moodCo de=EVTN]/outboundRelationship[1][@typeCode=SPRT][relatedInvestigation/code/@code=2][@code System=2,16,840,1,113883,3,989,2,1,1,22][1]/relatedInvestigation[1][@classCode=INVTG][@mood Code=EVTN]/subjectOf2[@typeCode=SUBJ][controlActEvent[1][@classCode=CACT][@moodCode= EVTN]/author[1][@typeCode=AUT][assignedEntity[1][@classCode=ASIGNED]/representedOrganizatio n[1][@classCode=ORG][1][@determinerCode=INSTANCE]/assignedEntity[1][@classCode=ASIGNED]/r epresentedOrganization[1][@classCode=ORG][1][@determinerCode=INSTANCE]/name/NullFlavor
e	C.2.r.2.2	報告者の部署	60AN	Organization Name (ON)	name=Entity Name Part (ENXP)	値	/MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORG_IN049016UV[1]/controlActProcess[@classCode=CACT][@mood Code=EVTN]/subject[@typeCode=SUBJ][1]/investigationEvent[1][@classCode=INVTG][@moodCo de=EVTN]/outboundRelationship[1][@typeCode=SPRT][relatedInvestigation/code/@code=2][@code System=2,16,840,1,113883,3,989,2,1,1,22][1]/relatedInvestigation[1][@classCode=INVTG][@mood Code=EVTN]/subjectOf2[@typeCode=SUBJ][controlActEvent[1][@classCode=CACT][@moodCode= EVTN]/author[1][@typeCode=AUT][assignedEntity[1][@classCode=ASIGNED]/representedOrganizatio n[1][@classCode=ORG][1][@determinerCode=INSTANCE]/assignedEntity[1][@classCode=ASIGNED]/r epresentedOrganization[1][@classCode=ORG][1][@determinerCode=INSTANCE]/name/text()
e						NullFlavor	/MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORG_IN049016UV[1]/controlActProcess[@classCode=CACT][@moo dCode=EVTN]/subject[@typeCode=SUBJ][1]/investigationEvent[1][@classCode=INVTG][@moodCo de=EVTN]/outboundRelationship[1][@typeCode=SPRT][relatedInvestigation/code/@code=2][@code System=2,16,840,1,113883,3,989,2,1,1,22][1]/relatedInvestigation[1][@classCode=INVTG][@mood Code=EVTN]/subjectOf2[@typeCode=SUBJ][controlActEvent[1][@classCode=CACT][@moodCode= EVTN]/author[1][@typeCode=AUT][assignedEntity[1][@classCode=ASIGNED]/representedOrganizatio n[1][@classCode=ORG][1][@determinerCode=INSTANCE]/name/NullFlavor
e	C.2.r.2.3	報告者の住所 (番地)	100AN	Postal Address (AD)	streetAddressLine=A address Part (ADXP)	値	/MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORG_IN049016UV[1]/controlActProcess[@classCode=CACT][@moo dCode=EVTN]/subject[@typeCode=SUBJ][1]/investigationEvent[1][@classCode=INVTG][@moodCo de=EVTN]/outboundRelationship[1][@typeCode=SPRT][relatedInvestigation/code/@code=2][@code System=2,16,840,1,113883,3,989,2,1,1,22][1]/relatedInvestigation[1][@classCode=INVTG][@mood Code=EVTN]/subjectOf2[@typeCode=SUBJ][controlActEvent[1][@classCode=CACT][@moodCode= EVTN]/author[1][@typeCode=AUT][assignedEntity[1][@classCode=ASIGNED]/representedOrganizatio n[1][@classCode=ORG][1][@determinerCode=INSTANCE]/name/NullFlavor

(別添 3)

e					NullFlavor	<pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/PORR_IN049016UVJ/controlActProcess[@classCode=CACT][@mood dCode=EVN]/subject[@typeCode=SUBJ][relatedInvestigation/@classCode=INVSIG][@moodCo de=EVN]/outboundRelationship[@typeCode=SPRT][relatedInvestigation/@code=2][@code System=2,16.840.1.113883.3.989.2.1.1.22][relatedInvestigation/@classCode=INVSIG][@mood Code=EVN]/subjectO2I[@typeCode=SUBJ]/controlActEvent[@classCode=CACT][@moodCode= EVN]/author[@typeCode=AUT]/assignedEntity[@classCode=ASSIGNED/addr1]/streetAddressLi ne1[@nullFlavor </pre>
e	C.2.1.2.4	報告者の住所 (市町村等)	35AN	Postal Address (AD)	city=Address Part (ADXP)	<pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/PORR_IN049016UVJ/controlActProcess[@classCode=CACT][@mood dCode=EVN]/subject[@typeCode=SUBJ][relatedInvestigation/@classCode=INVSIG][@moodCo de=EVN]/outboundRelationship[@typeCode=SPRT][relatedInvestigation/@code=2][@code System=2,16.840.1.113883.3.989.2.1.1.22][relatedInvestigation/@classCode=INVSIG][@mood Code=EVN]/subjectO2I[@typeCode=SUBJ]/controlActEvent[@classCode=CACT][@moodCode= EVN]/author[@typeCode=AUT]/assignedEntity[@classCode=ASSIGNED/addr1]/city1/text() </pre>
e	C.2.1.2.5	報告者の住所 (都道府県等)	40AN	Postal Address (AD)	state=Address Part (ADXP)	<pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/PORR_IN049016UVJ/controlActProcess[@classCode=CACT][@mood dCode=EVN]/subject[@typeCode=SUBJ][relatedInvestigation/@classCode=INVSIG][@moodCo de=EVN]/outboundRelationship[@typeCode=SPRT][relatedInvestigation/@code=2][@code System=2,16.840.1.113883.3.989.2.1.1.22][relatedInvestigation/@classCode=INVSIG][@mood Code=EVN]/subjectO2I[@typeCode=SUBJ]/controlActEvent[@classCode=CACT][@moodCode= EVN]/author[@typeCode=AUT]/assignedEntity[@classCode=ASSIGNED/addr1]/city1/ nullFla vor </pre>
e					NullFlavor	<pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/PORR_IN049016UVJ/controlActProcess[@classCode=CACT][@mood dCode=EVN]/subject[@typeCode=SUBJ][relatedInvestigation/@classCode=INVSIG][@moodCo de=EVN]/outboundRelationship[@typeCode=SPRT][relatedInvestigation/@code=2][@code System=2,16.840.1.113883.3.989.2.1.1.22][relatedInvestigation/@classCode=INVSIG][@mood Code=EVN]/subjectO2I[@typeCode=SUBJ]/controlActEvent[@classCode=CACT][@moodCode= EVN]/author[@typeCode=AUT]/assignedEntity[@classCode=ASSIGNED/addr1]/state1/text() </pre>
e	C.2.1.2.6	報告者の住所 (郵便番号)	15AN	Postal Address (AD)	postalCode=Address Part (ADXP)	<pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/PORR_IN049016UVJ/controlActProcess[@classCode=CACT][@mood dCode=EVN]/subject[@typeCode=SUBJ][relatedInvestigation/@classCode=INVSIG][@moodCo de=EVN]/outboundRelationship[@typeCode=SPRT][relatedInvestigation/@code=2][@code System=2,16.840.1.113883.3.989.2.1.1.22][relatedInvestigation/@classCode=INVSIG][@mood Code=EVN]/subjectO2I[@typeCode=SUBJ]/controlActEvent[@classCode=CACT][@moodCode= EVN]/author[@typeCode=AUT]/assignedEntity[@classCode=ASSIGNED/addr1]/postalCode1[Me x] </pre>

e				NullFlavor	<pre> /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UV/f/controlActProcess[@classCode=CACT][@moo dCode=EVN]/subject[@typeCode=SUBJ]/investigationEvent[@classCode=INVTG][@moodCo de=EVN]/outboundRelationship[@typeCode=SPRT][relatedInvestigationCode=2][@code System=2,16,840,1,113883,3,989,2,1,1,22][f/relatedInvestigation/@classCode=INVTG][@mood Code=EVN]/subjectOf2[@typeCode=SUBJ]/controlActEvent[@classCode=CACT][@moodCode= EVN]/author[@typeCode=AUT]/assignedEntity[@classCode=ASSIGNED][addrf1/postalCodef1] @nullFlavor </pre>
e	C.2.r.2.7	報告者の電話番号	33AN	Telecommunication Address (TEL)	<pre> substring(MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UV/f/controlActProcess[@classCode=CACT][@moo dCode=EVN]/subject[@typeCode=SUBJ]/investigationEvent[@classCode=INVTG][@moodCo de=EVN]/outboundRelationship[@typeCode=SPRT][relatedInvestigationCode=2][@code System=2,16,840,1,113883,3,989,2,1,1,22][f/relatedInvestigation/@classCode=INVTG][@mood Code=EVN]/subjectOf2[@typeCode=SUBJ]/controlActEvent[@classCode=CACT][@moodCode= EVN]/author[@typeCode=AUT]/assignedEntity[@classCode=ASSIGNED]/telecomStarts-with[@v alue,'tel:']/value, 5) </pre>
e				NullFlavor	<pre> /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UV/f/controlActProcess[@classCode=CACT][@moo dCode=EVN]/subject[@typeCode=SUBJ]/investigationEvent[@classCode=INVTG][@moodCo de=EVN]/outboundRelationship[@typeCode=SPRT][relatedInvestigationCode=2][@code System=2,16,840,1,113883,3,989,2,1,1,22][f/relatedInvestigation/@classCode=INVTG][@mood Code=EVN]/subjectOf2[@typeCode=SUBJ]/controlActEvent[@classCode=CACT][@moodCode= EVN]/author[@typeCode=AUT]/assignedEntity[@classCode=ASSIGNED]/telecomStarts-with[@v alue,'tel:']/value, 5) </pre>
e	C.2.r.3	報告者の国コード	2A	Concept Descriptor (CD) code=Character String (ST)	<pre> /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UV/f/controlActProcess[@classCode=CACT][@moo dCode=EVN]/subject[@typeCode=SUBJ]/investigationEvent[@classCode=INVTG][@moodCo de=EVN]/outboundRelationship[@typeCode=SPRT][relatedInvestigationCode=2][@code System=2,16,840,1,113883,3,989,2,1,1,22][f/relatedInvestigation/@classCode=INVTG][@mood Code=EVN]/subjectOf2[@typeCode=SUBJ]/controlActEvent[@classCode=CACT][@moodCode= EVN]/author[@typeCode=AUT]/assignedEntity[@classCode=ASSIGNED]/assignedPerson[@clas sCode=PSN][@determinerCode=INSTANCE][aslocatedEntity[@classCode=LOCE][location]@ classCode=COUNTRY][@determinerCode=INSTANCE][codeSystem=1,0,3166,1,2,2]@n ullFlavor </pre>
e				NullFlavor	<pre> /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UV/f/controlActProcess[@classCode=CACT][@moo dCode=EVN]/subject[@typeCode=SUBJ]/investigationEvent[@classCode=INVTG][@moodCo de=EVN]/outboundRelationship[@typeCode=SPRT][relatedInvestigationCode=2][@code System=2,16,840,1,113883,3,989,2,1,1,22][f/relatedInvestigation/@classCode=INVTG][@mood Code=EVN]/subjectOf2[@typeCode=SUBJ]/controlActEvent[@classCode=CACT][@moodCode= EVN]/author[@typeCode=AUT]/assignedEntity[@classCode=ASSIGNED]/assignedPerson[@clas sCode=PSN][@determinerCode=INSTANCE][aslocatedEntity[@classCode=LOCE][location]@ classCode=COUNTRY][@determinerCode=INSTANCE][codeSystem=1,0,3166,1,2,2]@n ullFlavor </pre>

(別添3)

e	C.2.r.4	資格	1N	Coded With Equivalents (CE)	code=Character String (ST)	値	/MCC1_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCC1_IN200100UV01.xsd]/PDRR_IN049016UV1/controlActProcess[@classCode=CACT][@moodCode=EYN]/subject[@typeCode=SUBJ]/investigationEvent[@classCode=INVTG][@moodCode=EYN]/outboundRelationship[@typeCode=SPRT][relatedInvestigation/@code=2][@codeSystem=2.16.840.1.113883.3.989.2.1.1.22][relatedInvestigation/@classCode=INVTG][@moodCode=EYN]/subjectOf2[@typeCode=SUBJ]/controlActEvent[@classCode=CACT][@moodCode=EYN]/author[@typeCode=AUT]/assignedEntity[@classCode=ASSIGNED]/assignedPerson[@classCode=PSN][@determinerCode=INSTANCE]/asQualifiedEntity[@classCode=QUAL][@code/@codeSystem=2.16.840.1.113883.3.989.2.1.1.67][@code
e						NullFlavor	/MCC1_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCC1_IN200100UV01.xsd]/PDRR_IN049016UV1/controlActProcess[@classCode=CACT][@moodCode=EYN]/subject[@typeCode=SUBJ]/investigationEvent[@classCode=INVTG][@moodCode=EYN]/outboundRelationship[@typeCode=SPRT][relatedInvestigation/@code=2][@codeSystem=2.16.840.1.113883.3.989.2.1.1.22][relatedInvestigation/@classCode=INVTG][@moodCode=EYN]/subjectOf2[@typeCode=SUBJ]/controlActEvent[@classCode=CACT][@moodCode=EYN]/author[@typeCode=AUT]/assignedEntity[@classCode=ASSIGNED]/assignedPerson[@classCode=PSN][@determinerCode=INSTANCE]/asQualifiedEntity[@classCode=QUAL][@code/@codeSystem=2.16.840.1.113883.3.989.2.1.1.67][@nullFlavor
e	C.2.r.5	規制目的上の第一次情報源	1N	Real Number (REAL)		値	/MCC1_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCC1_IN200100UV01.xsd]/PDRR_IN049016UV1/controlActProcess[@classCode=CACT][@moodCode=EYN]/subject[@typeCode=SUBJ]/investigationEvent[@classCode=INVTG][@moodCode=EYN]/outboundRelationship[@typeCode=SPRT][relatedInvestigation/@code=2][@codeSystem=2.16.840.1.113883.3.989.2.1.1.22][priorityNumber/@value
h	C-3	症例安全性報告の送信者に関する情報					
e	C.3.1	送信者の種類	1N	Coded With Equivalents (CE)	code=Character String (ST)	値	/MCC1_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCC1_IN200100UV01.xsd]/PDRR_IN049016UV1/controlActProcess[@classCode=CACT][@moodCode=EYN]/subjectOf1[@typeCode=SUBJ]/investigationEvent[@classCode=INVTG][@moodCode=EYN]/author[@typeCode=AUT]/assignedEntity[@classCode=ASSIGNED]/code/@codeSystem=2.16.840.1.113883.3.989.2.1.1.7][@code
e	C.3.2	送信者の組織	100AN	Organization Name (ON)	name=Entity Name Part (ENXP)	値	/MCC1_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCC1_IN200100UV01.xsd]/PDRR_IN049016UV1/controlActProcess[@classCode=CACT][@moodCode=EYN]/subjectOf1[@typeCode=SUBJ]/investigationEvent[@classCode=INVTG][@moodCode=EYN]/author[@typeCode=AUT]/assignedEntity[@classCode=ASSIGNED]/representedOrganization[@classCode=ORG][@determinerCode=INSTANCE]/assignedEntity[@classCode=ASSIGNED]/representedOrganization[@classCode=ORG][@determinerCode=INSTANCE]/name/text()
h	C.3.3	報告送信者の責任者					
e	C.3.3.1	送信者の部署	60AN	Organization Name (ON)	name=Entity Name Part (ENXP)	値	/MCC1_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCC1_IN200100UV01.xsd]/PDRR_IN049016UV1/controlActProcess[@classCode=CACT][@moodCode=EYN]/subjectOf1[@typeCode=SUBJ]/investigationEvent[@classCode=INVTG][@moodCode=EYN]/author[@typeCode=AUT]/assignedEntity[@classCode=ASSIGNED]/code/@codeSystem=2.16.840.1.113883.3.989.2.1.1.7][@code

(別添3)

e	C.3.3.2	送信者の職名	50AN	Person Name (PN)	prefix=Entity Name Part (ENXP)	値	/MCCJ_IN200100UV01[@ITSVersion='XML_1.0']/@xsi:schemaLocation='urn:hl7-org:v3 MCCJ_IN200100UV01.xsd'/P/PORR_IN049016UV/r/controlActProcess/@classCode=CACCT[@moodCode=EVN]/subject/@typeCode=SUBJ/ /investigationEvent/@classCode=INVTG[@moodCode=EVN]/subjectOr1/@typeCode=SUBJ/ /controlActEvent/assignedEntity/code/@codeSystemId=2.16.840.1.113883.3.989.2.1.1.7/ /controlActEvent/@classCode=CACCT[@moodCode=EVN]/author/@typeCode=AUT/assignedEntity/@classCode=ASSIGNED/assignedPerson/@classCode=PSN/ /@determinerCode=INSTANCE/ name/given[1]/text()
e	C.3.3.3	送信者の名前	60AN	Person Name (PN)	given=Entity Name Part (ENXP)	値	/MCCJ_IN200100UV01[@ITSVersion='XML_1.0']/@xsi:schemaLocation='urn:hl7-org:v3 MCCJ_IN200100UV01.xsd'/P/PORR_IN049016UV/r/controlActProcess/@classCode=CACCT[@moodCode=EVN]/subject/@typeCode=SUBJ/ /investigationEvent/@classCode=INVTG[@moodCode=EVN]/subjectOr1/@typeCode=SUBJ/ /controlActEvent/assignedEntity/code/@codeSystemId=2.16.840.1.113883.3.989.2.1.1.7/ /controlActEvent/@classCode=CACCT[@moodCode=EVN]/author/@typeCode=AUT/assignedEntity/@classCode=ASSIGNED/assignedPerson/@classCode=PSN/ /@determinerCode=INSTANCE/ name/given[1]/text()
e	C.3.3.4	送信者の中間名	60AN	Person Name (PN)	given=Entity Name Part (ENXP)	値	/MCCJ_IN200100UV01[@ITSVersion='XML_1.0']/@xsi:schemaLocation='urn:hl7-org:v3 MCCJ_IN200100UV01.xsd'/P/PORR_IN049016UV/r/controlActProcess/@classCode=CACCT[@moodCode=EVN]/subject/@typeCode=SUBJ/ /investigationEvent/@classCode=INVTG[@moodCode=EVN]/subjectOr1/@typeCode=SUBJ/ /controlActEvent/assignedEntity/code/@codeSystemId=2.16.840.1.113883.3.989.2.1.1.7/ /controlActEvent/@classCode=CACCT[@moodCode=EVN]/author/@typeCode=AUT/assignedEntity/@classCode=ASSIGNED/assignedPerson/@classCode=PSN/ /@determinerCode=INSTANCE/ name/given[2]/text()
e	C.3.3.5	送信者の姓	60AN	Person Name (PN)	family=Entity Name Part (ENXP)	値	/MCCJ_IN200100UV01[@ITSVersion='XML_1.0']/@xsi:schemaLocation='urn:hl7-org:v3 MCCJ_IN200100UV01.xsd'/P/PORR_IN049016UV/r/controlActProcess/@classCode=CACCT[@moodCode=EVN]/subject/@typeCode=SUBJ/ /investigationEvent/@classCode=INVTG[@moodCode=EVN]/subjectOr1/@typeCode=SUBJ/ /controlActEvent/assignedEntity/code/@codeSystemId=2.16.840.1.113883.3.989.2.1.1.7/ /controlActEvent/@classCode=CACCT[@moodCode=EVN]/author/@typeCode=AUT/assignedEntity/@classCode=ASSIGNED/assignedPerson/@classCode=PSN/ /@determinerCode=INSTANCE/ name/family[1]/text()
h	C.3.4	送信者の住所、FAX番号、電話番号及び電子メールアドレス					
e	C.3.4.1	送信者の住所 (番地)	100AN	Postal Address (AD)	streetAddressLine=Address Part (ADXP)	値	/MCCJ_IN200100UV01[@ITSVersion='XML_1.0']/@xsi:schemaLocation='urn:hl7-org:v3 MCCJ_IN200100UV01.xsd'/P/PORR_IN049016UV/r/controlActProcess/@classCode=CACCT[@moodCode=EVN]/subject/@typeCode=SUBJ/ /investigationEvent/@classCode=INVTG[@moodCode=EVN]/subjectOr1/@typeCode=SUBJ/ /controlActEvent/assignedEntity/code/@codeSystemId=2.16.840.1.113883.3.989.2.1.1.7/ /controlActEvent/@classCode=CACCT[@moodCode=EVN]/author/@typeCode=AUT/assignedEntity/@classCode=ASSIGNED/addr[1]/streetAddressLine[1]/text()
e	C.3.4.2	送信者の住所 (市町村特)	35AN	Postal Address (AD)	city=Address Part (ADXP)	値	/MCCJ_IN200100UV01[@ITSVersion='XML_1.0']/@xsi:schemaLocation='urn:hl7-org:v3 MCCJ_IN200100UV01.xsd'/P/PORR_IN049016UV/r/controlActProcess/@classCode=CACCT[@moodCode=EVN]/subject/@typeCode=SUBJ/ /investigationEvent/@classCode=INVTG[@moodCode=EVN]/subjectOr1/@typeCode=SUBJ/ /controlActEvent/assignedEntity/code/@codeSystemId=2.16.840.1.113883.3.989.2.1.1.7/ /controlActEvent/@classCode=CACCT[@moodCode=EVN]/author/@typeCode=AUT/assignedEntity/@classCode=ASSIGNED/addr[1]/city[1]/text()

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e	C.3.4.3	送信者の住所 (都道府県等)	40AN	Postal Address (AD)	state=Address Part (ADXP)	値	/MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UV1/controlActProcess[@classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUBJ][investigationEvent/@classCode=INVTG][@moodCode=EVN]/subjectOrI[@typeCode=SUBJ][controlActEvent/assignedEntity/code/@codeSystem=2.16.840.1.113883.3.989.2.1.1.7][controlActEvent/@classCode=CACT][@moodCode=EVN]/author[@typeCode=AUT]/assignedEntity[@addr1/state1/text]
e	C.3.4.4	送信者の住所 (郵便番号)	15AN	Postal Address (AD)	postalCode=Address Part (ADXP)	値	/MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UV1/controlActProcess[@classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUBJ][investigationEvent/@classCode=INVTG][@moodCode=EVN]/subjectOrI[@typeCode=SUBJ][controlActEvent/assignedEntity/code/@codeSystem=2.16.840.1.113883.3.989.2.1.1.7][controlActEvent/@classCode=CACT][@moodCode=EVN]/author[@typeCode=AUT]/assignedEntity[@addr1/postalCode1/text]
e	C.3.4.5	送信者の住所 (国コード)	2A	Concept Descriptor (CD)	code=Character String (ST)	値	/MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UV1/controlActProcess[@classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUBJ][investigationEvent/@classCode=INVTG][@moodCode=EVN]/subjectOrI[@typeCode=SUBJ][controlActEvent/assignedEntity/code/@codeSystem=2.16.840.1.113883.3.989.2.1.1.7][controlActEvent/@classCode=CACT][@moodCode=EVN]/author[@typeCode=AUT]/assignedEntity[@classCode=ASSIGNED]/person/@classCode=PSN[@determinerCode=INSTANCE]/asLocatedEntity[@classCode=LOCE][location/@classCode=COUNTRY][@determinerCode=INSTANCE]/code/@codeSystem=1.0.3166.1.2.2][code]
e	C.3.4.6	送信者の電話番号	33AN	Telecommunication Address (TEL)		値	substring(/MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UV1/controlActProcess[@classCode=CACT][@moodCode=EVN]/subjectOrI[@typeCode=SUBJ][controlActEvent/assignedEntity/code/@codeSystem=2.16.840.1.113883.3.989.2.1.1.7][controlActEvent/@classCode=CACT][@moodCode=EVN]/author[@typeCode=AUT]/assignedEntity[@classCode=ASSIGNED]/telecom[starts-with(@value,'tel:')]1/@value, 5)
e	C.3.4.7	送信者の FAX 番号	33AN	Telecommunication Address (TEL)		値	substring(/MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UV1/controlActProcess[@classCode=CACT][@moodCode=EVN]/subjectOrI[@typeCode=SUBJ][controlActEvent/assignedEntity/code/@codeSystem=2.16.840.1.113883.3.989.2.1.1.7][controlActEvent/@classCode=CACT][@moodCode=EVN]/author[@typeCode=AUT]/assignedEntity[@classCode=ASSIGNED]/telecom[starts-with(@value,'fax:')]1/@value, 5)
e	C.3.4.8	送信者の電子メールアドレス	100AN	Telecommunication Address (TEL)		値	substring(/MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UV1/controlActProcess[@classCode=CACT][@moodCode=EVN]/subjectOrI[@typeCode=SUBJ][investigationEvent/@classCode=INVTG][@moodCode=EVN]/subjectOrI[@typeCode=SUBJ][controlActEvent/assignedEntity/code/@codeSystem=2.16.840.1.113883.3.989.2.1.1.7][controlActEvent/@classCode=CACT][@moodCode=EVN]/author[@typeCode=AUT]/assignedEntity[@classCode=ASSIGNED]/telecom[starts-with(@value,'mailto:')]1/@value, 8)
h	C.4.r	引用文献 (必要に応じ繰り返す)				繰り返しの ノード	/MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UV1/controlActProcess[@classCode=CACT][@moodCode=EVN]/subjectOrI[@typeCode=SUBJ][investigationEvent/@classCode=INVTG][@moodCode=EVN]/reference[@typeCode=REFR][documentCode/@code=2][@codeSystem=2.16.840.1.1.113883.3.989.2.1.1.27]

e	C.4.r.1	引用文献	500AN	Encapsulated Data (ED)	値	<pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/PARR_IN049016UV/r/controlActProcess[@classCode=CACT][@moo dCode=EVN]/subject[@typeCode=SUBJ]/investigationEvent[@classCode=INVTG][@moodCo de=EVN]/reference[@typeCode=REFR][documentCode=2][@codeSystem=2.16.840.1.11 3883.3.989.2.1.1.27][document/@classCode=DOC][@moodCode=EVN]/bibliographicDesignati onText/text </pre>
e					NullFlavor	<pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/PARR_IN049016UV/r/controlActProcess[@classCode=CACT][@moo dCode=EVN]/subject[@typeCode=SUBJ]/investigationEvent[@classCode=INVTG][@moodCo de=EVN]/reference[@typeCode=REFR][documentCode=2][@codeSystem=2.16.840.1.11 3883.3.989.2.1.1.27][document/@classCode=DOC][@moodCode=EVN]/bibliographicDesignati onText/@nullFlavor </pre>
e	C.4.r.2	含まれる資料	N/A	Encapsulated Data (ED)	値	<pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/PARR_IN049016UV/r/controlActProcess[@classCode=CACT][@moo dCode=EVN]/subject[@typeCode=SUBJ]/investigationEvent[@classCode=INVTG][@moodCo de=EVN]/reference[@typeCode=REFR][documentCode=2][@codeSystem=2.16.840.1.11 3883.3.989.2.1.1.27][document/@classCode=DOC][@moodCode=EVN]/text </pre>
h	C.5	試験の識別				
h	C.5.1.r	試験の登録情報 (必要に応じ 繰り返す)			繰り返し コード	<pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/PARR_IN049016UV/r/investigationEvent[@classCode=CACT][@moo dCode=EVN]/component[@typeCode=COMP]/adverseEventAssessment[1]/adverseEventAssessment [@classCode=INVTG][@moodCode=EVN]/subject[1]/typeCode=SBJ[1]/primaryRole[1]/classC ode=INVSBJ/subjectOf[1]/typeCode=SBJ[1]/researchStudy[1]/researchStudy[@classCode=CLNTRL][@moodCo de=EVN]/authorization[1]/typeCode=AUTH[1] </pre>
e	C.5.1.r.1	試験の登録番号	50AN	Instance Identifier (I)	extension=Character String (ST)	<pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/PARR_IN049016UV/r/controlActProcess[@classCode=CACT][@moo dCode=EVN]/subject[@typeCode=SUBJ]/investigationEvent[@classCode=INVTG][@moodCo de=EVN]/component[@typeCode=COMP]/adverseEventAssessment[1]/adverseEventAssessment [@classCode=INVTG][@moodCode=EVN]/subject[1]/typeCode=SBJ[1]/primaryRole[1]/classC ode=INVSBJ/subjectOf[1]/typeCode=SBJ[1]/researchStudy[1]/researchStudy[@classCode=CLNTRL][@moodCo de=EVN]/authorization[1]/typeCode=AUTH[1]/studyRegistration[1]/extension </pre>
e					NullFlavor	<pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/PARR_IN049016UV/r/controlActProcess[@classCode=CACT][@moo dCode=EVN]/subject[@typeCode=SUBJ]/investigationEvent[@classCode=INVTG][@moodCo de=EVN]/component[@typeCode=COMP]/adverseEventAssessment[1]/adverseEventAssessment [@classCode=INVTG][@moodCode=EVN]/subject[1]/typeCode=SBJ[1]/primaryRole[1]/classC ode=INVSBJ/subjectOf[1]/typeCode=SBJ[1]/researchStudy[1]/researchStudy[@classCode=CLNTRL][@moodCo de=EVN]/authorization[1]/typeCode=AUTH[1]/studyRegistration[1]/classCode=ACT[1]/@nullFlavor </pre>

e	C.5.1.r.2	試験の登録国	2A	Concept Descriptor (CD)	code=Character String (ST)	値	<pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/PARR_IN049016UV/]/controlActProcess[@classCode=CACT][@moodCo de=EVN]/subject[@typeCode=SUBJ]/investigationEvent[@classCode=INVTG][@moodCo de=EVN]/component[@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment [@classCode=INVTG][@typeCode=EVN]/subject[1]/researchStudy[@classCode=CLNTRL][@moodCo de=EVN]/subjectOf[1]/typeCode=SBJ]/researchStudy[@classCode=ACT][@moodCode de=EVN]/author[1]/typeCode=AUT]/territorialAuthority[@classCode=TERR]/governingPlace[1]@class Code=COUNTRY][@determinerCode=INSTANCE]/code/@codeSystem=1.0.3.166.1.2.2/]]@code System=urn:hl7-org:v3 /MCCL_IN200100UV01.xsd]/PARR_IN049016UV/]/controlActProcess[@classCode=CACT][@moodCo de=EVN]/subject[@typeCode=SUBJ]/investigationEvent[@classCode=INVTG][@moodCo de=EVN]/component[@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment [@classCode=INVTG][@typeCode=EVN]/subject[1]/researchStudy[@classCode=CLNTRL][@moodCo de=EVN]/subjectOf[1]/typeCode=SBJ]/researchStudy[@classCode=ACT][@moodCode de=EVN]/author[1]/typeCode=AUT]/territorialAuthority[@classCode=TERR]/governingPlace[1]@class Code=COUNTRY][@determinerCode=INSTANCE]/code/@codeSystem=1.0.3.166.1.2.2/]]@nullFla vor </pre>
e				NullFlavor		NullFlavor	
e	C.5.2	試験名	2000AN	Character String (ST)		値	<pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/PARR_IN049016UV/]/controlActProcess[@classCode=CACT][@moodCo de=EVN]/subject[@typeCode=SUBJ]/investigationEvent[@classCode=INVTG][@moodCo de=EVN]/component[@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment [@classCode=INVTG][@typeCode=EVN]/subject[1]/researchStudy[@classCode=CLNTRL][@moodCo de=EVN]/subjectOf[1]/typeCode=SBJ]/researchStudy[@classCode=ACT][@moodCode de=EVN]/author[1]/typeCode=AUT]/territorialAuthority[@classCode=TERR]/governingPlace[1]@class Code=COUNTRY][@determinerCode=INSTANCE]/code/@codeSystem=1.0.3.166.1.2.2/]]@nullFla vor </pre>
e				NullFlavor		NullFlavor	
e	C.5.3	試験依頼者 (スポンサー) の 試験番号	50AN	Instance Identifier (I)	extension=Character String (ST)	値	<pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/PARR_IN049016UV/]/controlActProcess[@classCode=CACT][@moodCo de=EVN]/subject[@typeCode=SUBJ]/investigationEvent[@classCode=INVTG][@moodCo de=EVN]/component[@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment [@classCode=INVTG][@typeCode=EVN]/subject[1]/researchStudy[@classCode=CLNTRL][@moodCo de=EVN]/subjectOf[1]/typeCode=SBJ]/researchStudy[@classCode=ACT][@moodCode de=EVN]/author[1]/typeCode=AUT]/territorialAuthority[@classCode=TERR]/governingPlace[1]@class Code=COUNTRY][@determinerCode=INSTANCE]/code/@codeSystem=1.0.3.166.1.2.2/]]@extension </pre>
e				NullFlavor		NullFlavor	

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e	C.5.4	副作用 / 有害事象が観察された試験の種類	1N	Coded With Equivalents (CE)	code=Character String (ST)	値	/MCCLI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCLI_IN200100UV01.xsd]JPORR_IN049016UVU1[controlActProcess/@classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUBJ][investigationEvent/@classCode=INVTG][@moodCode=EVN]/component[@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment/@classCode=INVTG][@moodCode=EVN]/subject[1][@typeCode=SBJ][primaryRole/@classCode=INVSBJ]/subjectOr[1][@typeCode=SBJ][researchStudy/@classCode=CLNTRL][@moodCode=EVN][code/@codeSystem=2.16.840.1.113883.3.989.2.1.1.8][code]
h	D	患者特性					/MCCLI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCLI_IN200100UV01.xsd]JPORR_IN049016UVU1[controlActProcess/@classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUBJ][investigationEvent/@classCode=INVTG][@moodCode=EVN]/component[@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment/@classCode=INVTG][@moodCode=EVN]/subject[1][@typeCode=SBJ][primaryRole/@classCode=INVSBJ]/player[1][@classCode=PSN][determinerCode=INSTANCE]/name[1]/text()
e	D.1	患者 (名前又はイニシヤル)	60AN	Entity Name (EN)	name=Entity Name Part (ENXP)	値	/MCCLI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCLI_IN200100UV01.xsd]JPORR_IN049016UVU1[investigationEvent/@classCode=INVTG][@moodCode=EVN]/subject[@typeCode=SUBJ][adverseEventAssessment[1]/adverseEventAssessment/@classCode=INVTG][@moodCode=EVN]/subject[1][@typeCode=SBJ][primaryRole/@classCode=INVSBJ]/player[1][@classCode=PSN][determinerCode=INSTANCE]/name[1]/text()
e						NullFlavor	/MCCLI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCLI_IN200100UV01.xsd]JPORR_IN049016UVU1[controlActProcess/@classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUBJ][investigationEvent/@classCode=INVTG][@moodCode=EVN]/component[@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment/@classCode=INVTG][@moodCode=EVN]/subject[1][@typeCode=SBJ][primaryRole/@classCode=INVSBJ]/player[1][@classCode=PSN][determinerCode=INSTANCE]/name[1]/@nullFlavor
h	D.1.1	患者の診療記録番号及びその情報源 (記載が許可されている場合)					
e	D.1.1.1	患者の診療記録番号及びその情報源 (開業医診療記録番号)	20AN	Instance Identifier (II)	extension=Character String (ST)	値	/MCCLI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCLI_IN200100UV01.xsd]JPORR_IN049016UVU1[controlActProcess/@classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUBJ][investigationEvent/@classCode=INVTG][@moodCode=EVN]/component[@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment/@classCode=INVTG][@moodCode=EVN]/subject[1][@typeCode=SBJ][primaryRole/@classCode=INVSBJ]/player[1][@classCode=PSN][determinerCode=INSTANCE]/asIdentifierEntity[1][classCode=IDENT][code/@code=1][@codeSystem=2.16.840.1.113883.3.989.2.1.1.4][1]/id/@root=2.16.840.1.113883.3.989.2.1.3.7[1][1]/@extension
e						NullFlavor	/MCCLI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCLI_IN200100UV01.xsd]JPORR_IN049016UVU1[controlActProcess/@classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUBJ][investigationEvent/@classCode=INVTG][@moodCode=EVN]/component[@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment/@classCode=INVTG][@moodCode=EVN]/subject[1][@typeCode=SBJ][primaryRole/@classCode=INVSBJ]/player[1][@classCode=PSN][determinerCode=INSTANCE]/asIdentifierEntity[1][classCode=IDENT][code/@code=1][@codeSystem=2.16.840.1.113883.3.989.2.1.1.4][1]/id/@root=2.16.840.1.113883.3.989.2.1.3.7[1][1]/@nullFlavor

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e	D.1.1.2	患者の診療記録番号及びその情報源 (専門医診療記録番号)	20AN	Instance Identifier (II)	extension=Character String (ST)	値	<pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/PDRR_IN049016UVJ/controlActProcess[@classCode=CACT][@moo dCode=EVN]/subject[@typeCode=SUBJ][investigationEvent[@classCode=INVSIG][@moodCo de=EVN]/component[@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment [@classCode=INVSIG][@moodCode=EVN]/subject[@typeCode=SBJ][primaryRole[@classC ode=INVSBJ]/player1[@classCode=PSN][@determinerCode=INSTANCE]/asIdentifiedEntity[@cla ssCode=IDENT][code[@code=2][@codeSystem=2.16.840.1.1.13883.3.989.2.1.1.4][1]id[@root= 2.16.840.1.1.13883.3.989.2.1.3.8][1]@extension </pre>
e	D.1.1.3	患者の診療記録番号及びその情報源 (病院診療記録番号)	20AN	Instance Identifier (II)	extension=Character String (ST)	値	<pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/PDRR_IN049016UVJ/controlActProcess[@classCode=CACT][@moo dCode=EVN]/subject[@typeCode=SUBJ][investigationEvent[@classCode=INVSIG][@moodCo de=EVN]/component[@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment [@classCode=INVSIG][@moodCode=EVN]/subject[@typeCode=SBJ][primaryRole[@classC ode=INVSBJ]/player1[@classCode=PSN][@determinerCode=INSTANCE]/asIdentifiedEntity[@cla ssCode=IDENT][code[@code=2][@codeSystem=2.16.840.1.1.13883.3.989.2.1.1.4][1]id[@root= 2.16.840.1.1.13883.3.989.2.1.3.8][1]@nullFlavor </pre>
e	D.1.1.4	患者の診療記録番号及びその情報源 (試験) 中の患者識別番号	20AN	Instance Identifier (II)	extension=Character String (ST)	値	<pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/PDRR_IN049016UVJ/controlActProcess[@classCode=CACT][@moo dCode=EVN]/subject[@typeCode=SUBJ][investigationEvent[@classCode=INVSIG][@moodCo de=EVN]/component[@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment [@classCode=INVSIG][@moodCode=EVN]/subject[@typeCode=SBJ][primaryRole[@classC ode=INVSBJ]/player1[@classCode=PSN][@determinerCode=INSTANCE]/asIdentifiedEntity[@cla ssCode=IDENT][code[@code=3][@codeSystem=2.16.840.1.1.13883.3.989.2.1.1.4][1]id[@root= 2.16.840.1.1.13883.3.989.2.1.3.9][1]@nullFlavor </pre>
e	D.2	年齢情報				NullFlavor	<pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/PDRR_IN049016UVJ/controlActProcess[@classCode=CACT][@moo dCode=EVN]/subject[@typeCode=SUBJ][investigationEvent[@classCode=INVSIG][@moodCo de=EVN]/component[@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment [@classCode=INVSIG][@moodCode=EVN]/subject[@typeCode=SBJ][primaryRole[@classC ode=INVSBJ]/player1[@classCode=PSN][@determinerCode=INSTANCE]/asIdentifiedEntity[@cla ssCode=IDENT][code[@code=4][@codeSystem=2.16.840.1.1.13883.3.989.2.1.1.4][1]id[@root= 2.16.840.1.1.13883.3.989.2.1.3.10][1]@extension </pre>

(別添 3)

e	D.2.1	生年月日	日付/時間	Point in Time (TS)	値	<pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation="urn:hl7-org:v3 MCCL_IN200100UV01.xsd"/>PDRR_IN049016JVR/controlActProcess[@classCode=CACT][@moo dCode=EVN]/subject[@typeCode=SUBJ][investigationEvent[@classCode=INVESTG][@moodCo de=EVN]/component[@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment [@classCode=INVESTG][@moodCode=EVN]/subject1[@typeCode=SBJ][1]/primaryRole[@classC ode=INVSBJ]/subject1[@typeCode=PSN][determinerCode=INSTANCE]/birthTime/@value </pre>
e					Null Flavor	<pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation="urn:hl7-org:v3 MCCL_IN200100UV01.xsd"/>PDRR_IN049016JVR/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]/subject1[@typeCode=SBJ][1]/primaryRole[@classC ode=INVSBJ]/player1[@classCode=PSN][determinerCode=INSTANCE]/birthTime/@nullFlavor </pre>
h	D.2.2	副作用/有害事象発現時の 年齢				
e	D.2.2a	副作用/有害事象発現時の 年齢 (数)	5N	Physical Quantity (PQ)	値 value=Real Number (REAL)	<pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation="urn:hl7-org:v3 MCCL_IN200100UV01.xsd"/>PDRR_IN049016JVR/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]/subject1[@typeCode=SBJ][1]/primaryRole[@classC ode=INVSBJ]/subjectOf2[@typeCode=SBJ][observation/code/@code=3][@codeSystem=2.16.84 0.1.113883.3.989.2.1.1.19][1]/observation[@classCode=OBS][@moodCode=EVN]/value/@xsi:typ e=PQ[1]/@value </pre>
e	D.2.2b	副作用/有害事象発現時の 年齢 (単位)	50AN	Physical Quantity (PQ)	値 unit=Coded Simple Value (CS)	<pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation="urn:hl7-org:v3 MCCL_IN200100UV01.xsd"/>PDRR_IN049016JVR/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]/subject1[@typeCode=SBJ][1]/primaryRole[@classC ode=INVSBJ]/subjectOf2[@typeCode=SBJ][observation/code/@code=3][@codeSystem=2.16.84 0.1.113883.3.989.2.1.1.19][1]/observation[@classCode=OBS][@moodCode=EVN]/value/@xsi:typ e=PQ[1]/@unit </pre>
e	D.2.2.1a	胎児での副作用/有害事象 発現時の妊娠期間 (数)	3N	Physical Quantity (PQ)	値 value=Real Number (REAL)	<pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation="urn:hl7-org:v3 MCCL_IN200100UV01.xsd"/>PDRR_IN049016JVR/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]/subject1[@typeCode=SBJ][1]/primaryRole[@classC ode=INVSBJ]/subjectOf2[@typeCode=SBJ][observation/code/@code=16][@codeSystem=2.16.8 40.1.113883.3.989.2.1.1.19][1]/observation[@classCode=OBS][@moodCode=EVN]/value/@xsi:typ e=PQ[1]/@value </pre>
e	D.2.2.1b	胎児での副作用/有害事象 発現時の妊娠期間 (単位)	50AN	Physical Quantity (PQ)	値 unit=Coded Simple Value (CS)	<pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation="urn:hl7-org:v3 MCCL_IN200100UV01.xsd"/>PDRR_IN049016JVR/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]/subject1[@typeCode=SBJ][1]/primaryRole[@classC ode=INVSBJ]/subjectOf2[@typeCode=SBJ][observation/code/@code=16][@codeSystem=2.16.8 40.1.113883.3.989.2.1.1.19][1]/observation[@classCode=OBS][@moodCode=EVN]/value/@xsi:typ e=PQ[1]/@unit </pre>

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<p>e D.2.3</p> <p>患者の年齢群 (報告者の表現による)</p>	<p>1N</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']/PORR_IN049016UV1/controlActProcess[@classCode='CACT']/@moo dCode=EVN]/subject/@typeCode=SUBJ1/assessmentEvent[@classCode='INVESTG']/@moodCo de=EVN]/component/@typeCode=COMP1/adverseEventAssessment[1]/adverseEventAssessment [@classCode='INVESTG']/@moodCode=EVN]/subject1/@typeCode=SBJ1/primaryRole[@classC ode='INVSBJ']/subjectOf2/@typeCode=SBJ1/observation/code/@code=41/@codeSystem=2.16.84 0.1.113883.3.989.2.1.1.191/observation[@classCode='OBS']/@moodCode=EVN]/value/@xsi:typ e='CE'[@codeSystem=2.16.840.1.113883.3.989.2.1.1.91]/@value </pre>
<p>e D.3</p> <p>体重 (kg)</p>	<p>6N</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']/PORR_IN049016UV1/controlActProcess[@classCode='CACT']/@moo dCode=EVN]/subject/@typeCode=SUBJ1/assessmentEvent[@classCode='INVESTG']/@moodCo de=EVN]/component/@typeCode=COMP1/adverseEventAssessment[1]/adverseEventAssessment [@classCode='INVESTG']/@moodCode=EVN]/subject1/@typeCode=SBJ1/primaryRole[@classC ode='INVSBJ']/subjectOf2/@typeCode=SBJ1/observation/code/@code=71/@codeSystem=2.16.84 0.1.113883.3.989.2.1.1.191/observation[@classCode='OBS']/@moodCode=EVN]/value/@xsi:typ e='PQ'[@unit='kg']/@value </pre>
<p>e D.4</p> <p>身長 (cm)</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']/PORR_IN049016UV1/controlActProcess[@classCode='CACT']/@moo dCode=EVN]/subject/@typeCode=SUBJ1/assessmentEvent[@classCode='INVESTG']/@moodCo de=EVN]/component/@typeCode=COMP1/adverseEventAssessment[1]/adverseEventAssessment [@classCode='INVESTG']/@moodCode=EVN]/subject1/@typeCode=SBJ1/primaryRole[@classC ode='INVSBJ']/subjectOf2/@typeCode=SBJ1/observation/code/@code=41/@codeSystem=2.16.8 40.1.113883.3.989.2.1.1.191/observation[@classCode='OBS']/@moodCode=EVN]/value/@xsi:ty pe='PQ'[@unit='cm']/@value </pre>
<p>e D.5</p> <p>性別</p>	<p>1N</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']/PORR_IN049016UV1/controlActProcess[@classCode='CACT']/@moo dCode=EVN]/subject/@typeCode=SUBJ1/assessmentEvent[@classCode='INVESTG']/@moodCo de=EVN]/component/@typeCode=COMP1/adverseEventAssessment[1]/adverseEventAssessment [@classCode='INVESTG']/@moodCode=EVN]/subject1/@typeCode=SBJ1/primaryRole[@classC ode='INVSBJ']/player1[@classCode='PSN']/@determinerCode='INSTANCE'/administrativeGenderC ode[@codeSystem='1.0.5218']/@code </pre>
<p>e</p>			<p>NullFlavor</p>	
<p>e D.6</p> <p>最終月経日</p>	<p>日付/時間</p>	<p>Point in Time (TS)</p>	<p>値</p>	<p>値</p> <pre> /MCCL_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCL_IN200100UV01.xsd']/PORR_IN049016UV1/controlActProcess[@classCode='CACT']/@moo dCode=EVN]/subject/@typeCode=SUBJ1/assessmentEvent[@classCode='INVESTG']/@moodCo de=EVN]/component/@typeCode=COMP1/adverseEventAssessment[1]/adverseEventAssessment [@classCode='INVESTG']/@moodCode=EVN]/subject1/@typeCode=SBJ1/primaryRole[@classC ode='INVSBJ']/subjectOf2/@typeCode=SBJ1/observation/code/@code=221/@codeSystem=2.16.8 40.1.113883.3.989.2.1.1.191/observation[@classCode='OBS']/@moodCode=EVN]/value/@xsi:ty pe='TS'[@value </pre>

(別添 3)

e						NullFlavor	<pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 /MCCL_IN200100UV01.xsd]/PORR_IN049016UV[controlActProcess/@classCode=CACT][@moo dCode=EVN]/subject/@typeCode=SUBJ[1]/investigationEvent/@classCode=INVS[1][@moodCo de=EVN]/component/@typeCode=COMP[adverseEventAssessment[1]/adverseEventAssessment /@classCode=INVS[1][@moodCode=EVN]/subject/@typeCode=SBJ[1]/primaryRole/@classC ode=INVS[1]/subjectOr2/@typeCode=SBJ[observation/code/@code=2.16.840.1.113883.3.988.2.1.1.19][1]/observation/@classCode=OBS[1][@moodCode=EVN]/value/@xsi:ty pe=TS[1][@nullFlavor </pre>
h	D.7	関連する治療歴及び随伴症 状（副作用／有害事象を除 く）					<pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 /MCCL_IN200100UV01.xsd]/PORR_IN049016UV[controlActProcess/@classCode=CACT][@moo dCode=EVN]/subject/@typeCode=SUBJ[1]/investigationEvent/@classCode=INVS[1][@moodCo de=EVN]/component/@typeCode=COMP[adverseEventAssessment[1]/adverseEventAssessment /@classCode=INVS[1][@moodCode=EVN]/subject/@typeCode=SBJ[1]/primaryRole/@classC ode=INVS[1]/subjectOr2/@typeCode=SBJ[organizer/code/@code=1][@codeSystem=2.16.840.1 .113883.3.988.2.1.1.20][1]/organizer/@classCode=CATEGORY[1][@moodCode=EVN]/component[@typeCode=COMP[1]/observation/code/@codeSystem=2.16.840.1.113883.3.988.2.1.1.20][1] </pre>
h	D.7.1.r	関連する治療歴及び随伴症 状の構造化された情報（必要 に応じて繰り返し返す）		繰り返し返す ノード			<pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 /MCCL_IN200100UV01.xsd]/PORR_IN049016UV[controlActProcess/@classCode=CACT][@moo dCode=EVN]/subject/@typeCode=SUBJ[1]/investigationEvent/@classCode=INVS[1][@moodCo de=EVN]/component/@typeCode=COMP[adverseEventAssessment[1]/adverseEventAssessment /@classCode=INVS[1][@moodCode=EVN]/subject/@typeCode=SBJ[1]/primaryRole/@classC ode=INVS[1]/subjectOr2/@typeCode=SBJ[organizer/code/@code=1][@codeSystem=2.16.840.1 .113883.3.988.2.1.1.20][1]/organizer/@classCode=CATEGORY[1][@moodCode=EVN]/component[@typeCode=COMP[1]/observation/code/@codeSystem=2.16.840.1.113883.3.988.2.1.1.20][1] </pre>
e	D.7.1.r.1a	関連する治療歴及び随伴症 状の MedDRA パーシジョン	4AN	Concept Descriptor (CD)	codeSystemVersion= Character String (ST)	値	<pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 /MCCL_IN200100UV01.xsd]/PORR_IN049016UV[controlActProcess/@classCode=CACT][@moo dCode=EVN]/subject/@typeCode=SUBJ[1]/investigationEvent/@classCode=INVS[1][@moodCo de=EVN]/component/@typeCode=COMP[adverseEventAssessment[1]/adverseEventAssessment /@classCode=INVS[1][@moodCode=EVN]/subject/@typeCode=SBJ[1]/primaryRole/@classC ode=INVS[1]/subjectOr2/@typeCode=SBJ[organizer/code/@code=1][@codeSystem=2.16.840.1 .113883.3.988.2.1.1.20][1]/organizer/@classCode=CATEGORY[1][@moodCode=EVN]/component[@typeCode=COMP[1]/observation/code/@codeSystem=2.16.840.1.113883.3.988.2.1.1.20][1] </pre>
e	D.7.1.r.1b	関連する治療歴及び随伴症 状（疾病／手術処置／その 他）（MedDRA コード）	8N	Concept Descriptor (CD)	code=Character String (ST)	値	<pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 /MCCL_IN200100UV01.xsd]/PORR_IN049016UV[controlActProcess/@classCode=CACT][@moo dCode=EVN]/subject/@typeCode=SUBJ[1]/investigationEvent/@classCode=INVS[1][@moodCo de=EVN]/component/@typeCode=COMP[adverseEventAssessment[1]/adverseEventAssessment /@classCode=INVS[1][@moodCode=EVN]/subject/@typeCode=SBJ[1]/primaryRole/@classC ode=INVS[1]/subjectOr2/@typeCode=SBJ[organizer/code/@code=1][@codeSystem=2.16.840.1 .113883.3.988.2.1.1.20][1]/organizer/@classCode=CATEGORY[1][@moodCode=EVN]/component[@typeCode=COMP[1]/observation/code/@codeSystem=2.16.840.1.113883.3.988.2.1.1.20][1] </pre>
e	D.7.1.r.2	開始日	日付／時間	Interval of Point in Time (VL<TS>)	low=Interval Boundary (VXB)	値	<pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 /MCCL_IN200100UV01.xsd]/PORR_IN049016UV[controlActProcess/@classCode=CACT][@moo dCode=EVN]/subject/@typeCode=SUBJ[1]/investigationEvent/@classCode=INVS[1][@moodCo de=EVN]/component/@typeCode=COMP[adverseEventAssessment[1]/adverseEventAssessment /@classCode=INVS[1][@moodCode=EVN]/subject/@typeCode=SBJ[1]/primaryRole/@classC ode=INVS[1]/subjectOr2/@typeCode=SBJ[organizer/code/@code=1][@codeSystem=2.16.840.1 .113883.3.988.2.1.1.20][1]/organizer/@classCode=CATEGORY[1][@moodCode=EVN]/component[@typeCode=COMP[1]/observation/code/@codeSystem=2.16.840.1.113883.3.988.2.1.1.20][1] </pre>

(別添 3)

<p>e</p>	<p>Null Flavor</p>	<p>/MCCL_IN200100UV01[ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]PDRR_IN049016UV[controlActProcess][classCode=CACT][@moodCode=EVN]/subject[subject][typeCode=SUBJ][investigationEvent][classCode=INVTG][@moodCode=EVN]/component[component][typeCode=COMP][adverseEventAssessment][adverseEventAssessment][classCode=INVTG][@moodCode=EVN]/subject[subject][typeCode=SBJ][primaryRole][classCode=INVSBJ]/subjectO2[subjectO2][typeCode=SBJ]/organizer[organizer][@code=1][@codeSystem=2.16.840.1.113883.3.989.2.1.1.20][organizer][classCode=CATEGORY][@moodCode=EVN]/component[component][@code=13][@codeSystem=2.16.840.1.113883.3.989.2.1.1.19][observation][@classCode=OBS][@moodCode=EVN]/effectiveTime[time][xsi:type=IVL_TS][low][@nullFlavor]</p>	<p>値</p>
<p>e</p>	<p>Boolean (BL)</p>	<p>継続</p>	<p>値</p>
<p>e</p>	<p>Null Flavor</p>	<p>Interval of Point in Time (IVL<TS>)</p>	<p>値</p>
<p>e</p>	<p>高/時間境界 (VXB)</p>	<p>終了日</p>	<p>高/時間境界 (VXB)</p>
<p>e</p>	<p>Null Flavor</p>	<p>Interval of Point in Time (IVL<TS>)</p>	<p>値</p>

<p>e</p> <p>D.7.1.r.5</p> <p>備考</p> <p>2000AN</p> <p>Encapsulated Data (ED)</p>	<p>値</p>	<pre> /MCCL_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCL_IN200100UV01.xsd']/PDRR_IN049016UV1/controlActProcess/@classCode=CACTI][@moo dCode=EVN]/subject/@typeCode=SUBJ][1]/investigationEvent/@classCode=INVTG][@moodCo de=EVN]/component/@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment /@classCode=INVTG][@moodCode=EVN]/subject[1]/@typeCode=SBJ][1]/primaryRole/@classC ode=INVSBJ/subjectC2/@typeCode=SBJ][organizer/@code=1][@codeSystem=2.16.840.1 .113883.3.989.2.1.1.20][1]/organizer/@classCode=CATEGORY][@moodCode=EVN]/component[@typeCode=COMP][observation/@code=2.16.840.1.113883.6.163][1]/observation[classCode=OBS][@moodCode=EVN]/outboundRelationship2/@typeCode=COMP][observation/co de/@code=10][@codeSystem=2.16.840.1.113883.3.989.2.1.1.19][1]/observation/@classCode=O BS][@moodCode=EVN]/value[@xsi:type=ED][1]/text() </pre>
<p>e</p> <p>D.7.1.r.6</p> <p>家族歴</p> <p>ブール型</p> <p>Boolean (BL)</p>	<p>値</p>	<pre> /MCCL_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCL_IN200100UV01.xsd']/PDRR_IN049016UV1/controlActProcess/@classCode=CACTI][@moo dCode=EVN]/subject/@typeCode=SUBJ][1]/investigationEvent/@classCode=INVTG][@moodCo de=EVN]/component/@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment /@classCode=INVTG][@moodCode=EVN]/subject[1]/@typeCode=SBJ][1]/primaryRole/@classC ode=INVSBJ/subjectC2/@typeCode=SBJ][organizer/@code=1][@codeSystem=2.16.840.1 .113883.3.989.2.1.1.20][1]/organizer/@classCode=CATEGORY][@moodCode=EVN]/component[@typeCode=COMP][observation/@code=2.16.840.1.113883.6.163][1]/observation[classCode=OBS][@moodCode=EVN]/outboundRelationship2/@typeCode=EXPL][observation/co de/@code=38][@codeSystem=2.16.840.1.113883.3.989.2.1.1.19][1]/observation/@classCode=O BS][@moodCode=EVN]/value[@xsi:type=BL][1]/@value </pre>
<p>e</p> <p>D.7.2</p> <p>関連する治療歴及び副作用 状（副作用／有害事象を除 く）の記述情報</p> <p>10000AN</p> <p>Encapsulated Data (ED)</p>	<p>値</p>	<pre> /MCCL_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCL_IN200100UV01.xsd']/PDRR_IN049016UV1/controlActProcess/@classCode=CACTI][@moo dCode=EVN]/subject/@typeCode=SUBJ][1]/investigationEvent/@classCode=INVTG][@moodCo de=EVN]/component/@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment /@classCode=INVTG][@moodCode=EVN]/subject[1]/@typeCode=SBJ][1]/primaryRole/@classC ode=INVSBJ/subjectC2/@typeCode=SBJ][organizer/@code=1][@codeSystem=2.16.840.1 .113883.3.989.2.1.1.20][1]/organizer/@classCode=CATEGORY][@moodCode=EVN]/component[@typeCode=COMP][observation/@code=18][@codeSystem=2.16.840.1.113883.3.989.2.1.1 .19][1]/observation/@classCode=OBS][@moodCode=EVN]/value[@xsi:type=ED][1]/text() </pre>
<p>e</p> <p>D.7.3</p> <p>併用療法</p> <p>ブール型</p> <p>Boolean (BL)</p>	<p>値</p>	<pre> /MCCL_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCL_IN200100UV01.xsd']/PDRR_IN049016UV1/controlActProcess/@classCode=CACTI][@moo dCode=EVN]/subject/@typeCode=SUBJ][1]/investigationEvent/@classCode=INVTG][@moodCo de=EVN]/component/@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment /@classCode=INVTG][@moodCode=EVN]/subject[1]/@typeCode=SBJ][1]/primaryRole/@classC ode=INVSBJ/subjectC2/@typeCode=SBJ][organizer/@code=1][@codeSystem=2.16.840.1 .113883.3.989.2.1.1.20][1]/organizer/@classCode=CATEGORY][@moodCode=EVN]/component[@typeCode=COMP][observation/@code=18][@codeSystem=2.16.840.1.113883.3.989.2.1.1 .19][1]/observation/@classCode=OBS][@moodCode=EVN]/value[@xsi:type=ED][1]/@nullFlavor </pre>

(別添3)

h	D.8.f	関連する過去の医薬品使用歴 (必要に応じて繰り返す)		繰り返し ノード	/MCC1_IN200100UV01/@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCC1_IN200100UV01.xsd]/PORR_IN049016UV7/controlActProcess/@classCode=CACT][@moodCode=EVN]/subject/@typeCode=SUBJ][investigationEvent/@classCode=INVSVC][@moodCode=EVN]/component/@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment/@classCode=INVSVC][@typeCode=EVN]/subject1/@typeCode=SBJ][1/primaryRole/@classCode=INVSBJ]/subjectOr2/@typeCode=SBJ][organizer/code/@code=2][@codeSystem=2.16.840.1.113883.3.989.2.1.1.20][1/organizer/@classCode=CATEGORY][@moodCode=EVN]/component/@typeCode=COMP][substanceAdministration]
e	D.8.r.1	医薬品名 (報告された薬物)	250AN	Entity Name (EN)	name=Entity Name Part (ENXP) 値
e				Null Flavor	/MCC1_IN200100UV01/@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCC1_IN200100UV01.xsd]/PORR_IN049016UV7/controlActProcess/@classCode=CACT][@moodCode=EVN]/subject/@typeCode=SUBJ][investigationEvent/@classCode=INVSVC][@moodCode=EVN]/component/@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment/@classCode=INVSVC][@typeCode=EVN]/subject1/@typeCode=SBJ][1/primaryRole/@classCode=INVSBJ]/subjectOr2/@typeCode=SBJ][organizer/code/@code=2][@codeSystem=2.16.840.1.113883.3.989.2.1.1.20][1/organizer/@classCode=CATEGORY][@moodCode=EVN]/component/@typeCode=COMP][substanceAdministration][substanceAdministration/@classCode=SBADM][@moodCode=EVN]/consumable/@typeCode=CSM][1/instanceOfKind/@classCode=INST]/kindOfProduct/@classCode=MMA1][@determinerCode=KIND]/name[1]/text()
e	D.8.r.2a	MPID パージョン日付/番号	M5 ガイドを参照	Coded With Equivalents (CE)	codeSystemVersion=Character String (ST) 値
e	D.8.r.2b	医薬品製品識別子 (MPID)	M5 ガイドを参照	Coded With Equivalents (CE)	code=Character String (ST) 値

(別添 3)

<p>e</p> <p>D.8.r.3a</p> <p>PHPID パージョン日付／番号</p>	<p>M5 ガイド参照</p>	<p>Coded With Equivalents (CE)</p>	<p>code=SystemVersion Character String (ST)</p>	<p>値</p>	<pre>/MCCI_IN200100UV01[@ITSVersion='XML_1.0']/@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd'P/PORR_IN049076UVU/f/controlActProcess/@classCode='CACT'[@moo 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'[/subjectCz/@typeCode='SBJ'[/organizer/@code='2']/@codeSystem='2.16.840.1 113883.3.989.2.1.1.20']]/organizer/@classCode='CATEGORY'[@moodCode='EVN']/component /@typeCode='COMP'[/substanceAdministration[/substanceAdministration/@classCode='SBADM'] @moodCode='EVN']/consumable/@typeCode='CSM'[/instanceOfKind/@classCode='INST'[/kindO fProduct/@classCode='MMAT'[/determinerCode='KIND'/@codeSystem='TBD-PPID']/@cod eSystemVersion</pre>
<p>e</p> <p>D.8.r.3b</p> <p>製剤識別子 (PhPID)</p>	<p>M5 ガイド参照</p>	<p>Coded With Equivalents (CE)</p>	<p>code=Character String (ST)</p>	<p>値</p>	<pre>/MCCI_IN200100UV01[@ITSVersion='XML_1.0']/@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd'P/PORR_IN049076UVU/f/controlActProcess/@classCode='CACT'[@moo 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'[/subjectCz/@typeCode='SBJ'[/organizer/@code='2']/@codeSystem='2.16.840.1 113883.3.989.2.1.1.20']]/organizer/@classCode='CATEGORY'[@moodCode='EVN']/component /@typeCode='COMP'[/substanceAdministration[/substanceAdministration/@classCode='SBADM'] @moodCode='EVN']/consumable/@typeCode='CSM'[/instanceOfKind/@classCode='INST'[/kindO fProduct/@classCode='MMAT'[/determinerCode='KIND'/@codeSystem='TBD-PPID']/@cod eSystemVersion</pre>
<p>e</p> <p>D.8.r.4</p> <p>開始日</p>	<p>日付／時間</p>	<p>Interval of Point in Time (IVL<TS>)</p>	<p>low=Interval Boundary (IVXB)</p>	<p>値</p>	<pre>/MCCI_IN200100UV01[@ITSVersion='XML_1.0']/@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd'P/PORR_IN049076UVU/f/controlActProcess/@classCode='CACT'[@moo 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'[/subjectCz/@typeCode='SBJ'[/organizer/@code='2']/@codeSystem='2.16.840.1 113883.3.989.2.1.1.20']]/organizer/@classCode='CATEGORY'[@moodCode='EVN']/component /@typeCode='COMP'[/substanceAdministration[/substanceAdministration/@classCode='SBADM'] @moodCode='EVN']/effectiveTime/@xsi:type='IVL_TS'[/low/@value</pre>
<p>e</p>	<p>NullFlavor</p>	<p>NullFlavor</p>	<p>NullFlavor</p>	<p>値</p>	<pre>/MCCI_IN200100UV01[@ITSVersion='XML_1.0']/@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd'P/PORR_IN049076UVU/f/controlActProcess/@classCode='CACT'[@moo 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'[/subjectCz/@typeCode='SBJ'[/organizer/@code='2']/@codeSystem='2.16.840.1 113883.3.989.2.1.1.20']]/organizer/@classCode='CATEGORY'[@moodCode='EVN']/component /@typeCode='COMP'[/substanceAdministration[/substanceAdministration/@classCode='SBADM'] @moodCode='EVN']/effectiveTime/@xsi:type='IVL_TS'[/low/@value</pre>
<p>e</p> <p>D.8.r.5</p> <p>終了日</p>	<p>日付／時間</p>	<p>Interval of Point in Time (IVL<TS>)</p>	<p>high=Interval Boundary (IVXB)</p>	<p>値</p>	<pre>/MCCI_IN200100UV01[@ITSVersion='XML_1.0']/@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd'P/PORR_IN049076UVU/f/controlActProcess/@classCode='CACT'[@moo 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'[/subjectCz/@typeCode='SBJ'[/organizer/@code='2']/@codeSystem='2.16.840.1 113883.3.989.2.1.1.20']]/organizer/@classCode='CATEGORY'[@moodCode='EVN']/component /@typeCode='COMP'[/substanceAdministration[/substanceAdministration/@classCode='SBADM'] @moodCode='EVN']/effectiveTime/@xsi:type='IVL_TS'[/high/@value</pre>

(別添 3)

e				NullFlavor	<pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 /MCCL_IN200100UV01.xsd]/PORR_IN049016JVR/controlActProcess[@classCode=CACT][@moodCode=EVN]/component[@typeCode=SUBJ][@investigationEvent][@classCode=INVESTG][@moodCode=EVN]/component[@typeCode=COMP][@adverseEventAssessment][@adverseEventAssessmentCode=INVESTG][@moodCode=EVN]/subject1[@typeCode=SBJ][@primaryRole][@classCode=INVSBJ][@subjectOf2][@typeCode=SBJ][@organizerCode][@code=2][@codeSystem=2.16.840.1.113883.3.989.2.1.1.20][@organizer][@classCode=CATEGORY][@moodCode=EVN]/component[@typeCode=COMP][@substanceAdministration][@substanceAdministrationCode=SBADM][@moodCode=EVN]/effectiveTime[@xsi:type=IVL_TS][@high/@nullFlavor </pre>	
e	D.8.1.6a	使用理由の 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]/PORR_IN049016JVR/controlActProcess[@classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUBJ][@investigationEvent][@classCode=INVESTG][@moodCode=EVN]/component[@typeCode=COMP][@adverseEventAssessment][@adverseEventAssessmentCode=INVESTG][@moodCode=EVN]/subject1[@typeCode=SBJ][@primaryRole][@classCode=INVSBJ][@subjectOf2][@typeCode=SBJ][@organizerCode][@code=2][@codeSystem=2.16.840.1.113883.3.989.2.1.1.20][@organizer][@classCode=CATEGORY][@moodCode=EVN]/component[@typeCode=COMP][@substanceAdministration][@substanceAdministrationCode=SBADM][@moodCode=EVN]/outboundRelationship2[@typeCode=RSN][@observationCode][@code=19][@codeSystem=2.16.840.1.113883.3.989.2.1.1.19][@observation][@classCode=OBS][@moodCode=EVN]/value[@xsi:type=CE][@codeSystem=2.16.840.1.113883.6.163][@codeSystemVersion </pre>
e	D.8.1.6b	使用理由 (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]/PORR_IN049016JVR/controlActProcess[@classCode=CACT][@moodCode=EVN]/component[@typeCode=SUBJ][@investigationEvent][@classCode=INVESTG][@moodCode=EVN]/component[@typeCode=COMP][@adverseEventAssessment][@adverseEventAssessmentCode=INVESTG][@moodCode=EVN]/subject1[@typeCode=SBJ][@primaryRole][@classCode=INVSBJ][@subjectOf2][@typeCode=SBJ][@organizerCode][@code=2][@codeSystem=2.16.840.1.113883.3.989.2.1.1.20][@organizer][@classCode=CATEGORY][@moodCode=EVN]/component[@typeCode=COMP][@substanceAdministration][@substanceAdministrationCode=SBADM][@moodCode=EVN]/outboundRelationship2[@typeCode=RSN][@observationCode][@code=19][@codeSystem=2.16.840.1.113883.3.989.2.1.1.19][@observation][@classCode=OBS][@moodCode=EVN]/value[@xsi:type=CE][@codeSystem=2.16.840.1.113883.6.163][@codeSystemVersion </pre>
e	D.8.1.7a	副作用の 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]/PORR_IN049016JVR/controlActProcess[@classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUBJ][@investigationEvent][@classCode=INVESTG][@moodCode=EVN]/component[@typeCode=COMP][@adverseEventAssessment][@adverseEventAssessmentCode=INVESTG][@moodCode=EVN]/subject1[@typeCode=SBJ][@primaryRole][@classCode=INVSBJ][@subjectOf2][@typeCode=SBJ][@organizerCode][@code=2][@codeSystem=2.16.840.1.113883.3.989.2.1.1.20][@organizer][@classCode=CATEGORY][@moodCode=EVN]/component[@typeCode=COMP][@substanceAdministration][@substanceAdministrationCode=SBADM][@moodCode=EVN]/outboundRelationship2[@typeCode=CAUS][@observationCode][@code=29][@codeSystem=2.16.840.1.113883.3.989.2.1.1.19][@observation][@classCode=OBS][@moodCode=EVN]/value[@xsi:type=CE][@codeSystem=2.16.840.1.113883.6.163][@codeSystemVersion </pre>

(別添 3)

e	D.8.r.7b	副作用 (MedDRA コード)	8N	Coded With Equivalents (CE)	code=Character String (ST)	値	/MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3:MCCL_IN200100UV01.xsd]/PDRR_IN049016UV01/controlActProcess[@classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUBJ][@investigationEvent[@classCode=INVTG][@moodCode=EVN]/component[@typeCode=COMP][@adverseEventAssessment[@typeCode=SBJ][@primaryRoleAssessment[@classCode=INVSBJ][@typeCode=EVN]/subject[@code=2][@codeSystem=2.16.840.1.113883.3.989.2.1.1.2][@organizer[@classCode=CATEGOR][@moodCode=EVN]/component[@typeCode=COMP][@substanceAdministration[@typeCode=CAUS][@observationCode=29][@moodCode=EVN]/outboundRelationship[@typeCode=CAUS][@observationCode=OBS][@moodCode=EVN]/value[@xsi:type=CIE][@codeSystem=2.16.840.1.113883.6.163][@code
h	D.9	死亡の場合					/MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3:MCCL_IN200100UV01.xsd]/PDRR_IN049016UV01/controlActProcess[@classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUBJ][@investigationEvent[@classCode=INVTG][@moodCode=EVN]/component[@typeCode=COMP][@adverseEventAssessment[@typeCode=SBJ][@primaryRoleAssessment[@classCode=INVSBJ][@typeCode=EVN]/subject[@code=PSN][@determinerCode=INSTANCE][@value
e	D.9.1	死亡日	日付/時間	Point in Time (TS)		値	/MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3:MCCL_IN200100UV01.xsd]/PDRR_IN049016UV01/controlActProcess[@classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUBJ][@investigationEvent[@classCode=INVTG][@moodCode=EVN]/component[@typeCode=COMP][@adverseEventAssessment[@typeCode=SBJ][@primaryRoleAssessment[@classCode=INVSBJ][@typeCode=EVN]/subject[@code=PSN][@determinerCode=INSTANCE][@value
e						NullFlavor	/MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3:MCCL_IN200100UV01.xsd]/PDRR_IN049016UV01/controlActProcess[@classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUBJ][@investigationEvent[@classCode=INVTG][@moodCode=EVN]/component[@typeCode=COMP][@adverseEventAssessment[@typeCode=SBJ][@primaryRoleAssessment[@classCode=INVSBJ][@typeCode=EVN]/subject[@code=PSN][@determinerCode=INSTANCE][@value
h	D.9.2.r	報告された死因 (必要に応じ 繰り返す)				繰り返し コード	/MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3:MCCL_IN200100UV01.xsd]/PDRR_IN049016UV01/controlActProcess[@classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUBJ][@investigationEvent[@classCode=INVTG][@moodCode=EVN]/component[@typeCode=COMP][@adverseEventAssessment[@typeCode=SBJ][@primaryRoleAssessment[@classCode=INVSBJ][@typeCode=EVN]/subject[@code=PSN][@determinerCode=INSTANCE][@value
e	D.9.2.r.1a	報告された死因の ハージョン	4AN	Coded With Equivalents (CE)	code=SystemVersion=Character String (ST)	値	/MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3:MCCL_IN200100UV01.xsd]/PDRR_IN049016UV01/controlActProcess[@classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUBJ][@investigationEvent[@classCode=INVTG][@moodCode=EVN]/component[@typeCode=COMP][@adverseEventAssessment[@typeCode=SBJ][@primaryRoleAssessment[@classCode=INVSBJ][@typeCode=EVN]/subject[@code=PSN][@determinerCode=INSTANCE][@value
e	D.9.2.r.1b	報告された死因 (MedDRA コード)	8N	Coded With Equivalents (CE)	code=Character String (ST)	値	/MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3:MCCL_IN200100UV01.xsd]/PDRR_IN049016UV01/controlActProcess[@classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUBJ][@investigationEvent[@classCode=INVTG][@moodCode=EVN]/component[@typeCode=COMP][@adverseEventAssessment[@typeCode=SBJ][@primaryRoleAssessment[@classCode=INVSBJ][@typeCode=EVN]/subject[@code=PSN][@determinerCode=INSTANCE][@value

(別添 3)

e	D.9.2.r.2	報告された死因 (自由記載)	250AN	Coded With Equivalents (CE)	originalText = Encapsulated Data (ED)	値	/MCCL_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3:MCCL_IN200100UV01.xsd']/PORR_IN049016UV/r/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ']/investigationEvent[@classCode='INVTG'][@moodCode='EVN']/component[@typeCode='COMP']/adverseEventAssessment[1]/adverseEventAssessment[@classCode='INVTG'][@moodCode='EVN']/subject1[@typeCode='SBJ']/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ']/observation/code[@code='32'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19'][@codeSystem='2.16.840.1.113883.6.163']/originalText/text[1]
e	D.9.3	剖検は実施されたか?	ブール型	Boolean (BL)		値	/MCCL_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3:MCCL_IN200100UV01.xsd']/PORR_IN049016UV/r/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ']/investigationEvent[@classCode='INVTG'][@moodCode='EVN']/component[@typeCode='COMP']/adverseEventAssessment[1]/adverseEventAssessment[@classCode='INVTG'][@moodCode='EVN']/subject1[@typeCode='SBJ']/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ']/observation/code[@code='5'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19'][@codeSystem='2.16.840.1.113883.6.163']/value
e						NullFlavor	/MCCL_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3:MCCL_IN200100UV01.xsd']/PORR_IN049016UV/r/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ']/investigationEvent[@classCode='INVTG'][@moodCode='EVN']/component[@typeCode='COMP']/adverseEventAssessment[1]/adverseEventAssessment[@classCode='INVTG'][@moodCode='EVN']/subject1[@typeCode='SBJ']/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ']/observation/code[@code='5'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19'][@codeSystem='2.16.840.1.113883.6.163']/value
h	D.9.4.r	剖検による死因 (必要に応じ 繰り返す)				繰り返し ノード	/MCCL_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3:MCCL_IN200100UV01.xsd']/PORR_IN049016UV/r/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ']/investigationEvent[@classCode='INVTG'][@moodCode='EVN']/component[@typeCode='COMP']/adverseEventAssessment[1]/adverseEventAssessment[@classCode='INVTG'][@moodCode='EVN']/subject1[@typeCode='SBJ']/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ']/observation/code[@code='5'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19'][@codeSystem='2.16.840.1.113883.6.163']
e	D.9.4.r.1a	剖検による死因の MedDRA パージョン	4AN	Coded With Equivalents (CE)	codeSystemVersion = Character String (ST)	値	/MCCL_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3:MCCL_IN200100UV01.xsd']/PORR_IN049016UV/r/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ']/investigationEvent[@classCode='INVTG'][@moodCode='EVN']/component[@typeCode='COMP']/adverseEventAssessment[1]/adverseEventAssessment[@classCode='INVTG'][@moodCode='EVN']/subject1[@typeCode='SBJ']/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ']/observation/code[@code='5'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19'][@codeSystem='2.16.840.1.113883.6.163']

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e	D.9.4.r.1b	剖検による死因 (MedDRA コード)	8N	Coded With Equivalents (CE)	code=Character String (ST)	値	/MCCI_IN200100UV01@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]P/PORR_IN049016UV/f/controlActProcess/@classCode=CACT][@moodCode=EVN]/subject/@typeCode=SUBJ][f/investigationEvent/@classCode=INVTG][@moodCode=EVN]/component/@typeCode=COMP][adverseEventAssessment][f/adverseEventAssessment/@classCode=INVTG][@moodCode=EVN]/subject/@typeCode=EVN]/subject1/@typeCode=SBJ][f/primaryRole/@classCode=INVSBJ]/subject/@typeCode=SBJ][f/observation/@code=5][@codeSystem=2.16.84.0.1.113883.3.989.2.1.1.19][f/observation/@classCode=OBS][@moodCode=EVN]/outboundRelationship2/@typeCode=DRV1][f/observation/@code=8][@codeSystem=2.16.84.0.1.113883.3.989.2.1.1.19][f/observation/@classCode=OBS][@moodCode=EVN]/value/@xsi:type=CE][@codeSystem=2.16.84.0.1.113883.3.163][f]/code
e	D.9.4.r.2	剖検による死因 (自由記載)	250AN	Coded With Equivalents (CE)	originalText = Encapsulated Data (ED)	値	/MCCI_IN200100UV01@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]P/PORR_IN049016UV/f/controlActProcess/@classCode=CACT][@moodCode=EVN]/subject/@typeCode=SUBJ][f/investigationEvent/@classCode=INVTG][@moodCode=EVN]/component/@typeCode=COMP][adverseEventAssessment][f/adverseEventAssessment/@classCode=INVTG][@moodCode=EVN]/subject/@typeCode=SBJ][f/primaryRole/@classCode=INVSBJ]/subject/@typeCode=SBJ][f/observation/@code=5][@codeSystem=2.16.84.0.1.113883.3.989.2.1.1.19][f/observation/@classCode=OBS][@moodCode=EVN]/outboundRelationship2/@typeCode=DRV1][f/observation/@code=8][@codeSystem=2.16.84.0.1.113883.3.989.2.1.1.19][f/observation/@classCode=OBS][@moodCode=EVN]/value/@xsi:type=CE][@codeSystem=2.16.84.0.1.113883.3.163][f]/originalText/text()
h	D.10	親一子/胎児報告における、親に関する情報					
e	D.10.1	親の識別	60AN	Entity Name (EN)	name=Entity Name Part (ENXP)	値	/MCCI_IN200100UV01@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]P/PORR_IN049016UV/f/controlActProcess/@classCode=CACT][@moodCode=EVN]/subject/@typeCode=SUBJ][f/investigationEvent/@classCode=INVTG][@moodCode=EVN]/component/@typeCode=COMP][adverseEventAssessment][f/adverseEventAssessment/@classCode=INVTG][@moodCode=EVN]/subject/@typeCode=SBJ][f/primaryRole/@classCode=INVSBJ]/player1/@classCode=PSN][@determinerCode=INSTANCE]/role/@classCode=PR S][f]/associatedPerson/@classCode=PSN][@determinerCode=INSTANCE]/name[1]/text()
e						NullFlavor	/MCCI_IN200100UV01@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]P/PORR_IN049016UV/f/controlActProcess/@classCode=CACT][@moodCode=EVN]/subject/@typeCode=SUBJ][f/investigationEvent/@classCode=INVTG][@moodCode=EVN]/component/@typeCode=COMP][adverseEventAssessment][f/adverseEventAssessment/@classCode=INVTG][@moodCode=EVN]/subject/@typeCode=SBJ][f/primaryRole/@classCode=INVSBJ]/player1/@classCode=PSN][@determinerCode=INSTANCE]/role/@classCode=PR S][f]/associatedPerson/@classCode=PSN][@determinerCode=INSTANCE]/name[1]/nullFlavor
h	D.10.2	親の年齢情報					
e	D.10.2.1	親の生年月日	日付/時間	Point in Time (TS)		値	/MCCI_IN200100UV01@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]P/PORR_IN049016UV/f/controlActProcess/@classCode=CACT][@moodCode=EVN]/subject/@typeCode=SUBJ][f/investigationEvent/@classCode=INVTG][@moodCode=EVN]/component/@typeCode=COMP][adverseEventAssessment][f/adverseEventAssessment/@classCode=INVTG][@moodCode=EVN]/subject1/@typeCode=SBJ][f/primaryRole/@classCode=INVSBJ]/player1/@classCode=PSN][@determinerCode=INSTANCE]/birthTime/@value S][f]/associatedPerson/@classCode=PSN][@determinerCode=INSTANCE]/birthTime/@value

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e				NullFlavor	/MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]PARR_IN049016UVr/controlActProcess[classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUBJ][investigationEvent][@classCode=INVTG][@moodCode=EVN]/component[@typeCode=COMP][adverseEventAssessment][1]adverseEventAssessment[@classCode=INVTG][@moodCode=EVN]/subject[1]@typeCode=SBJ[1]primaryRole[classCode=INVSBJ]/player[1][@classCode=PSN][@determinerCode=INSTANCE]/role[classCode=PRST][associatePerson][@classCode=PSN][@determinerCode=INSTANCE]/birthTime[@nullFlavor]	
e	D.10.2.2a	親の年齢 (数)	3N	Physical Quantity (PQ)	value=Real Number (REAL)	/MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]PARR_IN049016UVr/controlActProcess[classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUBJ][investigationEvent][@classCode=INVTG][@moodCode=EVN]/component[@typeCode=COMP][adverseEventAssessment][1]adverseEventAssessment[@classCode=INVTG][@moodCode=EVN]/subject[1]@typeCode=SBJ[1]primaryRole[classCode=INVSBJ]/player[1][@classCode=PSN][@determinerCode=INSTANCE]/role[classCode=PRST][1]observation[@classCode=OBS][@moodCode=EVN]/value[@xsi:type=PQ][1]/@value
e	D.10.2.2b	親の年齢 (単位)	50AN	Physical Quantity (PQ)	unit=Coded Simple Value (CS)	/MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]PARR_IN049016UVr/controlActProcess[classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUBJ][investigationEvent][@classCode=INVTG][@moodCode=EVN]/component[@typeCode=COMP][adverseEventAssessment][1]adverseEventAssessment[@classCode=INVTG][@moodCode=EVN]/subject[1]@typeCode=SBJ[1]primaryRole[classCode=INVSBJ]/player[1][@classCode=PSN][@determinerCode=INSTANCE]/role[classCode=PRST][1]observation[@classCode=OBS][@code=3][@codeSystem=2,16,840,1,11388,3,3,989,2,1,1,19][1]observation[@classCode=OBS][@moodCode=EVN]/value[@xsi:type=PQ][1]/@unit
e	D.10.3	親の最終月経日	日付/時間	Point in Time (TS)	値	/MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]PARR_IN049016UVr/controlActProcess[classCode=CACT][@moodCode=EVN]/component[@typeCode=SUBJ][investigationEvent][@classCode=INVTG][@moodCode=EVN]/subject[1]@typeCode=SBJ[1]primaryRole[classCode=INVSBJ]/player[1][@classCode=PSN][@determinerCode=INSTANCE]/role[classCode=PRST][1]observation[@classCode=OBS][@code=22][@codeSystem=2,16,840,1,11388,3,3,989,2,1,1,19][1]observation[@classCode=OBS][@moodCode=EVN]/value[@xsi:type=TS][1]/@value
e				NullFlavor	/MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]PARR_IN049016UVr/controlActProcess[classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUBJ][investigationEvent][@classCode=INVTG][@moodCode=EVN]/component[@typeCode=COMP][adverseEventAssessment][1]adverseEventAssessment[@classCode=INVTG][@moodCode=EVN]/subject[1]@typeCode=SBJ[1]primaryRole[classCode=INVSBJ]/player[1][@classCode=PSN][@determinerCode=INSTANCE]/role[classCode=PRST][1]observation[@classCode=OBS][@code=22][@codeSystem=2,16,840,1,11388,3,3,989,2,1,1,19][1]observation[@classCode=OBS][@moodCode=EVN]/value[@xsi:type=TS][1]/@nullFlavor	

e	D.10.4	親の体重 (kg)	6N	Physical Quantity (PQ)	value=Real Number (REAL)	値	/MCC1_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3-MCC1_IN200100UV01.xsd]/PORR_IN049016UV1/controlActProcess[@classCode=CACT][@moodCode=EVN]/component[@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment[@classCode=INVESTG][@typeCode=SBJ][1]/primaryRole[@classCode=PR ST][1]/subjectOf2[@typeCode=SBJ][observationCode=INSTANCE][role[@classCode=PR ST][1]/subjectOf2[1]]/observationCode[@code=7][@codeSystem=2.16.840.1.113883.3.989.2.1.1.19][1]/observationCode[@classCode=OBS][@moodCode=EVN][value[@xsi:type=PQ][@unit=kg][1]]/@value
e	D.10.5	親の身長 (cm)	3N	Physical Quantity (PQ)	value=Real Number (REAL)	値	/MCC1_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3-MCC1_IN200100UV01.xsd]/PORR_IN049016UV1/controlActProcess[@classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUBJ][1]/investigationEvent[@classCode=INVESTG][@moodCode=EVN]/component[@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment[@classCode=INVESTG][@typeCode=SBJ][1]/primaryRole[@classCode=PR ST][1]/subjectOf2[1]]/observationCode[@code=17][@codeSystem=2.16.840.1.113883.3.989.2.1.1.19][1]/observationCode[@classCode=OBS][@moodCode=EVN][value[@xsi:type=PQ][@unit=cm][1]]/@value
e	D.10.6	親の性別	1N	Coded With Equivalents (CE)	code=Character String (ST)	値	/MCC1_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3-MCC1_IN200100UV01.xsd]/PORR_IN049016UV1/controlActProcess[@classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUBJ][1]/investigationEvent[@classCode=INVESTG][@moodCode=EVN]/component[@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment[@classCode=INVESTG][@typeCode=SBJ][1]/primaryRole[@classCode=PR ST][1]/associatedPerson[@classCode=PSN][@determinerCode=INSTANCE][role[@classCode=PR ST][1]/associatedPerson[1]]/observationCode[@code=17][@codeSystem=2.16.840.1.113883.3.989.2.1.1.19][1]/observationCode[@classCode=OBS][@moodCode=EVN][value[@xsi:type=PQ][@unit=cm][1]]/@value
e					NullFlavor		/MCC1_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3-MCC1_IN200100UV01.xsd]/PORR_IN049016UV1/controlActProcess[@classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUBJ][1]/investigationEvent[@classCode=INVESTG][@moodCode=EVN]/component[@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment[@classCode=INVESTG][@typeCode=SBJ][1]/primaryRole[@classCode=PR ST][1]/associatedPerson[@classCode=PSN][@determinerCode=INSTANCE][role[@classCode=PR ST][1]/associatedPerson[1]]/observationCode[@code=17][@codeSystem=2.16.840.1.113883.3.989.2.1.1.19][1]/observationCode[@classCode=OBS][@moodCode=EVN][value[@xsi:type=PQ][@unit=cm][1]]/@value
h	D.10.7	親の関連する治療歴及び随伴症状					
h	D.10.7.1.r	親の構造化された情報 (必要に依り繰り返し)				繰り返しノード	/MCC1_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3-MCC1_IN200100UV01.xsd]/PORR_IN049016UV1/controlActProcess[@classCode=CACT][@moodCode=EVN]/component[@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment[@classCode=INVESTG][@typeCode=SBJ][1]/primaryRole[@classCode=PR ST][1]/subjectOf2[1]]/observationCode[@code=1][@codeSystem=2.16.840.1.113883.3.989.2.1.1.20][1]/organizer[@classCode=CATEGORY][@moodCode=EVN]/component[@typeCode=COMP][observationCode[@classCode=OBS][@codeSystem=2.16.840.1.113883.6.163]]

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e	D.10.7.1.r.1a	親の関連する治療歴及び随伴症状の MedDRA パージョン	4AN	Concept Descriptor (CD)	code=SystemVersion=Character String (ST)	/MCCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3:MCCCL_IN200100UV01.xsd]/PQRR_IN049016UVJr/controlActProcess[@classCode=CACT][@moodCode=EVN]/component[@typeCode=COMP]/adverseEventAssessment[1]/adverseEventAssessment[@classCode=INVSCTG][@moodCode=EVN]/subject[1]/typeCode=SB.J[1]/primaryRole[@classCode=INVSBJ]/player1[@classCode=PSN][@determinerCode=INSTANCE]/role[@classCode=PR.3.989.2.1.1.20][1]/organizer[@classCode=CATEGORY][@moodCode=EVN]/component[@typeCode=COMP][@codeSystem=2.16.840.1.1.13883.6.163][r/observation/@classCode=OBS][@moodCode=EVN]/code/@codeSystemVersion
e	D.10.7.1.r.1b	親の関連する治療歴及び随伴症状 (疾病 / 手術処置 / その他) (MedDRA コード)	8N	Concept Descriptor (CD)	code=Character String (ST)	/MCCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3:MCCCL_IN200100UV01.xsd]/PQRR_IN049016UVJr/controlActProcess[@classCode=CACT][@moodCode=EVN]/component[@typeCode=SUBJ][1]/investigationEvent[1]/adverseEventAssessment[1]/adverseEventAssessment[@classCode=INVSCTG][@moodCode=EVN]/subject[1]/typeCode=EVN/subject[1]/typeCode=SB.J[1]/primaryRole[@classCode=INVSBJ]/player1[@classCode=PSN][@determinerCode=INSTANCE]/role[@classCode=PR.SI][1]/subjectOrZ1[@typeCode=SB.J][organizer/@code=1][@codeSystem=2.16.840.1.1.13883.3.989.2.1.1.20][1]/organizer[@classCode=CATEGORY][@moodCode=EVN]/component[@typeCode=COMP][@codeSystem=2.16.840.1.1.13883.6.163][r/observation/@classCode=OBS][@moodCode=EVN]/code/@code
e	D.10.7.1.r.2	開始日	日付 / 時間	Interval of Point in Time (IVL<TS>)	low=Interval Boundary (VXB)	/MCCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3:MCCCL_IN200100UV01.xsd]/PQRR_IN049016UVJr/controlActProcess[@classCode=CACT][@moodCode=EVN]/component[@typeCode=SUBJ][1]/investigationEvent[1]/adverseEventAssessment[1]/adverseEventAssessment[@classCode=INVSCTG][@moodCode=EVN]/subject[1]/typeCode=EVN/subject[1]/typeCode=SB.J[1]/primaryRole[@classCode=INVSBJ]/player1[@classCode=PSN][@determinerCode=INSTANCE]/role[@classCode=PR.SI][1]/subjectOrZ1[@typeCode=SB.J][organizer/@code=1][@codeSystem=2.16.840.1.1.13883.3.989.2.1.1.20][1]/organizer[@classCode=CATEGORY][@moodCode=EVN]/component[@typeCode=COMP][@codeSystem=2.16.840.1.1.13883.6.163][r/observation/@classCode=OBS][@moodCode=EVN]/effectiveTime[@xsi:type=IVL_TS]/low/@value
e				Null Flavor		/MCCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3:MCCCL_IN200100UV01.xsd]/PQRR_IN049016UVJr/controlActProcess[@classCode=CACT][@moodCode=EVN]/component[@typeCode=SUBJ][1]/investigationEvent[1]/adverseEventAssessment[1]/adverseEventAssessment[@classCode=INVSCTG][@moodCode=EVN]/subject[1]/typeCode=EVN/subject[1]/typeCode=SB.J[1]/primaryRole[@classCode=INVSBJ]/player1[@classCode=PSN][@determinerCode=INSTANCE]/role[@classCode=PR.SI][1]/subjectOrZ1[@typeCode=SB.J][organizer/@code=1][@codeSystem=2.16.840.1.1.13883.3.989.2.1.1.20][1]/organizer[@classCode=CATEGORY][@moodCode=EVN]/component[@typeCode=COMP][@codeSystem=2.16.840.1.1.13883.6.163][r/observation/@classCode=OBS][@moodCode=EVN]/effectiveTime[@xsi:type=IVL_TS]/low/@nullFlavor

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<p>e</p> <p>D.10.7.1.r.3</p> <p>継続</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_IN049016UV/]/controlActProcess/@classCode=CACT][@moodCo dCode=EVN]/subject/@typeCode=SUBJ][1]/investigationEvent/@classCode=INVTG][@moodCo de=EVN]/component/@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment [@classCode=INVTG][@moodCode=EVN]/subject[1]/typeCode=SBJ][1]/primaryRole/@classC ode=INVSBJ/primaryRole/@classCode=PSN][@determinerCode=INSTANCE/role/@classCode=PR 3.989.2.1.1.20][1]/organizer/@classCode=CATEGORY][@moodCode=EVN]/component/@typeC ode=COMP][observation/@code/@codeSystem=2.16.840.1.113883.6.163][1]/observation/@classCo de=OBS][@moodCode=EVN]/inboundRelationship/@typeCode=REFR][observation/@code/ @codeSystem=2.16.840.1.113883.3.989.2.1.1.19][1]/observation/@classCode=OBS][@mo odCode=EVN]/value/@xsi:type=BL][1]/@value </pre>	<p>値</p>	<p>Interval of Point in Time (VL<TS>)</p> <p>high=interval Boundary (VXB)</p>	<p>値</p>	<pre> /MCCI_IN200100UV01/@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PDRR_IN049016UV/]/controlActProcess/@classCode=CACT][@moodCo dCode=EVN]/subject/@typeCode=SUBJ][1]/investigationEvent/@classCode=INVTG][@moodCo de=EVN]/component/@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment [@classCode=INVTG][@moodCode=EVN]/subject[1]/typeCode=SBJ][1]/primaryRole/@classC ode=INVSBJ/primaryRole/@classCode=PSN][@determinerCode=INSTANCE/role/@classCode=PR 3.989.2.1.1.20][1]/organizer/@classCode=CATEGORY][@moodCode=EVN]/component/@typeC ode=COMP][observation/@code/@codeSystem=2.16.840.1.113883.6.163][1]/observation/@typeC ode=OBS][@moodCode=EVN]/effectiveTime/@xsi:type=IVL_TS][1]/high/@value </pre>
<p>e</p> <p>D.10.7.1.r.4</p> <p>終了日</p> <p>日付/時間</p> <p>Interval of Point in Time (VL<TS>)</p> <p>high=interval Boundary (VXB)</p> <p>Null Flavor</p>	<pre> /MCCI_IN200100UV01/@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PDRR_IN049016UV/]/controlActProcess/@classCode=CACT][@moodCo dCode=EVN]/subject/@typeCode=SUBJ][1]/investigationEvent/@classCode=INVTG][@moodCo de=EVN]/component/@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment [@classCode=INVTG][@moodCode=EVN]/subject[1]/typeCode=SBJ][1]/primaryRole/@classC ode=INVSBJ/primaryRole/@classCode=PSN][@determinerCode=INSTANCE/role/@classCode=PR 3.989.2.1.1.20][1]/organizer/@classCode=CATEGORY][@moodCode=EVN]/component/@typeC ode=COMP][observation/@code/@codeSystem=2.16.840.1.113883.6.163][1]/observation/@typeC ode=OBS][@moodCode=EVN]/effectiveTime/@xsi:type=IVL_TS][1]/high/@value </pre>	<p>値</p>	<p>Interval of Point in Time (VL<TS>)</p> <p>high=interval Boundary (VXB)</p>	<p>Null Flavor</p>	<pre> /MCCI_IN200100UV01/@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PDRR_IN049016UV/]/controlActProcess/@classCode=CACT][@moodCo dCode=EVN]/subject/@typeCode=SUBJ][1]/investigationEvent/@classCode=INVTG][@moodCo de=EVN]/component/@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment [@classCode=INVTG][@moodCode=EVN]/subject[1]/typeCode=SBJ][1]/primaryRole/@classC ode=INVSBJ/primaryRole/@classCode=PSN][@determinerCode=INSTANCE/role/@classCode=PR 3.989.2.1.1.20][1]/organizer/@classCode=CATEGORY][@moodCode=EVN]/component/@typeC ode=COMP][observation/@code/@codeSystem=2.16.840.1.113883.6.163][1]/observation/@typeC ode=OBS][@moodCode=EVN]/effectiveTime/@xsi:type=IVL_TS][1]/high/@value </pre>
<p>e</p> <p>D.10.7.1.r.5</p> <p>備考</p> <p>2000AN</p> <p>Encapsulated Data (ED)</p> <p>値</p>	<pre> /MCCI_IN200100UV01/@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PDRR_IN049016UV/]/controlActProcess/@classCode=CACT][@moodCo dCode=EVN]/subject/@typeCode=SUBJ][1]/investigationEvent/@classCode=INVTG][@moodCo de=EVN]/component/@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment [@classCode=INVTG][@moodCode=EVN]/subject[1]/typeCode=SBJ][1]/primaryRole/@classC ode=INVSBJ/primaryRole/@classCode=PSN][@determinerCode=INSTANCE/role/@classCode=PR 3.989.2.1.1.20][1]/organizer/@classCode=CATEGORY][@moodCode=EVN]/component/@typeC ode=COMP][observation/@code/@codeSystem=2.16.840.1.113883.6.163][1]/observation/@typeC ode=OBS][@moodCode=EVN]/effectiveTime/@xsi:type=IVL_TS][1]/high/@value </pre>	<p>値</p>	<p>Encapsulated Data (ED)</p>	<p>2000AN</p>	<pre> /MCCI_IN200100UV01/@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PDRR_IN049016UV/]/controlActProcess/@classCode=CACT][@moodCo dCode=EVN]/subject/@typeCode=SUBJ][1]/investigationEvent/@classCode=INVTG][@moodCo de=EVN]/component/@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment [@classCode=INVTG][@moodCode=EVN]/subject[1]/typeCode=SBJ][1]/primaryRole/@classC ode=INVSBJ/primaryRole/@classCode=PSN][@determinerCode=INSTANCE/role/@classCode=PR 3.989.2.1.1.20][1]/organizer/@classCode=CATEGORY][@moodCode=EVN]/component/@typeC ode=COMP][observation/@code/@codeSystem=2.16.840.1.113883.6.163][1]/observation/@typeC ode=OBS][@moodCode=EVN]/effectiveTime/@xsi:type=IVL_TS][1]/high/@value </pre>

(別添3)

<p>e</p> <p>D.10.7.2</p> <p>親の関連する治療歴及び随 伴症状の記述情報</p> <p>10000AN</p> <p>Encapsulated Data (ED)</p> <p>値</p>	<pre> /MCCL_IN200100UV01[ITSVersion=XML_1.0][xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]PARR_IN049016UV[controlActProcess/@classCode=CACT][@moo dCode=EVN]/subject/@typeCode=SUBJ[1]investigationEvent[1]adverseEventAssessment de=EVN]/component/@typeCode=COMP[1]adverseEventAssessment[1]adverseEventAssessment [1]classCode=INVSTG[1]moodCode=EVN]/subject1[1]typeCode=SBJ[1]primaryRole[1]classC ode=INVSB[1]player1[1]classCode=PSN[1]determinerCode=INSTANCE[1]role[1]classCode=PR S[1]subjectO2[1]typeCode=SBJ[1]organizer/code[1]code=1[1]codeSystem=2.16.840.1.1.13888. 3.989.2.1.1.20[1]organizer/@classCode=CATEGORY[1]moodCode=EVN]/component/@typeC ode=COMP[1]observation/code[1]code=18[1]codeSystem=2.16.840.1.1.13888.3.989.2.1.1.19[1] observation/@classCode=OBS[1]@moodCode=EVN]/value[1]type=ED[1]text() </pre>
<p>h</p> <p>D.10.8.r</p> <p>親の関連する過去の医薬品 使用歴 (必要に応じて繰り返 す)</p> <p>250AN</p> <p>Entity Name (EN)</p> <p>name=Entity Name Part (ENXP)</p> <p>値</p>	<pre> /MCCL_IN200100UV01[ITSVersion=XML_1.0][xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]PARR_IN049016UV[controlActProcess/@classCode=CACT][@moo dCode=EVN]/subject/@typeCode=SUBJ[1]investigationEvent[1]adverseEventAssessment de=EVN]/component/@typeCode=COMP[1]adverseEventAssessment[1]adverseEventAssessment [1]classCode=INVSTG[1]moodCode=EVN]/subject1[1]typeCode=SBJ[1]primaryRole[1]classC ode=INVSB[1]player1[1]classCode=PSN[1]determinerCode=INSTANCE[1]role[1]classCode=PR S[1]subjectO2[1]typeCode=SBJ[1]organizer/code[1]code=2[1]codeSystem=2.16.840.1.1.13888. 3.989.2.1.1.20[1]organizer/@classCode=CATEGORY[1]moodCode=EVN]/component/@typeC ode=COMP[1]substanceAdministration </pre>
<p>e</p> <p>D.10.8.r.1</p> <p>医薬品名 (報告された表現)</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> /MCCL_IN200100UV01[ITSVersion=XML_1.0][xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]PARR_IN049016UV[controlActProcess/@classCode=CACT][@moo dCode=EVN]/subject/@typeCode=SUBJ[1]investigationEvent[1]adverseEventAssessment de=EVN]/component/@typeCode=COMP[1]adverseEventAssessment[1]adverseEventAssessment [1]classCode=INVSTG[1]moodCode=EVN]/subject1[1]typeCode=SBJ[1]primaryRole[1]classC ode=INVSB[1]player1[1]classCode=PSN[1]determinerCode=INSTANCE[1]role[1]classCode=PR S[1]subjectO2[1]typeCode=SBJ[1]organizer/code[1]code=2[1]codeSystem=2.16.840.1.1.13888. 3.989.2.1.1.20[1]organizer/@classCode=CATEGORY[1]moodCode=EVN]/component/@typeC ode=COMP[1]substanceAdministration[1]instanceOfKind[1]classCode=INST[1]kindOfProduc t[1]classCode=MMA[1]@determinerCode=KIND[1]text() </pre>
<p>e</p> <p>D.10.8.r.2a</p> <p>MPID パージョン日付/番号</p> <p>codeSystemVersion= Character String (ST)</p> <p>値</p>	<pre> /MCCL_IN200100UV01[ITSVersion=XML_1.0][xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]PARR_IN049016UV[controlActProcess/@classCode=CACT][@moo dCode=EVN]/subject/@typeCode=SUBJ[1]investigationEvent[1]adverseEventAssessment de=EVN]/component/@typeCode=COMP[1]adverseEventAssessment[1]adverseEventAssessment [1]classCode=INVSTG[1]moodCode=EVN]/subject1[1]typeCode=SBJ[1]primaryRole[1]classC ode=INVSB[1]player1[1]classCode=PSN[1]determinerCode=INSTANCE[1]role[1]classCode=PR S[1]subjectO2[1]typeCode=SBJ[1]organizer/code[1]code=2[1]codeSystem=2.16.840.1.1.13888. 3.989.2.1.1.20[1]organizer/@classCode=CATEGORY[1]moodCode=EVN]/component/@typeC ode=COMP[1]substanceAdministration[1]instanceOfKind[1]classCode=INST[1]kindOfProduc t[1]classCode=MMA[1]@determinerCode=KIND[1]instanceOfKind[1]codeSystem=TBD-MPID[1]@codeSyste mVersion </pre>

<p>e</p> <p>D.10.8.r.2b</p> <p>医薬品製品識別子 (MPID)</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]/PDRR_IN049016UV1/controlActProcess/@classCode=CACT][@moodCo dCode=EVN]/subject/@typeCode=SUBJ][investigationEvent/@classCode=INVTG][@moodCo de=EVN]/component/@typeCode=COMP][adverseEventAssessment][adverseEventAssessment /@classCode=INVTG][@moodCode=EVN]/subject[1]/typeCode=SBJ][primaryRole/@class code=INVSBJ]/player[1]/classCode=PSN][determinerCode=INSTANCE]/role/@classCode=PR S][subjectOf2/@typeCode=SBJ]/organizer/@code=2][@codeSystem=2.16.840.1.113883. 3.989.2.1.1.20][organizer/@classCode=CATEGORY][@moodCode=EVN]/component/@typeC ode=COMP][substanceAdministration][substanceAdministration/@classCode=SBADM][@mood code=EVN]/consumable/@typeCode=CSM][instanceOfKind/@classCode=INST]/kindOfProduc t/@classCode=MMA][determinerCode=KIND]/code/@codeSystem=TBD-MPID]/@code</pre>
<p>e</p> <p>D.10.8.r.3a</p> <p>PHPID 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>code=SystemVersion 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=CACT][@moodCo dCode=EVN]/subject/@typeCode=SUBJ][investigationEvent/@classCode=INVTG][@moodCo de=EVN]/component/@typeCode=COMP][adverseEventAssessment][adverseEventAssessment /@classCode=INVTG][@moodCode=EVN]/subject[1]/typeCode=SBJ][primaryRole/@class code=INVSBJ]/player[1]/classCode=PSN][determinerCode=INSTANCE]/role/@classCode=PR S][subjectOf2/@typeCode=SBJ]/organizer/@code=2][@codeSystem=2.16.840.1.113883. 3.989.2.1.1.20][organizer/@classCode=CATEGORY][@moodCode=EVN]/component/@typeC ode=COMP][substanceAdministration][substanceAdministration/@classCode=SBADM][@mood code=EVN]/consumable/@typeCode=CSM][instanceOfKind/@classCode=INST]/kindOfProduc t/@classCode=MMA][determinerCode=KIND]/code/@codeSystem=TBD-PhPID]/@codeSystem mVersion</pre>
<p>e</p> <p>D.10.8.r.3b</p> <p>製剤識別子 (PHPID)</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]/PDRR_IN049016UV1/controlActProcess/@classCode=CACT][@moodCo dCode=EVN]/subject/@typeCode=SUBJ][investigationEvent/@classCode=INVTG][@moodCo de=EVN]/component/@typeCode=COMP][adverseEventAssessment][adverseEventAssessment /@classCode=INVTG][@moodCode=EVN]/subject[1]/typeCode=SBJ][primaryRole/@class code=INVSBJ]/player[1]/classCode=PSN][determinerCode=INSTANCE]/role/@classCode=PR S][subjectOf2/@typeCode=SBJ]/organizer/@code=2][@codeSystem=2.16.840.1.113883. 3.989.2.1.1.20][organizer/@classCode=CATEGORY][@moodCode=EVN]/component/@typeC ode=COMP][substanceAdministration][substanceAdministration/@classCode=SBADM][@mood code=EVN]/consumable/@typeCode=CSM][instanceOfKind/@classCode=INST]/kindOfProduc t/@classCode=MMA][determinerCode=KIND]/code/@codeSystem=TBD-PhPID]/@code</pre>
<p>e</p> <p>D.10.8.r.4</p> <p>開始日</p>	<p>日付/時間</p>	<p>Interval of Point in Time (IVL-TS>)</p> <p>low=Interval Boundary (IVXB)</p>	<p>値</p>	<pre>/MCCI_IN200100UV01/@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PDRR_IN049016UV1/controlActProcess/@classCode=CACT][@moodCo dCode=EVN]/subject/@typeCode=SUBJ][investigationEvent/@classCode=INVTG][@moodCo de=EVN]/component/@typeCode=COMP][adverseEventAssessment][adverseEventAssessment /@classCode=INVTG][@moodCode=EVN]/subject[1]/typeCode=SBJ][primaryRole/@class code=INVSBJ]/player[1]/classCode=PSN][determinerCode=INSTANCE]/role/@classCode=PR S][subjectOf2/@typeCode=SBJ]/organizer/@code=2][@codeSystem=2.16.840.1.113883. 3.989.2.1.1.20][organizer/@classCode=CATEGORY][@moodCode=EVN]/component/@typeC ode=COMP][substanceAdministration][substanceAdministration/@classCode=SBADM][@mood code=EVN]/effectiveTime/@xsi:type=IVL_TS]/@value</pre>

(別添 3)

<p>e</p>	<p>NullFlavor</p>	<p>値</p>	<p>high=Interval Boundary (VXB)</p>	<p>Interval of Point in Time (IVL<TS>)</p>	<p>日付/時間</p>	<p>終了日</p>	<p>D.10.8.r.5</p>
<p>/MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/PDRR_IN049016UV01/controlActProcess[@classCode=CACT][@moodCode=EVN]/subject/@typeCode=SUBJ[1]/investigationEvent[@classCode=INVTG][@moodCode=EVN]/component/@typeCode=COMP[1]/adverseEventAssessment[1]/adverseEventAssessment[@classCode=INVTG][@moodCode=EVN]/subject[1]/typeCode=SBJ[1]/primaryRole/@classCode=PR[S][1]/subjectOr2/@typeCode=SBJ[1]/determinerCode=INSTANCE/role/@classCode=PR[S][1]/subjectOr2/@typeCode=SBJ[1]/organizer/code/@code=2[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[1]/substanceAdministration[@classCode=SBADM][@moodCode=EVN]/effectiveTime[@xsi:type=IVL_TS]/high/@value</p>	<p>値</p>	<p>Interval of Point in Time (IVL<TS>)</p>	<p>日付/時間</p>	<p>終了日</p>	<p>D.10.8.r.5</p>	<p>終了日</p>	<p>D.10.8.r.5</p>
<p>/MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/PDRR_IN049016UV01/controlActProcess[@classCode=CACT][@moodCode=EVN]/subject/@typeCode=SUBJ[1]/investigationEvent[@classCode=INVTG][@moodCode=EVN]/component/@typeCode=COMP[1]/adverseEventAssessment[1]/adverseEventAssessment[@classCode=INVTG][@moodCode=EVN]/subject[1]/typeCode=SBJ[1]/primaryRole/@classCode=PR[S][1]/subjectOr2/@typeCode=SBJ[1]/determinerCode=INSTANCE/role/@classCode=PR[S][1]/subjectOr2/@typeCode=SBJ[1]/organizer/code/@code=2[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[1]/substanceAdministration[@classCode=SBADM][@moodCode=EVN]/effectiveTime[@xsi:type=IVL_TS]/high/@value</p>	<p>NullFlavor</p>	<p>値</p>	<p>codeSystemVersion=Character String (ST)</p>	<p>Coded With Equivalents (CE)</p>	<p>4AN</p>	<p>使用理由の MedDRA パーシジョン</p>	<p>D.10.8.r.6a</p>
<p>/MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/PDRR_IN049016UV01/controlActProcess[@classCode=CACT][@moodCode=EVN]/subject/@typeCode=SUBJ[1]/investigationEvent[@classCode=INVTG][@moodCode=EVN]/component/@typeCode=COMP[1]/adverseEventAssessment[1]/adverseEventAssessment[@classCode=INVTG][@moodCode=EVN]/subject[1]/typeCode=SBJ[1]/primaryRole/@classCode=PR[S][1]/subjectOr2/@typeCode=SBJ[1]/determinerCode=INSTANCE/role/@classCode=PR[S][1]/subjectOr2/@typeCode=SBJ[1]/organizer/code/@code=2[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[1]/substanceAdministration[@classCode=SBADM][@moodCode=EVN]/effectiveTime[@xsi:type=IVL_TS]/high/@value</p>	<p>値</p>	<p>codeSystemVersion=Character String (ST)</p>	<p>Coded With Equivalents (CE)</p>	<p>4AN</p>	<p>使用理由の MedDRA パーシジョン</p>	<p>D.10.8.r.6a</p>	<p>D.10.8.r.6a</p>

2012年11月14日

<p>e</p> <p>D.10.8.r.6b</p> <p>使用理由 (MedDRA コード)</p> <p>8N</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]/PDRR_IN049016UV1/controlActProcess[@classCode=CACT][@moo dCode=EVN]/subject[@typeCode=SUBJ]/investigationEvent[@classCode=INVTG][@moodCo de=EVN]/component[@typeCode=COMP]/adverseEventAssessment[1]/adverseEventAssessment [@classCode=INVTG][@moodCode=EVN]/subject[1][@typeCode=SBJ][1]/primaryRole[class Code=INVSBJ]/player[1][@classCode=PSN][1]/determinerCode=INSTANCE/role[classCode=PR S][1]/subjectC2[2][@typeCode=SBJ]/organizer/code=2][@codeSystem=2,16,840,1.1.13883. 3.989.2.1.1.20][1]/organizer[1][@classCode=CATEGORY][@moodCode=EVN]/component[1]/typeC ode=COMP/substanceAdministration[1]/substanceAdministration[1][@classCode=SBADM][@mood Code=EVN]/outboundRelationship[2][@typeCode=RSON][observation/code=@code=19][@codeSy stem=2,16,840,1.1.13883.3.989.2.1.1.19][1]/observation[1][@classCode=OBS][1][@code value[@xsi:type=CE][@codeSystem=2,16,840,1.1.13883.6.163][1]/@code </pre>				
<p>e</p> <p>D.10.8.r.7a</p> <p>副作用の MedDRA ハーゾ ン</p> <p>4AN</p> <p>Coded With Equivalents (CE)</p> <p>codeSystemVersion= Character String (ST)</p> <p>値</p>	<pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/PDRR_IN049016UV1/controlActProcess[@classCode=CACT][@moo dCode=EVN]/subject[@typeCode=SUBJ]/investigationEvent[@classCode=INVTG][@moodCo de=EVN]/component[@typeCode=COMP]/adverseEventAssessment[1]/adverseEventAssessment [@classCode=INVTG][@moodCode=EVN]/subject[1][@typeCode=SBJ][1]/primaryRole[class Code=INVSBJ]/player[1][@classCode=PSN][1]/determinerCode=INSTANCE/role[classCode=PR S][1]/subjectC2[2][@typeCode=SBJ]/organizer/code=@code=2][@codeSystem=2,16,840,1.1.13883. 3.989.2.1.1.20][1]/organizer[1][@classCode=CATEGORY][@moodCode=EVN]/component[1]/typeC ode=COMP/substanceAdministration[1]/substanceAdministration[1][@classCode=SBADM][@mood Code=EVN]/outboundRelationship[2][@typeCode=CAUS][observation/code=@code=29][@codeSy stem=2,16,840,1.1.13883.3.989.2.1.1.19][1]/observation[1][@classCode=OBS][1][@code value[@xsi:type=CE][@codeSystem=2,16,840,1.1.13883.6.163][1]/@codeSystemVersion </pre>				
<p>e</p> <p>D.10.8.r.7b</p> <p>副作用 (MedDRA コード)</p> <p>8N</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]/PDRR_IN049016UV1/controlActProcess[@classCode=CACT][@moo dCode=EVN]/subject[@typeCode=SUBJ]/investigationEvent[@classCode=INVTG][@moodCo de=EVN]/component[@typeCode=COMP]/adverseEventAssessment[1]/adverseEventAssessment [@classCode=INVTG][@moodCode=EVN]/subject[1][@typeCode=SBJ][1]/primaryRole[class Code=INVSBJ]/player[1][@classCode=PSN][1]/determinerCode=INSTANCE/role[classCode=PR S][1]/subjectC2[2][@typeCode=SBJ]/organizer/code=@code=2][@codeSystem=2,16,840,1.1.13883. 3.989.2.1.1.20][1]/organizer[1][@classCode=CATEGORY][@moodCode=EVN]/component[1]/typeC ode=COMP/substanceAdministration[1]/substanceAdministration[1][@classCode=SBADM][@mood Code=EVN]/outboundRelationship[2][@typeCode=CAUS][observation/code=@code=29][@codeSy stem=2,16,840,1.1.13883.3.989.2.1.1.19][1]/observation[1][@classCode=OBS][1][@code value[@xsi:type=CE][@codeSystem=2,16,840,1.1.13883.6.163][1]/@code </pre>				
<p>h</p> <p>E.i.1</p> <p>副作用/有害事象 (必要に応 じ繰り返す)</p> <p>E.i.1</p> <p>繰り返し ノード</p>	<pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/PDRR_IN049016UV1/controlActProcess[@classCode=CACT][@moo dCode=EVN]/subject[@typeCode=SUBJ]/investigationEvent[@classCode=INVTG][@moodCo de=EVN]/component[@typeCode=COMP]/adverseEventAssessment[1]/adverseEventAssessment [@classCode=INVTG][@moodCode=EVN]/subject[1][@typeCode=SBJ][1]/primaryRole[class Code=INVSBJ]/subjectC2[2][@typeCode=SBJ]/organizer/code=@code=25][@codeSystem=2,1 6,840,1.1.13883.3.989.2.1.1.19][1] </pre>				
<p>h</p> <p>E.i.1</p> <p>第一次情報源により報告さ れた副作用/有害事象</p>					

(別添3)

e	E.I.1.1a	母国語で記載された、第一次情報源により報告された副作用/有害事象	250AN	Coded With Equivalents (CE)	originalText= Encapsulated Data (ED)	値	/MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/PORR_IN049016UV[controlActProcess/@classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUBJ]/investigationEvent[@classCode=INVSCTG][@moodCode=EVN]/component[@typeCode=COMP]/adverseEventAssessment[1]/adverseEventAssessment[@classCode=INVSCTG][@moodCode=EVN]/subject1[@typeCode=SBJ][1]/primaryRole[@classCode=INVSBJ]/subjectOf2[@typeCode=SBJ]/observation[id][code=29][@codeSystem=2.1.6.840.1.113883.3.989.2.1.1.19][1]/observation[@classCode=OBS][@moodCode=EVN]/value[@xsi:type=CE][@codeSystem=2.1.6.840.1.113883.6.163][1]/originalText/text()
e	E.I.1.1b	第一次情報源により報告された副作用/有害事象の言語	3A	Coded With Equivalents (CE)	originalText/language=Coded Simple Value (CS)	値	/MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/PORR_IN049016UV[controlActProcess/@classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUBJ]/investigationEvent[@classCode=INVSCTG][@moodCode=EVN]/component[@typeCode=COMP]/adverseEventAssessment[1]/adverseEventAssessment[@classCode=INVSCTG][@moodCode=EVN]/subject1[@typeCode=SBJ][1]/primaryRole[@classCode=INVSBJ]/subjectOf2[@typeCode=SBJ]/observation[id][code=29][@codeSystem=2.1.6.840.1.113883.3.989.2.1.1.19][1]/observation[@classCode=OBS][@moodCode=EVN]/value[@xsi:type=CE][@codeSystem=2.1.6.840.1.113883.6.163][1]/originalText/language
e	E.I.1.2	翻訳された、第一次情報源により報告された副作用/有害事象	250AN	Encapsulated Data (ED)		値	/MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/PORR_IN049016UV[controlActProcess/@classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUBJ]/investigationEvent[@classCode=INVSCTG][@moodCode=EVN]/component[@typeCode=COMP]/adverseEventAssessment[1]/adverseEventAssessment[@classCode=INVSCTG][@moodCode=EVN]/subject1[@typeCode=SBJ][1]/primaryRole[@classCode=INVSBJ]/subjectOf2[@typeCode=SBJ]/observation[id][code=29][@codeSystem=2.1.6.840.1.113883.3.989.2.1.1.19][1]/observation[@classCode=OBS][@moodCode=EVN]/outboundRelationship2[@typeCode=PERT][observation/code/@code=30][@codeSystem=2.1.6.840.1.113883.3.989.2.1.1.19][1]/observation[@classCode=OBS][@moodCode=EVN]/value[@xsi:type=ED][1]/text()
e	E.I.2.1a	副作用/有害事象の MedDRA パージョン	4AN	Coded With Equivalents (CE)	codeSystemVersion=Character String (ST)	値	/MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/PORR_IN049016UV[controlActProcess/@classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUBJ]/investigationEvent[@classCode=INVSCTG][@moodCode=EVN]/component[@typeCode=COMP]/adverseEventAssessment[1]/adverseEventAssessment[@classCode=INVSCTG][@moodCode=EVN]/subject1[@typeCode=SBJ][1]/primaryRole[@classCode=INVSBJ]/subjectOf2[@typeCode=SBJ]/observation[id][code=29][@codeSystem=2.1.6.840.1.113883.3.989.2.1.1.19][1]/observation[@classCode=OBS][@moodCode=EVN]/value[@xsi:type=CE][@codeSystem=2.1.6.840.1.113883.6.163][1]/codeSystemVersion
e	E.I.2.1b	副作用/有害事象 (MedDRA コード)	8N	Coded With Equivalents (CE)	code=Character String (ST)	値	/MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/PORR_IN049016UV[controlActProcess/@classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUBJ]/investigationEvent[@classCode=INVSCTG][@moodCode=EVN]/component[@typeCode=COMP]/adverseEventAssessment[1]/adverseEventAssessment[@classCode=INVSCTG][@moodCode=EVN]/subject1[@typeCode=SBJ][1]/primaryRole[@classCode=INVSBJ]/subjectOf2[@typeCode=SBJ]/observation[id][code=29][@codeSystem=2.1.6.840.1.113883.3.989.2.1.1.19][1]/observation[@classCode=OBS][@moodCode=EVN]/value[@xsi:type=CE][@codeSystem=2.1.6.840.1.113883.6.163][1]/code

(別添3)

<p>e</p> <p>E.i.3.1</p>	<p>報告者によって重要とされた副作用/有害事象</p>	<p>1N</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_IN049016UV/ControlActProcess[@classCode='CACT']/@moodCode=EVN/subject/@typeCode='SUBJ'/investigationEvent/@classCode='INVESTG']/@moodCode=EVN/component/@typeCode='COMP'/adverseEventAssessment[1]/adverseEventAssessment[@classCode='INVESTG']/@moodCode=EVN/subject1/@typeCode='SBJ'/primaryRole/@classCode='INVSBJ/subjectOf2/@typeCode='SBJ'/observation[id/@code='29']/@codeSystem=2.16.840.1.113883.3.989.2.1.1.19/observation/@classCode='OBS']/@moodCode='EVN'/outboundRelationship2/@typeCode='PERT'/observation/@code='37']/@codeSystem=2.16.840.1.113883.3.989.2.1.1.19/observation/@classCode='OBS']/@moodCode='EVN'/value/@xsi:type='CE']/@codeSystem=2.16.840.1.113883.3.989.2.1.1.10']/@code</pre>
<p>h</p> <p>E.i.3.2</p>	<p>有害事象ごとの重篤性の基準</p>				<p>値</p>	<pre>/MCCI_IN200100UV01[@ITSVersion='XML_1.0']/@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd/PORR_IN049016UV/ControlActProcess[@classCode='CACT']/@moodCode=EVN/subject/@typeCode='SUBJ'/investigationEvent/@classCode='INVESTG']/@moodCode=EVN/component/@typeCode='COMP'/adverseEventAssessment[1]/adverseEventAssessment[@classCode='INVESTG']/@moodCode=EVN/subject1/@typeCode='SBJ'/primaryRole/@classCode='INVSBJ/subjectOf2/@typeCode='SBJ'/observation[id/@code='29']/@codeSystem=2.16.840.1.113883.3.989.2.1.1.19/observation/@classCode='OBS']/@moodCode='EVN'/outboundRelationship2/@typeCode='PERT'/observation/@code='34']/@codeSystem=2.16.840.1.113883.3.989.2.1.1.19/observation/@classCode='OBS']/@moodCode='EVN'/value/@xsi:type='BL']/@value</pre>
<p>e</p> <p>E.i.3.2a</p>	<p>死に至るもの</p>	<p>ブール型</p>	<p>Boolean (BL)</p>	<p>NullFlavor</p>	<p>値</p>	<pre>/MCCI_IN200100UV01[@ITSVersion='XML_1.0']/@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd/PORR_IN049016UV/ControlActProcess[@classCode='CACT']/@moodCode=EVN/subject/@typeCode='SUBJ'/investigationEvent/@classCode='INVESTG']/@moodCode=EVN/component/@typeCode='COMP'/adverseEventAssessment[1]/adverseEventAssessment[@classCode='INVESTG']/@moodCode=EVN/subject1/@typeCode='SBJ'/primaryRole/@classCode='INVSBJ/subjectOf2/@typeCode='SBJ'/observation[id/@code='29']/@codeSystem=2.16.840.1.113883.3.989.2.1.1.19/observation/@classCode='OBS']/@moodCode='EVN'/outboundRelationship2/@typeCode='PERT'/observation/@code='34']/@codeSystem=2.16.840.1.113883.3.989.2.1.1.19/observation/@classCode='OBS']/@moodCode='EVN'/value/@xsi:type='BL']/@value</pre>
<p>e</p> <p>E.i.3.2b</p>	<p>生命を脅かすもの</p>	<p>ブール型</p>	<p>Boolean (BL)</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='CACT']/@moodCode=EVN/subject/@typeCode='SUBJ'/investigationEvent/@classCode='INVESTG']/@moodCode=EVN/component/@typeCode='COMP'/adverseEventAssessment[1]/adverseEventAssessment[@classCode='INVESTG']/@moodCode=EVN/subject1/@typeCode='SBJ'/primaryRole/@classCode='INVSBJ/subjectOf2/@typeCode='SBJ'/observation[id/@code='29']/@codeSystem=2.16.840.1.113883.3.989.2.1.1.19/observation/@classCode='OBS']/@moodCode='EVN'/outboundRelationship2/@typeCode='PERT'/observation/@code='21']/@codeSystem=2.16.840.1.113883.3.989.2.1.1.19/observation/@classCode='OBS']/@moodCode='EVN'/value/@xsi:type='BL']/@value</pre>

(別添3)

<p>e</p>	<p>NullFlavor</p>	<p>/MCCI_IN200100UV01[ITSVersion=XML_1.0][xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]PORR_IN049016UV[controlActProcess[classCode=CACT][@moodCode=EVN]/subject/@typeCode=SUBJ][investigationEvent[classCode=INVTG][@moodCode=EVN]/component/@typeCode=COMP][adverseEventAssessment[classCode=INVTG][@moodCode=EVN]/subject1[observation[id][code=29][@codeSystem=2.1.1.1.13883.3.989.2.1.1.19]]/observation[classCode=OBS][@moodCode=EVN]/outboundRelationship2[observation[code][@code=21][@codeSystem=2.16.840.1.113883.3.989.2.1.1.19]]/observation[classCode=OBS][@moodCode=EVN]value[xsi:type=BL][1]@value</p>	<p>値</p>	<p>NullFlavor</p>
<p>e</p>	<p>Boolean (BL)</p>	<p>Boolean (BL)</p>	<p>治療のための入院又は入院期間の延長が必要であるもの</p>	<p>E.I.3.2c</p>
<p>e</p>	<p>NullFlavor</p>	<p>/MCCI_IN200100UV01[ITSVersion=XML_1.0][xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]PORR_IN049016UV[controlActProcess[classCode=CACT][@moodCode=EVN]/subject/@typeCode=SUBJ][investigationEvent[classCode=INVTG][@moodCode=EVN]/component/@typeCode=COMP][adverseEventAssessment[classCode=INVTG][@moodCode=EVN]/subject1[observation[id][code=29][@codeSystem=2.1.1.1.13883.3.989.2.1.1.19]]/observation[classCode=OBS][@moodCode=EVN]/outboundRelationship2[observation[code][@code=33][@codeSystem=2.16.840.1.113883.3.989.2.1.1.19]]/observation[classCode=OBS][@moodCode=EVN]value[xsi:type=BL][1]@value</p>	<p>値</p>	<p>NullFlavor</p>
<p>e</p>	<p>Boolean (BL)</p>	<p>Boolean (BL)</p>	<p>永続的又は顕著な障害・機能不全に陥るもの</p>	<p>E.I.3.2d</p>
<p>e</p>	<p>NullFlavor</p>	<p>/MCCI_IN200100UV01[ITSVersion=XML_1.0][xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]PORR_IN049016UV[controlActProcess[classCode=CACT][@moodCode=EVN]/subject/@typeCode=SUBJ][investigationEvent[classCode=INVTG][@moodCode=EVN]/component/@typeCode=COMP][adverseEventAssessment[classCode=INVTG][@moodCode=EVN]/subject1[observation[id][code=29][@codeSystem=2.1.1.1.13883.3.989.2.1.1.19]]/observation[classCode=OBS][@moodCode=EVN]/outboundRelationship2[observation[code][@code=35][@codeSystem=2.16.840.1.113883.3.989.2.1.1.19]]/observation[classCode=OBS][@moodCode=EVN]value[xsi:type=BL][1]@value</p>	<p>値</p>	<p>NullFlavor</p>

(別添 3)

<p>e</p> <p>E.i.3.2e</p> <p>先天異常を来すもの</p>	<p>Boolean (BL)</p> <p>ブール型</p>	<p>値</p>	<pre> /MCCL_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCL_IN200100UV01.xsd']/PORR_IN049016UV1/controlActProcess/@classCode=CACTI/@mo dCode=EVN/subject/@typeCode=SUBJ/1/investigationEvent/@classCode=INVTG/1/@moodCo de=EVN/component/@typeCode=COMP/1/adverseEventAssessment/1/adverseEventAssessme nt/@classCode=INVTG/1/@moodCode=EVN/subject/1/primaryRole/@class code=INVSBJ/subjectOf/@typeCode=SBJ/observation[id]/code/@code=29/1/@codeSystem=2.1 6.840.1.113883.3.989.2.1.1.19/1/observation/@classCode=OBS/1/@moodCode=EVN/outbound Relationship2/@typeCode=PERT/1/observation/code/@code=12/1/@codeSystem=2.16.840.1.11388 3.3.989.2.1.1.19/1/observation/@classCode=OBS/1/@moodCode=EVN/1/value[@xsi:type=BL/1/ @value </pre>
<p>e</p>	<p>NullFlavor</p>	<p>NullFlavor</p>	<pre> /MCCL_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCL_IN200100UV01.xsd']/PORR_IN049016UV1/controlActProcess/@classCode=CACTI/@mo dCode=EVN/subject/@typeCode=SUBJ/1/investigationEvent/@classCode=INVTG/1/@moodCo de=EVN/component/@typeCode=COMP/1/adverseEventAssessment/1/adverseEventAssessme nt/@classCode=INVTG/1/@moodCode=EVN/subject/1/primaryRole/@class code=INVSBJ/subjectOf/@typeCode=SBJ/observation[id]/code/@code=29/1/@codeSystem=2.1 6.840.1.113883.3.989.2.1.1.19/1/observation/@classCode=OBS/1/@moodCode=EVN/outbound Relationship2/@typeCode=PERT/1/observation/code/@code=12/1/@codeSystem=2.16.840.1.11388 3.3.989.2.1.1.19/1/observation/@classCode=OBS/1/@moodCode=EVN/1/value[@xsi:type=BL/1/ @nullFlavor </pre>
<p>e</p> <p>E.i.3.2f</p> <p>その他の医学的に重要な状 態</p>	<p>Boolean (BL)</p> <p>ブール型</p>	<p>値</p>	<pre> /MCCL_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCL_IN200100UV01.xsd']/PORR_IN049016UV1/controlActProcess/@classCode=CACTI/@mo dCode=EVN/subject/@typeCode=SUBJ/1/investigationEvent/@classCode=INVTG/1/@moodCo de=EVN/component/@typeCode=COMP/1/adverseEventAssessment/1/adverseEventAssessme nt/@classCode=INVTG/1/@moodCode=EVN/subject/1/primaryRole/@class code=INVSBJ/subjectOf/@typeCode=SBJ/observation[id]/code/@code=29/1/@codeSystem=2.1 6.840.1.113883.3.989.2.1.1.19/1/observation/@classCode=OBS/1/@moodCode=EVN/outbound Relationship2/@typeCode=PERT/1/observation/code/@code=12/1/@codeSystem=2.16.840.1.11388 3.3.989.2.1.1.19/1/observation/@classCode=OBS/1/@moodCode=EVN/1/value[@xsi:type=BL/1/ @value </pre>
<p>e</p>	<p>NullFlavor</p>	<p>NullFlavor</p>	<pre> /MCCL_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCL_IN200100UV01.xsd']/PORR_IN049016UV1/controlActProcess/@classCode=CACTI/@mo dCode=EVN/subject/@typeCode=SUBJ/1/investigationEvent/@classCode=INVTG/1/@moodCo de=EVN/component/@typeCode=COMP/1/adverseEventAssessment/1/adverseEventAssessme nt/@classCode=INVTG/1/@moodCode=EVN/subject/1/primaryRole/@class code=INVSBJ/subjectOf/@typeCode=SBJ/observation[id]/code/@code=29/1/@codeSystem=2.1 6.840.1.113883.3.989.2.1.1.19/1/observation/@classCode=OBS/1/@moodCode=EVN/outbound Relationship2/@typeCode=PERT/1/observation/code/@code=12/1/@codeSystem=2.16.840.1.11388 3.3.989.2.1.1.19/1/observation/@classCode=OBS/1/@moodCode=EVN/1/value[@xsi:type=BL/1/ @nullFlavor </pre>

<p>e</p> <p>E.i.4</p>	<p>副作用/有害事象の発現日</p>	<p>日付/時間</p>	<p>1.E.i.4, E.i.5 及び E.i.6 のすべての項目が表示されない場合</p> <p>HL7 データ型: Interval of Point in Time (IVL<TS>)</p>	<p>1.E.i.4, E.i.5 及び E.i.6 のすべての項目が表示されない場合</p> <p>low=Interval Boundary (IVXB)</p>	<p>値</p> <pre>/MCCLI_IN200100UV01[ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCLI_IN200100UV01.xsd]/PORR_IN049016UV/r/controlActProcess[@classCode=CACT][@mo 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][1]/primaryRole[1][@class code=INVSBJ]/subjectC2[2][@typeCode=SBJ][observation[id][code=@code=29][@codeSystem=2.1 6.840.1.113883.3.989.2.1.1.19]]]]/observation[1][@classCode=OBS][@moodCode=EVN]/effectiveTi me[@xsi:type=IVL_TS]/low/@value</pre>
<p>e</p>				<p>NullFlavor</p>	<p>NullFlavor</p> <pre>/MCCLI_IN200100UV01[ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCLI_IN200100UV01.xsd]/PORR_IN049016UV/r/controlActProcess[@classCode=CACT][@mo 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][1]/primaryRole[1][@class code=INVSBJ]/subjectC2[2][@typeCode=SBJ][observation[id][code=@code=29][@codeSystem=2.1 6.840.1.113883.3.989.2.1.1.19]]]]/observation[1][@classCode=OBS][@moodCode=EVN]/effectiveTi me[@xsi:type=IVL_TS]/low/@nullFlavor</pre>
<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</p> <p>データ型 SXPRT を伴う最初の comp 項目</p> <p>HL7 データ型: Parenthetic Set Expression of Point in Time (SXPRTS)</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</p> <p>データ型 SXPRT を伴う最初の comp 項目</p> <p>comp/low=Interval Boundary (IVXB)</p>	<p>値</p> <pre>/MCCLI_IN200100UV01[ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCLI_IN200100UV01.xsd]/PORR_IN049016UV/r/controlActProcess[@classCode=CACT][@mo 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][1]/primaryRole[1][@class code=INVSBJ]/subjectC2[2][@typeCode=SBJ][observation[id][code=@code=29][@codeSystem=2.1 6.840.1.113883.3.989.2.1.1.19]]]]/observation[1][@classCode=OBS][@moodCode=EVN]/effectiveTi me[@xsi:type=SXPRTS]/comp[@xsi:type=IVL_TS]/low/@value</pre>
<p>e</p>				<p>NullFlavor</p>	<p>NullFlavor</p> <pre>/MCCLI_IN200100UV01[ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCLI_IN200100UV01.xsd]/PORR_IN049016UV/r/controlActProcess[@classCode=CACT][@mo 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][1]/primaryRole[1][@class code=INVSBJ]/subjectC2[2][@typeCode=SBJ][observation[id][code=@code=29][@codeSystem=2.1 6.840.1.113883.3.989.2.1.1.19]]]]/observation[1][@classCode=OBS][@moodCode=EVN]/effectiveTi me[@xsi:type=SXPRTS]/comp[@xsi:type=IVL_TS]/low/@nullFlavor</pre>

(別添 3)

	<p>3.E.1.4, E.1.5 及び E.1.6 のすべての項目が表示される場合。 データ型 SXPRT を伴う 2 番目の comp 項目</p> <p>HL7 データ型: Parenthetic Set Expression of Point in Time (SXPRT<TS>)</p>	<p>3.E.1.4, E.1.5 及び E.1.6 のすべての項目が表示される場合 データ型 SXPRT を伴う 2 番目の comp 項目 comp/low=Interval Boundary (VXB)</p>	<p>値</p>	<pre>/MCCI_IN200100UV01/@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PDRR_IN049076UVU[controlActProcess/@classCode=CACT][@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/@typeCode=SBJ[1]/primaryRole/@classCode=INVSBJ[1]/subjectOr2/@typeCode=SBJ[1]/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=SXPRT[1]/comp[1]/operator=@/low/@value</pre>
		<p>NullFlavor</p>	<p>値</p>	<pre>/MCCI_IN200100UV01/@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PDRR_IN049076UVU[controlActProcess/@classCode=CACT][@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/@typeCode=SBJ[1]/primaryRole/@classCode=INVSBJ[1]/subjectOr2/@typeCode=SBJ[1]/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=SXPRT[1]/comp[1]/operator=@/low/@nullFlavor</pre>
<p>e</p>	<p>E.1.5 画作用/有書事象の終了日 日付/時間</p>	<p>1.E.1.4, E.1.5 及び E.1.6 のすべての項目が表示されない場合 high=Interval Boundary (VXB)</p>	<p>値</p>	<pre>/MCCI_IN200100UV01/@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PDRR_IN049076UVU[controlActProcess/@classCode=CACT][@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/@typeCode=SBJ[1]/primaryRole/@classCode=INVSBJ[1]/subjectOr2/@typeCode=SBJ[1]/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=IVL_TS[1]/high/@value</pre>
<p>e</p>		<p>NullFlavor</p>	<p>値</p>	<pre>/MCCI_IN200100UV01/@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PDRR_IN049076UVU[controlActProcess/@classCode=CACT][@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/@typeCode=SBJ[1]/primaryRole/@classCode=INVSBJ[1]/subjectOr2/@typeCode=SBJ[1]/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=IVL_TS[1]/high/@nullFlavor</pre>

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		<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</p> <p>データ型 SXPР を伴う最初の comp 項目</p> <p>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</p> <p>データ型 SXPР を伴う最初の comp 項目</p> <p>comp/high=Interval Boundary (VXB)</p>	<p>値</p>	<pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:h7-org:v3 MCCL_IN200100UV01.xsd]/PОРR_IN049016UV/]/controlActProcess[@classCode=CACT][@moodCode=EVN]/subject/@typeCode=SUBJ]/investigationEvent[@classCode=INVTG][@moodCode=EVN]/component/@typeCode=COMP]/adverseEventAssessment[1]/adverseEventAssessment[@classCode=INVTG][@moodCode=EVN]/subject[1]/primaryRole/@classCode=INVSBJ]/subjectOf2/@typeCode=SBJ]/observation[id][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=IVL_TS]/high/@value </pre>
		<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</p> <p>データ型 SXPР を伴う 2 番目の comp 項目</p> <p>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</p> <p>データ型 SXPР を伴う 2 番目の comp 項目</p> <p>comp/high=Interval Boundary (VXB)</p>	<p>NullFlavor</p>	<pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:h7-org:v3 MCCL_IN200100UV01.xsd]/PОРR_IN049016UV/]/controlActProcess[@classCode=CACT][@moodCode=EVN]/subject/@typeCode=SUBJ]/investigationEvent[@classCode=INVTG][@moodCode=EVN]/component/@typeCode=COMP]/adverseEventAssessment[1]/adverseEventAssessment[@classCode=INVTG][@moodCode=EVN]/subject[1]/primaryRole/@classCode=INVSBJ]/subjectOf2/@typeCode=SBJ]/observation[id][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=IVL_TS]/high/@nullFlavor </pre>
		<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</p> <p>データ型 SXPР を伴う 2 番目の comp 項目</p> <p>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</p> <p>データ型 SXPР を伴う 2 番目の comp 項目</p> <p>comp/high=Interval Boundary (VXB)</p>	<p>値</p>	<pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:h7-org:v3 MCCL_IN200100UV01.xsd]/PОРR_IN049016UV/]/controlActProcess[@classCode=CACT][@moodCode=EVN]/subject/@typeCode=SUBJ]/investigationEvent[@classCode=INVTG][@moodCode=EVN]/component/@typeCode=COMP]/adverseEventAssessment[1]/adverseEventAssessment[@classCode=INVTG][@moodCode=EVN]/subject[1]/primaryRole/@classCode=INVSBJ]/subjectOf2/@typeCode=SBJ]/observation[id][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=IVL_TS]/operator=@A]/high/@value </pre>
		<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</p> <p>データ型 SXPР を伴う 2 番目の comp 項目</p> <p>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</p> <p>データ型 SXPР を伴う 2 番目の comp 項目</p> <p>comp/high=Interval Boundary (VXB)</p>	<p>NullFlavor</p>	<pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:h7-org:v3 MCCL_IN200100UV01.xsd]/PОРR_IN049016UV/]/controlActProcess[@classCode=CACT][@moodCode=EVN]/subject/@typeCode=SUBJ]/investigationEvent[@classCode=INVTG][@moodCode=EVN]/component/@typeCode=COMP]/adverseEventAssessment[1]/adverseEventAssessment[@classCode=INVTG][@moodCode=EVN]/subject[1]/primaryRole/@classCode=INVSBJ]/subjectOf2/@typeCode=SBJ]/observation[id][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=IVL_TS]/operator=@A]/high/@nullFlavor </pre>

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<p>e</p> <p>E.i.6a</p>	<p>副作用/有害事象の持続期間 (数)</p>	<p>5N</p>	<p>1.E.i.4, E.i.5 及び E.i.6 のすべての項目が表示されない場合</p> <p>HL7 データ型: Interval of Point in Time (IVL<TS>)</p>	<p>1.E.i.4, E.i.5 及び E.i.6 のすべての項目が表示されない場合</p> <p>width/Value=Real Number (REAL)</p>	<p>値</p> <p>/MCCLI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCLI_IN200100UV01.xsd]PARR_IN049016UV[?/controlActProcess/@classCode=CACT][@moodCode=EVN]/subject/@typeCode=SUBJ[?/investigationEvent/@classCode=INVTG][@moodCode=EVN]/component/@typeCode=COMP[?/adverseEventAssessment[?/adverseEventAssessment/@classCode=INVTG][@moodCode=EVN]/subject[?/typeCode=SBJ[?/primaryRole/@classCode=INVSBJ[?/subjectO2/@typeCode=SBJ[?/observation[id]/code/@code=29][@codeSystem=2.1.6.840.1.1.13883.3.989.2.1.1.19]]][?/observation[id]/code/@code=29][@codeSystem=2.1.6.840.1.1.13883.3.989.2.1.1.19]]][?/observation/@classCode=OBS][@moodCode=EVN]/effectiveTime[@xsi:type=IVL_TS]/width/@value</p>
<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</p> <p>データ型 SXPР を伴う最初の comp 項目</p> <p>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</p> <p>データ型 SXPР を伴う最初の comp 項目</p> <p>comp/width/Value=Real Number (REAL)</p>	<p>値</p> <p>/MCCLI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCLI_IN200100UV01.xsd]PARR_IN049016UV[?/controlActProcess/@classCode=CACT][@moodCode=EVN]/subject/@typeCode=SUBJ[?/investigationEvent/@classCode=INVTG][@moodCode=EVN]/component/@typeCode=COMP[?/adverseEventAssessment[?/adverseEventAssessment/@classCode=INVTG][@moodCode=EVN]/subject[?/typeCode=SBJ[?/primaryRole/@classCode=INVSBJ[?/subjectO2/@typeCode=SBJ[?/observation[id]/code/@code=29][@codeSystem=2.1.6.840.1.1.13883.3.989.2.1.1.19]]][?/observation[id]/code/@code=29][@codeSystem=2.1.6.840.1.1.13883.3.989.2.1.1.19]]][?/observation/@classCode=OBS][@moodCode=EVN]/effectiveTime[@xsi:type=SXPР_TS]/comp[@xsi:type=IVL_TS]/width/@value</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</p> <p>データ型 SXPР を伴う 2 番目の comp 項目</p> <p>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</p> <p>データ型 SXPР を伴う 2 番目の comp 項目</p> <p>comp/width/Value=Real Number (REAL)</p>	<p>値</p> <p>/MCCLI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCLI_IN200100UV01.xsd]PARR_IN049016UV[?/controlActProcess/@classCode=CACT][@moodCode=EVN]/subject/@typeCode=SUBJ[?/investigationEvent/@classCode=INVTG][@moodCode=EVN]/component/@typeCode=COMP[?/adverseEventAssessment[?/adverseEventAssessment/@classCode=INVTG][@moodCode=EVN]/subject[?/typeCode=SBJ[?/primaryRole/@classCode=INVSBJ[?/subjectO2/@typeCode=SBJ[?/observation[id]/code/@code=29][@codeSystem=2.1.6.840.1.1.13883.3.989.2.1.1.19]]][?/observation[id]/code/@code=29][@codeSystem=2.1.6.840.1.1.13883.3.989.2.1.1.19]]][?/observation/@classCode=OBS][@moodCode=EVN]/effectiveTime[@xsi:type=SXPР_TS]/comp[@xsi:type=IVL_TS]/operator=A]/width/@value</p>
<p>e</p> <p>E.i.6b</p>	<p>副作用/有害事象の持続期間 (単位)</p>	<p>50AN</p>	<p>1.E.i.4, E.i.5 及び E.i.6 のすべての項目が表示されない場合</p> <p>HL7 データ型: Interval of Point in Time (IVL<TS>)</p>	<p>1.E.i.4, E.i.5 及び E.i.6 のすべての項目が表示されない場合</p> <p>width/unit=Coded Simple Value (CS)</p>	<p>値</p> <p>/MCCLI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCLI_IN200100UV01.xsd]PARR_IN049016UV[?/controlActProcess/@classCode=CACT][@moodCode=EVN]/subject/@typeCode=SUBJ[?/investigationEvent/@classCode=INVTG][@moodCode=EVN]/component/@typeCode=COMP[?/adverseEventAssessment[?/adverseEventAssessment/@classCode=INVTG][@moodCode=EVN]/subject[?/typeCode=SBJ[?/primaryRole/@classCode=INVSBJ[?/subjectO2/@typeCode=SBJ[?/observation[id]/code/@code=29][@codeSystem=2.1.6.840.1.1.13883.3.989.2.1.1.19]]][?/observation[id]/code/@code=29][@codeSystem=2.1.6.840.1.1.13883.3.989.2.1.1.19]]][?/observation/@classCode=OBS][@moodCode=EVN]/effectiveTime[@xsi:type=IVL_TS]/width/@unit</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 SXPTR を伴う最初の comp 項目 HL7 データ型: Parenthetic Set Expression of Point In Time (SXPTR<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 SXPTR を伴う最初の comp 項目 comp/width/unit=Coded Simple Value (CS)</p>	<p>値</p> <pre>/MCCLI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3:MCCLI_IN200100UV01.xsd']/PDRR_IN049016UV1/controlActProcess[@classCode='CACT']/@moodCode=EVN]/subject/@typeCode='SUBJ']/investigationEvent[@classCode='INVESTG']/@moodCode=EVN]/component/@typeCode='COMP']/adverseEventAssessment[1]/adverseEventAssessment[@classCode='INVESTG']/@moodCode=EVN]/subject1[@typeCode='SBJ']/primaryRole[@classCode='INVSBJ']/subjectOf2/@typeCode='SB']/observation[id]/@code=29]]/@codeSystem=2.16.840.1.113883.3.989.2.1.1.19]]]]/observation[@classCode='OBS']/@moodCode=EVN]/effectiveTime[@xsi:type='SXPTR_TS']/comp[1]/@xsi:type='IVL_TS']/width/@unit</pre>
	<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 SXPTR を伴う 2 番目の comp 項目 HL7 データ型: Parenthetic Set Expression of Point In Time (SXPTR<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 SXPTR を伴う 2 番目の comp 項目 comp/width/unit=Coded Simple Value (CS)</p>	<p>値</p> <pre>/MCCLI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3:MCCLI_IN200100UV01.xsd']/PDRR_IN049016UV1/controlActProcess[@classCode='CACT']/@moodCode=EVN]/subject/@typeCode='SUBJ']/investigationEvent[@classCode='INVESTG']/@moodCode=EVN]/component/@typeCode='COMP']/adverseEventAssessment[1]/adverseEventAssessment[@classCode='INVESTG']/@moodCode=EVN]/subject1[@typeCode='SBJ']/primaryRole[@classCode='INVSBJ']/subjectOf2/@typeCode='SB']/observation[id]/@code=29]]/@codeSystem=2.16.840.1.113883.3.989.2.1.1.19]]]]/observation[@classCode='OBS']/@moodCode=EVN]/effectiveTime[@xsi:type='SXPTR_TS']/comp[2]/@xsi:type='A']/width/@unit</pre>
<p>E.i.7</p>	<p>最終観察時の副作用/有害事象の転帰</p>	<p>値</p>	<p>値</p> <pre>/MCCLI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3:MCCLI_IN200100UV01.xsd']/PDRR_IN049016UV1/controlActProcess[@classCode='CACT']/@moodCode=EVN]/subject/@typeCode='SUBJ']/investigationEvent[@classCode='INVESTG']/@moodCode=EVN]/component/@typeCode='COMP']/adverseEventAssessment[1]/adverseEventAssessment[@classCode='INVESTG']/@moodCode=EVN]/subject1[@typeCode='SBJ']/primaryRole[@classCode='INVSBJ']/subjectOf2/@typeCode='SB']/observation[id]/@code=29]]/@codeSystem=2.16.840.1.113883.3.989.2.1.1.19]]]]/observation[@classCode='OBS']/@moodCode=EVN]/outboundRelationship2[@typeCode='PERT']/observation[id]/@code=27]]/@codeSystem=2.16.840.1.113883.3.989.2.1.1.19]]]]/observation[@classCode='OBS']/@moodCode=EVN]/value[@xsi:type='CE']/@codeSystem=2.16.840.1.113883.3.989.2.1.1.19]]]]/@code</pre>
<p>E.i.8</p>	<p>医療専門家による医学的確認</p>	<p>値</p>	<p>値</p> <pre>/MCCLI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3:MCCLI_IN200100UV01.xsd']/PDRR_IN049016UV1/controlActProcess[@classCode='CACT']/@moodCode=EVN]/subject/@typeCode='SUBJ']/investigationEvent[@classCode='INVESTG']/@moodCode=EVN]/component/@typeCode='COMP']/adverseEventAssessment[1]/adverseEventAssessment[@classCode='INVESTG']/@moodCode=EVN]/subject1[@typeCode='SBJ']/primaryRole[@classCode='INVSBJ']/subjectOf2/@typeCode='SB']/observation[id]/@code=29]]/@codeSystem=2.16.840.1.113883.3.989.2.1.1.19]]]]/observation[@classCode='OBS']/@moodCode=EVN]/outboundRelationship2[@typeCode='PERT']/observation[id]/@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>

e	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	/MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xmlns:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/PDRR_IN049016UVJ/controlActProcess[@classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUBJ][@investigationEvent[@classCode=INVTG][@moodCode=EVN]/component[@typeCode=COMP][@adverseEventAssessment[1]/adverseEventAssessment[@classCode=INVTG][@moodCode=EVN]/subject[1]/primaryRole/@classCode=INVSBJ][@subjectOf[1]/observation[1][code=29][@codeSystem=2.16.840.1.113883.3.989.2.1.1.19][@observation/@classCode=OBS][@moodCode=EVN]/location[1]/typeCode=LOC][@category/@classCode=LOCE][@category/@classCode=COUNTRY][@dataMinerCode=INSTANCE][code/@codeSystem=1.0.3166.1.2.27][code]
h	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)				繰り返し ノード	/MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xmlns:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/PDRR_IN049016UVJ/controlActProcess[@classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUBJ][@investigationEvent[@classCode=INVTG][@moodCode=EVN]/component[@typeCode=COMP][@adverseEventAssessment[1]/adverseEventAssessment[@classCode=INVTG][@moodCode=EVN]/subject[1]/primaryRole/@classCode=INVSBJ][@subjectOf[1]/observation[1][code=29][@codeSystem=2.16.840.1.113883.3.989.2.1.1.20][@observation/@classCode=OBS][@moodCode=EVN]/component[1]/typeCode=COMP][@observation/@codeSystem=2.16.840.1.113883.6.163][@value]
e	F.r.1	日付(検査)	日付/時間	Point in Time (TS)		値	/MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xmlns:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/PDRR_IN049016UVJ/controlActProcess[@classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUBJ][@investigationEvent[@classCode=INVTG][@moodCode=EVN]/component[@typeCode=COMP][@adverseEventAssessment[1]/adverseEventAssessment[@classCode=INVTG][@moodCode=EVN]/subject[1]/primaryRole/@classCode=INVSBJ][@subjectOf[1]/observation[1][code=29][@codeSystem=2.16.840.1.113883.3.989.2.1.1.20][@observation/@classCode=OBS][@moodCode=EVN]/component[1]/typeCode=OBS][@observation/@codeSystem=2.16.840.1.113883.6.163][@value]
e						NullFlavor	/MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xmlns:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/PDRR_IN049016UVJ/controlActProcess[@classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUBJ][@investigationEvent[@classCode=INVTG][@moodCode=EVN]/component[@typeCode=COMP][@adverseEventAssessment[1]/adverseEventAssessment[@classCode=INVTG][@moodCode=EVN]/subject[1]/primaryRole/@classCode=INVSBJ][@subjectOf[1]/observation[1][code=29][@codeSystem=2.16.840.1.113883.3.989.2.1.1.20][@observation/@classCode=OBS][@moodCode=EVN]/component[1]/typeCode=OBS][@observation/@codeSystem=2.16.840.1.113883.6.163][@value]
h	F.r.2	検査名					/MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xmlns:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/PDRR_IN049016UVJ/controlActProcess[@classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUBJ][@investigationEvent[@classCode=INVTG][@moodCode=EVN]/component[@typeCode=COMP][@adverseEventAssessment[1]/adverseEventAssessment[@classCode=INVTG][@moodCode=EVN]/subject[1]/primaryRole/@classCode=INVSBJ][@subjectOf[1]/observation[1][code=29][@codeSystem=2.16.840.1.113883.3.989.2.1.1.20][@observation/@classCode=OBS][@moodCode=EVN]/component[1]/typeCode=OBS][@observation/@codeSystem=2.16.840.1.113883.6.163][@value]
e	F.r.2.1	検査名(自由記載)	250AN	Concept Descriptor (CD)	originalText=Encapsulated Data (ED)	値	/MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xmlns:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/PDRR_IN049016UVJ/controlActProcess[@classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUBJ][@investigationEvent[@classCode=INVTG][@moodCode=EVN]/component[@typeCode=COMP][@adverseEventAssessment[1]/adverseEventAssessment[@classCode=INVTG][@moodCode=EVN]/subject[1]/primaryRole/@classCode=INVSBJ][@subjectOf[1]/observation[1][code=29][@codeSystem=2.16.840.1.113883.3.989.2.1.1.20][@observation/@classCode=OBS][@moodCode=EVN]/component[1]/typeCode=OBS][@observation/@codeSystem=2.16.840.1.113883.6.163][@value]

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e	F.r.2.2a	検査名の MedDRA パーシヨ	4AN	Concept Descriptor (CD)	code=SystemVersion= Character String (ST)	値	<pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/PORR_IN049016UV[controlActProcess/@classCode=CACT][@moo dCode=EVN]/subject/@typeCode=SUBJ[1]/investigationEvent/@classCode=INVTG[1]/moodCo de=EVN/component/@typeCode=COMP[1]/adverseEventAssessment[1]/adverseEventAssessment [classCode=INVTG][@moodCode=EVN]/subject/@typeCode=SBJ[1]/primaryRole/@classC ode=INVSBJ[1]/subject/@typeCode=SBJ[1]/organizer/@code=3][@codeSystem=2.16.840.1 .113883.3.989.2.1.1.20][1]/organizer/@classCode=CATEGORY[1]/moodCode=EVN/component[@typeCode=COMP][observation/@code/@codeSystem=2.16.840.1.113883.6.163][1]/observation[classCode=OBS][@moodCode=EVN]/code/@codeSystemVersion /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/PORR_IN049016UV[controlActProcess/@classCode=CACT][@moo dCode=EVN]/subject/@typeCode=SUBJ[1]/investigationEvent/@classCode=INVTG[1]/moodCo de=EVN/component/@typeCode=COMP[1]/adverseEventAssessment[1]/adverseEventAssessment [classCode=INVTG][@moodCode=EVN]/subject/@typeCode=SBJ[1]/primaryRole/@classC ode=INVSBJ[1]/subject/@typeCode=SBJ[1]/organizer/@code=3][@codeSystem=2.16.840.1 .113883.3.989.2.1.1.20][1]/organizer/@classCode=CATEGORY[1]/moodCode=EVN/component[@typeCode=COMP][observation/@code/@codeSystem=2.16.840.1.113883.6.163][1]/observation[classCode=OBS][@moodCode=EVN]/code/@code </pre>
e	F.r.2.2b	検査名 (MedDRA コード)	8N	Concept Descriptor (CD)	code=Character String (ST)	値	<pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/PORR_IN049016UV[controlActProcess/@classCode=CACT][@moo dCode=EVN]/subject/@typeCode=SUBJ[1]/investigationEvent/@classCode=INVTG[1]/moodCo de=EVN/component/@typeCode=COMP[1]/adverseEventAssessment[1]/adverseEventAssessment [classCode=INVTG][@moodCode=EVN]/subject/@typeCode=SBJ[1]/primaryRole/@classC ode=INVSBJ[1]/subject/@typeCode=SBJ[1]/organizer/@code=3][@codeSystem=2.16.840.1 .113883.3.989.2.1.1.20][1]/organizer/@classCode=CATEGORY[1]/moodCode=EVN/component[@typeCode=COMP][observation/@code/@codeSystem=2.16.840.1.113883.6.163][1]/observation[classCode=OBS][@moodCode=EVN]/code/@code </pre>
h	F.r.3	検査結果					<pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/PORR_IN049016UV[controlActProcess/@classCode=CACT][@moo dCode=EVN]/subject/@typeCode=SUBJ[1]/investigationEvent/@classCode=INVTG[1]/moodCo de=EVN/component/@typeCode=COMP[1]/adverseEventAssessment[1]/adverseEventAssessment [classCode=INVTG][@moodCode=EVN]/subject/@typeCode=SBJ[1]/primaryRole/@classC ode=INVSBJ[1]/subject/@typeCode=SBJ[1]/organizer/@code=3][@codeSystem=2.16.840.1 .113883.3.989.2.1.1.20][1]/organizer/@classCode=CATEGORY[1]/moodCode=EVN/component[@typeCode=COMP][observation/@code/@codeSystem=2.16.840.1.113883.6.163][1]/observation[classCode=OBS][@moodCode=EVN]/interpretationCode/@codeSystem=2.16.840.1.113883.3.98 9.2.1.1.12][1]/@code </pre>
e	F.r.3.1	検査結果 (コード)	1N	Coded With Equivalents (OE)	code=Character String (ST)	値	<pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/PORR_IN049016UV[controlActProcess/@classCode=CACT][@moo dCode=EVN]/subject/@typeCode=SUBJ[1]/investigationEvent/@classCode=INVTG[1]/moodCo de=EVN/component/@typeCode=COMP[1]/adverseEventAssessment[1]/adverseEventAssessment [classCode=INVTG][@moodCode=EVN]/subject/@typeCode=SBJ[1]/primaryRole/@classC ode=INVSBJ[1]/subject/@typeCode=SBJ[1]/organizer/@code=3][@codeSystem=2.16.840.1 .113883.3.989.2.1.1.20][1]/organizer/@classCode=CATEGORY[1]/moodCode=EVN/component[@typeCode=COMP][observation/@code/@codeSystem=2.16.840.1.113883.6.163][1]/observation[classCode=OBS][@moodCode=EVN]/interpretationCode/@codeSystem=2.16.840.1.113883.3.98 9.2.1.1.12][1]/@code </pre>
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	<pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/PORR_IN049016UV[controlActProcess/@classCode=CACT][@moo dCode=EVN]/subject/@typeCode=SUBJ[1]/investigationEvent/@classCode=INVTG[1]/moodCo de=EVN/component/@typeCode=COMP[1]/adverseEventAssessment[1]/adverseEventAssessment [classCode=INVTG][@moodCode=EVN]/subject/@typeCode=SBJ[1]/primaryRole/@classC ode=INVSBJ[1]/subject/@typeCode=SBJ[1]/organizer/@code=3][@codeSystem=2.16.840.1 .113883.3.989.2.1.1.20][1]/organizer/@classCode=CATEGORY[1]/moodCode=EVN/component[@typeCode=COMP][observation/@code/@codeSystem=2.16.840.1.113883.6.163][1]/observation[classCode=OBS][@moodCode=EVN]/value[@xsi:type=IVL_PQ][1]/center/@value </pre>
e					2.GT low=Interval Boundary (IVXB)	値	<pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/PORR_IN049016UV[controlActProcess/@classCode=CACT][@moo dCode=EVN]/subject/@typeCode=SUBJ[1]/investigationEvent/@classCode=INVTG[1]/moodCo de=EVN/component/@typeCode=COMP[1]/adverseEventAssessment[1]/adverseEventAssessment [classCode=INVTG][@moodCode=EVN]/subject/@typeCode=SBJ[1]/primaryRole/@classC ode=INVSBJ[1]/subject/@typeCode=SBJ[1]/organizer/@code=3][@codeSystem=2.16.840.1 .113883.3.989.2.1.1.20][1]/organizer/@classCode=CATEGORY[1]/moodCode=EVN/component[@typeCode=COMP][observation/@code/@codeSystem=2.16.840.1.113883.6.163][1]/observation[classCode=OBS][@moodCode=EVN]/value[@xsi:type=IVL_PQ][1]/high/@nullFlavor=PINF[1]/low[@inclusive=false]/@value </pre>

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e	NullFlavor	/MCCL_IN200100UV01@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/PDRR_IN049016UV[controlActProcess/@classCode=CACT][@moodCode=EVN]/subject/@typeCode=SUBJ][investigationEvent/@classCode=INVTG][@moodCode=EVN]/component/@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment/@classCode=INVTG][@moodCode=EVN]/subject/@typeCode=EVN][subject/@typeCode=SBJ][1/primaryRole/@classCode=INVSBJ][subject/@typeCode=SBJ][organizer/@code=3][@codeSystem=2.16.840.1.113883.3.989.2.1.1.20][1/organizer/@code=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][low/@nullFlavor]
e	3.GE low=Interval Boundary (IVXB)	/MCCL_IN200100UV01@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/PDRR_IN049016UV[controlActProcess/@classCode=CACT][@moodCode=EVN]/subject/@typeCode=SUBJ][1/investigationEvent/@classCode=INVTG][@moodCode=EVN]/component/@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment/@classCode=INVTG][@moodCode=EVN]/subject/@typeCode=EVN][subject/@typeCode=SBJ][1/primaryRole/@classCode=INVSBJ][subject/@typeCode=SBJ][organizer/@code=3][@codeSystem=2.16.840.1.113883.3.989.2.1.1.20][1/organizer/@code=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][high/@nullFlavor=PINF][1/low/@inclusive=true][@value]
e	NullFlavor	/MCCL_IN200100UV01@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/PDRR_IN049016UV[controlActProcess/@classCode=CACT][@moodCode=EVN]/subject/@typeCode=SUBJ][1/investigationEvent/@classCode=INVTG][@moodCode=EVN]/component/@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment/@classCode=INVTG][@moodCode=EVN]/subject/@typeCode=EVN][subject/@typeCode=SBJ][1/primaryRole/@classCode=INVSBJ][subject/@typeCode=SBJ][organizer/@code=3][@codeSystem=2.16.840.1.113883.3.989.2.1.1.20][1/organizer/@code=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]
e	4.LT high=Interval Boundary (IVXB)	/MCCL_IN200100UV01@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/PDRR_IN049016UV[controlActProcess/@classCode=CACT][@moodCode=EVN]/subject/@typeCode=SUBJ][1/investigationEvent/@classCode=INVTG][@moodCode=EVN]/component/@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment/@classCode=INVTG][@moodCode=EVN]/subject/@typeCode=EVN][subject/@typeCode=SBJ][1/primaryRole/@classCode=INVSBJ][subject/@typeCode=SBJ][organizer/@code=3][@codeSystem=2.16.840.1.113883.3.989.2.1.1.20][1/organizer/@code=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][low/@nullFlavor=NINF][1/high/@inclusive=false][@value]
e	NullFlavor	/MCCL_IN200100UV01@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/PDRR_IN049016UV[controlActProcess/@classCode=CACT][@moodCode=EVN]/subject/@typeCode=SUBJ][1/investigationEvent/@classCode=INVTG][@moodCode=EVN]/component/@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment/@classCode=INVTG][@moodCode=EVN]/subject/@typeCode=EVN][subject/@typeCode=SBJ][1/primaryRole/@classCode=INVSBJ][subject/@typeCode=SBJ][organizer/@code=3][@codeSystem=2.16.840.1.113883.3.989.2.1.1.20][1/organizer/@code=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]

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e				5. LEhigh=Interval Boundary (VXB)	値	<pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/PDRR_IN049016UV1/controlActProcess[@classCode=CACT][@moodCo dCode=EVN]/subject/@typeCode=SUBJ[1]/investigationEvent[@classCode=INVTG][@moodCo de=EVN]/component/@typeCode=COMP[1]adverseEventAssessment[1]adverseEventAssessment [@classCode=INVTG][@moodCode=EVN]/subject/@typeCode=SBJ[1]/primaryRole/@classC ode=INVSBJ/subjectCf2/@typeCode=SB[1]organizer/@code=3][@codeSystem=2.16.840.1 113883.3.989.2.1.1.20][1]organizer/@classCode=CATEGORY[1]@moodCode=EVN/component[@typeCode=OBS][@moodCode=EVN]/value[1]@xsi:type=IVL_PQ][low][@nullFlavor=NINF][1]high[@inclusive=true]/@unit </pre>
e					NullFlavor	<pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/PDRR_IN049016UV1/controlActProcess[@classCode=CACT][@moodCo dCode=EVN]/subject/@typeCode=SUBJ[1]/investigationEvent[@classCode=INVTG][@moodCo de=EVN]/component/@typeCode=COMP[1]adverseEventAssessment[1]adverseEventAssessment [@classCode=INVTG][@moodCode=EVN]/subject/@typeCode=SBJ[1]/primaryRole/@classC ode=INVSBJ/subjectCf2/@typeCode=SB[1]organizer/@code=3][@codeSystem=2.16.840.1 113883.3.989.2.1.1.20][1]organizer/@classCode=CATEGORY[1]@moodCode=EVN/component[@typeCode=OBS][@moodCode=EVN]/value[1]@xsi:type=IVL_PQ][1]high[1]low[1]@nullFlavor classCode=OBS][@moodCode=EVN]/value[1]@xsi:type=IVL_PQ][1]high[1]low[1]@nullFlavor </pre>
e	F.r.3.3	検査結果 (単位)	50AN	Interval of Physical Quantity (IVL-PQ>)	値	<pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/PDRR_IN049016UV1/controlActProcess[@classCode=CACT][@moodCo dCode=EVN]/subject/@typeCode=SUBJ[1]/investigationEvent[@classCode=INVTG][@moodCo de=EVN]/component/@typeCode=COMP[1]adverseEventAssessment[1]adverseEventAssessment [@classCode=INVTG][@moodCode=EVN]/subject/@typeCode=SBJ[1]/primaryRole/@classC ode=INVSBJ/subjectCf2/@typeCode=SB[1]organizer/@code=3][@codeSystem=2.16.840.1 113883.3.989.2.1.1.20][1]organizer/@classCode=CATEGORY[1]@moodCode=EVN/component[@typeCode=OBS][@moodCode=EVN]/value[1]@xsi:type=IVL_PQ][1]center[1]@unit </pre>
e				2.GT low/value/unit=Coded Simple Value (CS)	値	<pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/PDRR_IN049016UV1/controlActProcess[@classCode=CACT][@moodCo dCode=EVN]/subject/@typeCode=SUBJ[1]/investigationEvent[@classCode=INVTG][@moodCo de=EVN]/component/@typeCode=COMP[1]adverseEventAssessment[1]adverseEventAssessment [@classCode=INVTG][@moodCode=EVN]/subject/@typeCode=SBJ[1]/primaryRole/@classC ode=INVSBJ/subjectCf2/@typeCode=SB[1]organizer/@code=3][@codeSystem=2.16.840.1 113883.3.989.2.1.1.20][1]organizer/@classCode=CATEGORY[1]@moodCode=EVN/component[@typeCode=OBS][@moodCode=EVN]/value[1]@xsi:type=IVL_PQ][1]high[1]low[1]@nullFlavor= PINF][1]low[@inclusive=false]/@unit </pre>
e				3.GE low/value/unit=Coded Simple Value (CS)	値	<pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/PDRR_IN049016UV1/controlActProcess[@classCode=CACT][@moodCo dCode=EVN]/subject/@typeCode=SUBJ[1]/investigationEvent[@classCode=INVTG][@moodCo de=EVN]/component/@typeCode=COMP[1]adverseEventAssessment[1]adverseEventAssessment [@classCode=INVTG][@moodCode=EVN]/subject/@typeCode=SBJ[1]/primaryRole/@classC ode=INVSBJ/subjectCf2/@typeCode=SB[1]organizer/@code=3][@codeSystem=2.16.840.1 113883.3.989.2.1.1.20][1]organizer/@classCode=CATEGORY[1]@moodCode=EVN/component[@typeCode=OBS][@moodCode=EVN]/value[1]@xsi:type=IVL_PQ][1]high[1]low[1]@nullFlavor= PINF][1]low[@inclusive=true]/@unit </pre>

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e			4.LT high/value/unit=Code d Simple Value (CS)	値	<pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:n7-org:v3 MCCL_IN200100UV01.xsd]/P/PORR_IN049016UV/j/controlActProcess/@classCode=CACT][@moodCo dCode=EVN]/subject/@typeCode=SUBJ][j/investigationEvent/@classCode=INVTG][@moodCo dCode=EVN]/component/@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment [1]/classCode=INVTG][@moodCode=EVN]/subject/@typeCode=SBJ][1/primaryRole/@classCo de=INVSBJ]/subjectOzI/@typeCode=SBV][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][j/observation[@typeCode=OBS][@moodCode=EVN]/value[@xsi:type=IV_PQ][low/@nullFlavor=NINF][1/high @inclusive=false]/@unit </pre>
e			5.LE high/value/unit=Code d Simple Value (CS)	値	<pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:n7-org:v3 MCCL_IN200100UV01.xsd]/P/PORR_IN049016UV/j/controlActProcess/@classCode=CACT][@moo dCode=EVN]/subject/@typeCode=SUBJ][1/investigationEvent/@classCode=INVTG][@moodCo dCode=EVN]/component/@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment [1]/classCode=INVTG][@moodCode=EVN]/subject/@typeCode=SBJ][1/primaryRole/@classCo de=INVSBJ]/subjectOzI/@typeCode=SBV][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][j/observation[@typeCode=OBS][@moodCode=EVN]/value[@xsi:type=IV_PQ][low/@nullFlavor=NINF][1/high @inclusive=true]/@unit </pre>
e	F.r.3.4 検査結果に関する非構造化 データ (自由記載)	2000AN	Encapsulated Data (ED)	値	<pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:n7-org:v3 MCCL_IN200100UV01.xsd]/P/PORR_IN049016UV/j/investigationEvent/@classCode=CACT][@moo dCode=EVN]/component/@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment [1]/classCode=INVTG][@moodCode=EVN]/subject/@typeCode=SBJ][1/primaryRole/@classCo de=INVSBJ]/subjectOzI/@typeCode=SBV][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][j/observation[@typeCode=OBS][@moodCode=EVN]/value[@xsi:type=ED][1/text] </pre>
e	F.r.4 正常範囲 低値	50AN	Physical Quantity (PQ)	値	<pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:n7-org:v3 MCCL_IN200100UV01.xsd]/P/PORR_IN049016UV/j/controlActProcess/@classCode=CACT][@moo dCode=EVN]/subject/@typeCode=SUBJ][1/investigationEvent/@classCode=INVTG][@moodCo dCode=EVN]/component/@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment [1]/classCode=INVTG][@moodCode=EVN]/subject/@typeCode=SBJ][1/primaryRole/@classCo de=INVSBJ]/subjectOzI/@typeCode=SBV][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][j/observation[@typeCode=OBS][@moodCode=EVN]/referenceRange/@typeCode=REFV][observationRange/int erpretationCode/@code=L][@codeSystem=2.16.840.1.113883.5.83][1/observationRange/@class Code=OBS][@moodCode=EVN.CRT]/value[@xsi:type=PQ][1/value </pre>

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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]PARR_IN049016UV[r/controlActProcess/@classCode=CACT][@moodCo dCode=EVN]/subject/@typeCode=SUBJ[1]/investigationEvent/@classCode=INVESTG[@moodCo de=EVN]/component/@typeCode=COMP[1]/adverseEventAssessment[1]/adverseEventAssessment [classCode=INVESTG][@moodCode=EVN]/subject1/@typeCode=SBJ[1]/primaryRole/@classC ode=INVSBJ/subjectOr2/@typeCode=SBJ[1]/organizer/code/@code=3][@codeSystem=2.16.840.1 13883.3.989.2.1.1.20][1]/organizer/@codeSystem=2.16.840.1.113883.6.163][r/observation]@ @typeCode=COMP[1]/observation/code/@codeSystem=2.16.840.1.113883.6.163][r/observationRangeInt erpretationCode/@code=H][@codeSystem=2.16.840.1.113883.3.989.2.1.1.19][r/observationRange/@class Code=OBS][@moodCode=EVN_CRT][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]PARR_IN049016UV[r/controlActProcess/@classCode=CACT][@moodCo dCode=EVN]/subject/@typeCode=SUBJ[1]/investigationEvent/@classCode=INVESTG[@moodCo de=EVN]/component/@typeCode=COMP[1]/adverseEventAssessment[1]/adverseEventAssessment [classCode=INVESTG][@moodCode=EVN]/subject1/@typeCode=SBJ[1]/primaryRole/@classC ode=INVSBJ/subjectOr2/@typeCode=SBJ[1]/organizer/code/@code=3][@codeSystem=2.16.840.1 13883.3.989.2.1.1.20][1]/organizer/@codeSystem=2.16.840.1.113883.6.163][r/observation]@ @typeCode=COMP[1]/observation/code/@codeSystem=2.16.840.1.113883.6.163][r/observation/co de/@code=10][@codeSystem=2.16.840.1.113883.3.989.2.1.1.19][r/observation/@classCode=OBS][@moodCode=EVN][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]PARR_IN049016UV[r/controlActProcess/@classCode=CACT][@moodCo dCode=EVN]/subject/@typeCode=SUBJ[1]/investigationEvent/@classCode=INVESTG[@moodCo de=EVN]/component/@typeCode=COMP[1]/adverseEventAssessment[1]/adverseEventAssessment [classCode=INVESTG][@moodCode=EVN]/subject1/@typeCode=SBJ[1]/primaryRole/@classC ode=INVSBJ/subjectOr2/@typeCode=SBJ[1]/organizer/code/@code=3][@codeSystem=2.16.840.1 13883.3.989.2.1.1.20][1]/organizer/@codeSystem=2.16.840.1.113883.6.163][r/observation]@ @typeCode=COMP[1]/observation/code/@codeSystem=2.16.840.1.113883.6.163][r/observation/co de/@code=25][@codeSystem=2.16.840.1.113883.3.989.2.1.1.19][r/observation/@classCode=OBS][@moodCode=EVN][value/@xsi:type=BL][1]/value </pre>
h	G.k	医薬品情報 (必要に応じ繰り返し戻す)				繰り返し ノード	<pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]PARR_IN049016UV[r/controlActProcess/@classCode=CACT][@moodCo dCode=EVN]/subject/@typeCode=SUBJ[1]/investigationEvent/@classCode=INVESTG[@moodCo de=EVN]/component/@typeCode=COMP[1]/adverseEventAssessment[1]/adverseEventAssessment [classCode=INVESTG][@moodCode=EVN]/subject1/@typeCode=SBJ[1]/primaryRole/@classC ode=INVSBJ/subjectOr2/@typeCode=SBJ[1]/organizer/code/@code=4][@codeSystem=2.16.840.1 13883.3.989.2.1.1.20][1]/organizer/@codeSystem=2.16.840.1.113883.6.163][r/observation]@ @typeCode=COMP[1]/substanceAdministration/fd </pre>

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e	G.k.1	医薬品譲与の位置付け	1N	Coded With Equivalents (CE)	code=Character String (ST)	値	/MCC1_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3/MCC1_IN200100UV01.xsd]/PDRR_IN049016UV1[controlActProcess/@classCode=CACT][@moodCode=EVN]/subject/@typeCode=SUBJ[1]/investigationEvent/@classCode=INVS[1][@moodCode=EVN]/component/@typeCode=COMP[1]/adverseEventAssessment[1]/adverseEventAssessment/@classCode=INVS[1][@moodCode=EVN]/component/@typeCode=COMP[1]/causalityAssessment[1]/causalityAssessment/@classCode=OBS[1][@moodCode=EVN]/subject[2]/typeCode=SUBJ[1]/productUseReference/@classCode=SBADM[1][@moodCode=EVN]/id/@root=UID[1][@value=@xsi:type=CE][@codeSystem=2.16.840.1.113883.3.989.2.1.1.137]/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 パージョン日付/番号	M5 ガイド ラインを参照	Coded With Equivalents (CE)	code=SystemVersion=Character String (ST)	値	/MCC1_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3/MCC1_IN200100UV01.xsd]/PDRR_IN049016UV1[controlActProcess/@classCode=CACT][@moodCode=EVN]/subject/@typeCode=SUBJ[1]/investigationEvent/@classCode=INVS[1][@moodCode=EVN]/component/@typeCode=COMP[1]/adverseEventAssessment[1]/adverseEventAssessment/@classCode=INVS[1][@moodCode=EVN]/subject[1]/primaryRole/@classCode=INVS[1][@moodCode=EVN]/organizer/@code=4[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][K]/substanceAdministration/@classCode=SBADM[1][@moodCode=EVN]/consumable/@typeCode=CSM[1][instanceOfKind/@classCode=INST]/kindOfProduct/@classCode=MMA[1][@determinerCode=KIND]/code/@codeSystem=TBD-MPID]/codeSystemVersion
e	G.k.2.1.1b	医薬品製品識別子 (MPID)	M5 ガイド ラインを参照	Coded With Equivalents (CE)	code=Character String (ST)	値	/MCC1_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3/MCC1_IN200100UV01.xsd]/PDRR_IN049016UV1[controlActProcess/@classCode=CACT][@moodCode=EVN]/subject/@typeCode=SUBJ[1]/investigationEvent/@classCode=INVS[1][@moodCode=EVN]/component/@typeCode=COMP[1]/adverseEventAssessment[1]/adverseEventAssessment/@classCode=INVS[1][@moodCode=EVN]/subject[1]/primaryRole/@classCode=INVS[1][@moodCode=EVN]/organizer/@code=4[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][K]/substanceAdministration/@classCode=SBADM[1][@moodCode=EVN]/consumable/@typeCode=CSM[1][instanceOfKind/@classCode=INST]/kindOfProduct/@classCode=MMA[1][@determinerCode=KIND]/code/@codeSystem=TBD-MPID]/codeSystemVersion
e	G.k.2.1.2a	PhPID パージョン日付/番号	M5 ガイド ラインを参照	Coded With Equivalents (CE)	code=SystemVersion=Character String (ST)	値	/MCC1_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3/MCC1_IN200100UV01.xsd]/PDRR_IN049016UV1[controlActProcess/@classCode=CACT][@moodCode=EVN]/subject/@typeCode=SUBJ[1]/investigationEvent/@classCode=INVS[1][@moodCode=EVN]/component/@typeCode=COMP[1]/adverseEventAssessment[1]/adverseEventAssessment/@classCode=INVS[1][@moodCode=EVN]/subject[1]/primaryRole/@classCode=INVS[1][@moodCode=EVN]/organizer/@code=4[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][K]/substanceAdministration/@classCode=SBADM[1][@moodCode=EVN]/consumable/@typeCode=CSM[1][instanceOfKind/@classCode=INST]/kindOfProduct/@classCode=MMA[1][@determinerCode=KIND]/code/@codeSystem=TBD-PhPID]/codeSystemVersion

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e	G.k.2.1.2b	経刺識別子 (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=urn:hl7-org:v3 MCCl_IN200100UV01.xsd]/P/RR_IN049016UV/j/controlActProcess/@classCode=CACT][@moo dCode=EVN]/subject/@typeCode=SUBJ][j/investigationEvent/@classCode=INVTG][@moodCo de=EVN]/component/@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment /@classCode=INVTG][@moodCode=EVN]/subject[1]/primaryRole/@classC ode=INVSBJ]/subjectOrZi/@typeCode=SBJ]/organizer/code[4][@codeSystem=2.16.840.1 .113883.3.989.2.1.1.20][1]/organizer/@classCode=CATEGORY][@moodCode=EVN]/component /@typeCode=COMP][substanceAdministration/fd[k]/substanceAdministration/@classCode=SBADM][@moodCode=EVN]/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 Part (ENXP)	値	/MCCl_IN200100UV01@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCl_IN200100UV01.xsd]/P/RR_IN049016UV/j/controlActProcess/@classCode=CACT][@moo dCode=EVN]/subject/@typeCode=SUBJ][j/investigationEvent/@classCode=INVTG][@moodCo de=EVN]/component/@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment /@classCode=INVTG][@moodCode=EVN]/subject[1]/primaryRole/@classC ode=INVSBJ]/subjectOrZi/@typeCode=SBJ]/organizer/code[4][@codeSystem=2.16.840.1 .113883.3.989.2.1.1.20][1]/organizer/@classCode=CATEGORY][@moodCode=EVN]/component /@typeCode=COMP][substanceAdministration/fd[k]/substanceAdministration/@classCode=SBADM][@moodCode=EVN]/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 (必要に依り繰り返す)				繰り返し ノード	/MCCl_IN200100UV01@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCl_IN200100UV01.xsd]/P/RR_IN049016UV/j/controlActProcess/@classCode=CACT][@moo dCode=EVN]/subject/@typeCode=SUBJ][j/investigationEvent/@classCode=INVTG][@moodCo de=EVN]/component/@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment /@classCode=INVTG][@moodCode=EVN]/subject[1]/primaryRole/@classC ode=INVSBJ]/subjectOrZi/@typeCode=SBJ]/organizer/code[4][@codeSystem=2.16.840.1 .113883.3.989.2.1.1.20][1]/organizer/@classCode=CATEGORY][@moodCode=EVN]/component /@typeCode=COMP][substanceAdministration/fd[k]/substanceAdministration/@classCode=SBADM][@moodCode=EVN]/consumable/@typeCode=CSM][1]/instanceOfKind/@classCode=INST]/kind OfProduct/@classCode=MMAAT][@determinerCode=KIND]/ingredIdent/@classCode=ACT][1]
e	G.k.2.3.r.1	成分/特定成分名	250AN	Trivial Name (TN)	name=Entity Part (ENXP)	値	/MCCl_IN200100UV01@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCl_IN200100UV01.xsd]/P/RR_IN049016UV/j/controlActProcess/@classCode=CACT][@moo dCode=EVN]/subject/@typeCode=SUBJ][j/investigationEvent/@classCode=INVTG][@moodCo de=EVN]/component/@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment /@classCode=INVTG][@moodCode=EVN]/subject[1]/primaryRole/@classC ode=INVSBJ]/subjectOrZi/@typeCode=SBJ]/organizer/code[4][@codeSystem=2.16.840.1 .113883.3.989.2.1.1.20][1]/organizer/@classCode=CATEGORY][@moodCode=EVN]/component /@typeCode=COMP][substanceAdministration/fd[k]/substanceAdministration/@classCode=SBADM][@moodCode=EVN]/consumable/@typeCode=CSM][1]/instanceOfKind/@classCode=INST]/kind OfProduct/@classCode=MMAAT][@determinerCode=KIND]/ingredIdent/@classCode=ACT][1]/ingre dientSubstance/@classCode=MMAAT][@determinerCode=KIND]/name[1]/text()

(別添 3)

<p>e</p> <p>G.k.2.3.r.2a</p>	<p>成分/特定成分の ID パー ジョン日付/番号</p>	<p>M5 ガイド ラインを参 照</p>	<p>Coded With Equivalents (CE)</p>	<p>codeSystemVersion= Character String (ST)</p>	<p>値</p>	<pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 dCode=EVN]/subject/@typeCode=SUBJ][1]/investigationEvent/@classCode=CACT][@moodCo de=EVN]/component/@typeCode=COMP][adverseEventAssessment][1]/adverseEventAssessment /@classCode=INVTG][@moodCode=EVN]/subject/@typeCode=SBJ][1]/primaryRole/@classC ode=INVSBJ]/subjectOriz/@typeCode=SBJ][organizer/code/@code=4][@codeSystem=2.16.840.1 .113883.3.988.2.1.1.20][1]/organizer/@classCode=CATEGORY][@moodCode=EVN]/component[@typeCode=COMP][substanceAdministration/ k /substanceAdministration/@classCode=SBADM][@moodCode=EVN]/consumable/@typeCode=CSM][1]/instanceOfKind/@classCode=INST][kind OP/duct/@classCode=MMA][1]/determinerCode=KIND]/ingredient/@classCode=ACT][r]/ingre dientSubstance/@classCode=MMA][1]/determinerCode=KIND]/code/@codeSystem=TBD-Substa nce]/@codeSystemVersion </pre>
<p>e</p> <p>G.k.2.3.r.2b</p>	<p>成分/特定成分の ID</p>	<p>M5 ガイド ラインを参 照</p>	<p>Coded With Equivalents (CE)</p>	<p>code=Character String (ST)</p>	<p>値</p>	<pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 dCode=EVN]/subject/@typeCode=SUBJ][1]/investigationEvent/@classCode=CACT][@moo dCode=EVN]/component/@typeCode=COMP][adverseEventAssessment][1]/adverseEventAssessment /@classCode=INVTG][@moodCode=EVN]/subject/@typeCode=SBJ][1]/primaryRole/@classC ode=INVSBJ]/subjectOriz/@typeCode=SBJ][organizer/code/@code=4][@codeSystem=2.16.840.1 .113883.3.988.2.1.1.20][1]/organizer/@classCode=CATEGORY][@moodCode=EVN]/component[@typeCode=COMP][substanceAdministration/ k /substanceAdministration/@classCode=SBADM][@moodCode=EVN]/consumable/@typeCode=CSM][1]/instanceOfKind/@classCode=INST][kind OP/duct/@classCode=MMA][1]/determinerCode=KIND]/ingredient/@classCode=ACT][r]/ingre dientSubstance/@classCode=MMA][1]/determinerCode=KIND]/code/@codeSystem=TBD-Substa nce]/@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> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 dCode=EVN]/subject/@typeCode=SUBJ][1]/investigationEvent/@classCode=CACT][@moo dCode=EVN]/component/@typeCode=COMP][adverseEventAssessment][1]/adverseEventAssessment /@classCode=INVTG][@moodCode=EVN]/subject/@typeCode=SBJ][1]/primaryRole/@classC ode=INVSBJ]/subjectOriz/@typeCode=SBJ][organizer/code/@code=4][@codeSystem=2.16.840.1 .113883.3.988.2.1.1.20][1]/organizer/@classCode=CATEGORY][@moodCode=EVN]/component[@typeCode=COMP][substanceAdministration/ k /substanceAdministration/@classCode=SBADM][@moodCode=EVN]/consumable/@typeCode=CSM][1]/instanceOfKind/@classCode=INST][kind OP/duct/@classCode=MMA][1]/determinerCode=KIND]/ingredient/@classCode=ACT][r]/quant ityDenominator/@value="1"/numerator/@value </pre>
<p>e</p> <p>G.k.2.3.r.3b</p>	<p>含量 (単位)</p>	<p>50AN</p>	<p>Physical Quantity (PQ)</p>	<p>unit=Coded Simple Value (CS)</p>	<p>値</p>	<pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 dCode=EVN]/subject/@typeCode=SUBJ][1]/investigationEvent/@classCode=CACT][@moo dCode=EVN]/component/@typeCode=COMP][adverseEventAssessment][1]/adverseEventAssessment /@classCode=INVTG][@moodCode=EVN]/subject/@typeCode=SBJ][1]/primaryRole/@classC ode=INVSBJ]/subjectOriz/@typeCode=SBJ][organizer/code/@code=4][@codeSystem=2.16.840.1 .113883.3.988.2.1.1.20][1]/organizer/@classCode=CATEGORY][@moodCode=EVN]/component[@typeCode=COMP][substanceAdministration/ k /substanceAdministration/@classCode=SBADM][@moodCode=EVN]/consumable/@typeCode=CSM][1]/instanceOfKind/@classCode=INST][kind OP/duct/@classCode=MMA][1]/determinerCode=KIND]/ingredient/@classCode=ACT][r]/quant ityDenominator/@value="1"/numerator/@unit </pre>

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e	G.k.2.4	医薬品を入手した国の識別 2A	Postal Address (AD)	country=Address Part (ADXP)	値 /MCCL_IN200100UV01[(@ITSVersion=XML_1.0)]/@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd/y/PORR_IN049016UVJ/control/ActProcess[(@classCode=CACT)]/@moodCode=EVN/y/subject[(@typeCode=SUBJ)]/investigationEvent[(@classCode=INVESTG)]/@moodCode=EVN/y/component[(@typeCode=COMP)]/adverseEventAssessment[1]/adverseEventAssessment[(@classCode=INVESTG)]/@moodCode=EVN/y/subject[1]/primaryRole[(@classCode=INVSBJ)]/subjectOf[2]/typeCode=SBJ/y/organizer/code[4]/@codeSystem=2.16.840.1.113883.3.989.2.1.1.20]]/organizer[(@classCode=CATEGORY)]/@moodCode=EVN/y/component[1]/typeCode=COMP/y/substanceAdministration[1]/substanceAdministration[(@classCode=INST)]/subjectOf[1]/typeCode=SBJ/y/productEvent[(@classCode=ACT)]/@moodCode=EVN/y/code[(@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/y/addr/country[1]/text()
e	G.k.2.5	治験薬の盲検状況 ブール型	Boolean (BL)	値 /MCCL_IN200100UV01[(@ITSVersion=XML_1.0)]/@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd/y/PORR_IN049016UVJ/control/ActProcess[(@classCode=CACT)]/@moodCode=EVN/y/subject[(@typeCode=SUBJ)]/investigationEvent[(@classCode=INVESTG)]/@moodCode=EVN/y/component[(@typeCode=COMP)]/adverseEventAssessment[1]/adverseEventAssessment[(@classCode=INVESTG)]/@moodCode=EVN/y/subject[1]/primaryRole[(@classCode=INVSBJ)]/subjectOf[2]/typeCode=SBJ/y/organizer/code[4]/@codeSystem=2.16.840.1.113883.3.989.2.1.1.20]]/organizer[(@classCode=CATEGORY)]/@moodCode=EVN/y/component[1]/typeCode=COMP/y/substanceAdministration[1]/substanceAdministration[(@classCode=SBADM)]/@moodCode=EVN/y/outboundRelationship[2]/typeCode=PERT/y/observation/code[6]/@codeSystem=2.16.840.1.113883.3.989.2.1.1.19]]/observation[(@classCode=OBS)]/@moodCode=EVN/y/value[(@xsi:type=BL)]/@value	
h	G.k.3	医薬品の承認の取得者及び承認/申請番号			
e	G.k.3.1	承認/申請番号 35AN	Instance Identifier (II)	extension=Character String (ST)	値 /MCCL_IN200100UV01[(@ITSVersion=XML_1.0)]/@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd/y/PORR_IN049016UVJ/control/ActProcess[(@classCode=CACT)]/@moodCode=EVN/y/subject[(@typeCode=SUBJ)]/investigationEvent[(@classCode=INVESTG)]/@moodCode=EVN/y/component[(@typeCode=COMP)]/adverseEventAssessment[1]/adverseEventAssessment[(@classCode=INVESTG)]/@moodCode=EVN/y/subject[1]/primaryRole[(@classCode=INVSBJ)]/subjectOf[2]/typeCode=SBJ/y/organizer/code[4]/@codeSystem=2.16.840.1.113883.3.989.2.1.1.20]]/organizer[(@classCode=CATEGORY)]/@moodCode=EVN/y/component[1]/typeCode=COMP/y/substanceAdministration[1]/substanceAdministration[(@classCode=SBADM)]/@moodCode=EVN/y/consumable[(@typeCode=CSM)]/instanceOfKind[(@classCode=INST)]/kindOfProduct[(@classCode=MMACT)]/@determinerCode=KIND/y/manufacturedProduct[(@classCode=MANU)]/subjectOf[(@typeCode=SBJ)]/approval[(@classCode=CNTRCT)]/@moodCode=EVN/y/id/@root=2.16.840.1.113883.3.989.2.1.3.4/y/@extension

<p>e</p> <p>G.k.3.2</p> <p>承認/申請国</p> <p>2A</p> <p>Coded With Equivalent(s) (CE)</p> <p>code=Character String (ST)</p> <p>値</p>	<p>/MCC1_IN200100UV01@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCC1_IN200100UV01.xsd]/PDRR_IN049016UV[controlActProcess/@classCode=CACT][@moo dCode=EVN]/subject/@typeCode=SUBJ[1]/investigationEvent/@classCode=INVTG[1]@moodCo de=EVN]/component/@typeCode=COMP[adverseEventAssessment[1]/adverseEventAssessment /@classCode=INVTG[1]@moodCode=EVN]/subject[1]/typeCode=SBJ[1]/primaryRole/@classC ode=INVSBJ[1]/subjectO2/@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/@classCode=SBADM[1]@moodCode=EVN]/kind /@moodCode=EVN]/consument/@typeCode=CSM[1]/instanceOfKind/@classCode=INSTY[1]kind /@typeCode=COMP[1]/substanceAdministration/@classCode=SBADM[1]@moodCode=EVN]/aut MANU[1]/subjectOf/@typeCode=SBJ[1]/approval/@classCode=CTRCT[1]@moodCode=EVN]/aut hot/@typeCode=AUT[1]/territorialAuthority/@classCode=TERR[1]/territory/@classCode=NAT[1]@date mlinerCode=INSTANCE][code/@codeSystem=1.0.3.166.1.2.2][@code</p>				
<p>e</p> <p>G.k.3.3</p> <p>承認の取得者/申請者の名 称</p> <p>60AN</p> <p>Organization Name (ON)</p> <p>name=Entity Name Part (ENXP)</p> <p>値</p>	<p>/MCC1_IN200100UV01@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCC1_IN200100UV01.xsd]/PDRR_IN049016UV[controlActProcess/@classCode=CACT][@moo dCode=EVN]/subject/@typeCode=SUBJ[1]/investigationEvent/@classCode=INVTG[1]@moodCo de=EVN]/component/@typeCode=COMP[adverseEventAssessment[1]/adverseEventAssessment /@classCode=INVTG[1]@moodCode=EVN]/subject[1]/typeCode=SBJ[1]/primaryRole/@classC ode=INVSBJ[1]/subjectO2/@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/@classCode=SBADM[1]@moodCode=EVN]/kind /@moodCode=EVN]/consument/@typeCode=CSM[1]/instanceOfKind/@classCode=INSTY[1]kind /@typeCode=COMP[1]/substanceAdministration/@classCode=SBADM[1]@moodCode=EVN]/hol def/@typeCode=HLD[1]/role/@classCode=HLDR[1]/playingOrganization/@classCode=ORG[1]@date mlinerCode=INSTANCE][name/text()</p>				
<p>h</p> <p>G.k.4.r</p> <p>投与量及び関連情報 (必要に 応じ繰り返し)</p> <p>繰り返し ノード</p>	<p>/MCC1_IN200100UV01@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCC1_IN200100UV01.xsd]/PDRR_IN049016UV[controlActProcess/@classCode=CACT][@moo dCode=EVN]/subject/@typeCode=SUBJ[1]/investigationEvent/@classCode=INVTG[1]@moodCo de=EVN]/component/@typeCode=COMP[adverseEventAssessment[1]/adverseEventAssessment /@classCode=INVTG[1]@moodCode=EVN]/subject[1]/typeCode=SBJ[1]/primaryRole/@classC ode=INVSBJ[1]/subjectO2/@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/@classCode=SBADM[1]@moodCode=EVN] /@typeCode=EVN]/substanceAdministration/@classCode=SBADM[1]@moodCode=EVN]/sub stanceAdministration/@classCode=SBADM[1]@moodCode=EVN]/doseQuantity/@value</p>				
<p>e</p> <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>	<p>/MCC1_IN200100UV01@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCC1_IN200100UV01.xsd]/PDRR_IN049016UV[controlActProcess/@classCode=CACT][@moo dCode=EVN]/subject/@typeCode=SUBJ[1]/investigationEvent/@classCode=INVTG[1]@moodCo de=EVN]/component/@typeCode=COMP[adverseEventAssessment[1]/adverseEventAssessment /@classCode=INVTG[1]@moodCode=EVN]/subject[1]/typeCode=SBJ[1]/primaryRole/@classC ode=INVSBJ[1]/subjectO2/@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/@classCode=SBADM[1]@moodCode=EVN] /@typeCode=EVN]/substanceAdministration/@classCode=SBADM[1]@moodCode=EVN]/sub stanceAdministration/@classCode=SBADM[1]@moodCode=EVN]/doseQuantity/@value</p>				

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e		B.4.k.4.r.3 の単位が 合計の場合： Physical Quantity (PQ)	値	/MCC1_IN200100UV01[@ITSVersion='XML_1.0']/@xsi:schemaLocation='urn:hl7-org:v3 MCC1_IN200100UV01.xsd'/PORR_IN049016UVJ/controlActProcess[@classCode='CACTI']/@moodCode='EVN'/subject/@typeCode='SUBJ' /investigationEvent[@classCode='INVESTG']/@moodCode='EVN'/component/@typeCode='COMP' adverseEventAssessment[1]/adverseEventAssessment[@classCode='INVESTG']/@moodCode='EVN'/subject1/@typeCode='SBJ' /primaryRole[@classCode='INVSBJ']/subjectOr2/@typeCode='SBJ' organizer/code/@code='4' @codesSystem='2.16.840.1-113883.3.989.2.1.1.20' /organizer/@classCode='CATEGORY' /moodCode='EVN'/component/@typeCode='COMP' substanceAdministration[id]/k/substanceAdministration[@classCode='SBADM']/@moodCode='EVN'/outboundRelationship2/@typeCode='COMP' substanceAdministration[id]/substanceAdministration[@classCode='SBADM']/@moodCode='EVN'/doseCheckQuantity/denominator/@xsi:type='PQ' /numerator/@xsi:type='PQ']@value
e	G.k.4.r.1b 投与量 (単位)	Physical Quantity (PQ)	値	/MCC1_IN200100UV01[@ITSVersion='XML_1.0']/@xsi:schemaLocation='urn:hl7-org:v3 MCC1_IN200100UV01.xsd'/PORR_IN049016UVJ/controlActProcess[@classCode='CACTI']/@moodCode='EVN'/subject/@typeCode='SUBJ' /investigationEvent[@classCode='INVESTG']/@moodCode='EVN'/component/@typeCode='COMP' adverseEventAssessment[1]/adverseEventAssessment[@classCode='INVESTG']/@moodCode='EVN'/subject1/@typeCode='SBJ' /primaryRole[@classCode='INVSBJ']/subjectOr2/@typeCode='SBJ' organizer/code/@code='4' @codesSystem='2.16.840.1-113883.3.989.2.1.1.20' /organizer/@classCode='CATEGORY' /moodCode='EVN'/component/@typeCode='COMP' substanceAdministration[id]/k/substanceAdministration[@classCode='SBADM']/@moodCode='EVN'/outboundRelationship2/@typeCode='COMP' substanceAdministration[id]/substanceAdministration[@classCode='SBADM']/@moodCode='EVN'/doseQuantity/@unit
e		B.4.k.4.r.3 の単位が 合計の場合： Physical Quantity (PQ)	値	/MCC1_IN200100UV01[@ITSVersion='XML_1.0']/@xsi:schemaLocation='urn:hl7-org:v3 MCC1_IN200100UV01.xsd'/PORR_IN049016UVJ/controlActProcess[@classCode='CACTI']/@moodCode='EVN'/subject/@typeCode='SUBJ' /investigationEvent[@classCode='INVESTG']/@moodCode='EVN'/component/@typeCode='COMP' adverseEventAssessment[1]/adverseEventAssessment[@classCode='INVESTG']/@moodCode='EVN'/subject1/@typeCode='SBJ' /primaryRole[@classCode='INVSBJ']/subjectOr2/@typeCode='SBJ' organizer/code/@code='4' @codesSystem='2.16.840.1-113883.3.989.2.1.1.20' /organizer/@classCode='CATEGORY' /moodCode='EVN'/component/@typeCode='COMP' substanceAdministration[id]/k/substanceAdministration[@classCode='SBADM']/@moodCode='EVN'/outboundRelationship2/@typeCode='COMP' substanceAdministration[id]/substanceAdministration[@classCode='SBADM']/@moodCode='EVN'/doseCheckQuantity/denominator/@xsi:type='PQ' /numerator/@xsi:type='PQ']@unit

<p>e</p> <p>G.k.4.r.2</p>	<p>G.k.4.r.2</p> <p>投与間隔の単位数</p> <p>4N</p>	<p>1.以下の子データ項目の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</p> <p>Parenthetic Set Expression of Time (SXPР_TS) [Periodic Interval of Time (PVL_TS)]</p>	<p>値</p> <p>period/value=Real Number (REAL)</p>	<pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=um:hl7-019:v3 MCCL_IN200100UV01.xsd]/PORR_IN049016UV/r/controlAct/process[@classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUBJ]/investigationEvent[@classCode=INVSTG][@moodCode=EVN]/component[@typeCode=COMP]/adverseEventAssessment[1]/adverseEventAssessment[@classCode=INVSTG][@moodCode=EVN]/subject1[@typeCode=SBJ][1]/primaryRole[@classCode=INVSBJ/subjectOf2][@typeCode=SBJ][organizer/code/@code=4][@codeSystem=2.16.840.1.113883.3.989.2.1.1.20][1]/organizer[@classCode=CATEGORY][@moodCode=EVN]/component[1]/typeCode=COMP/substanceAdministration[id]/substanceAdministration[@classCode=SBADM][@moodCode=EVN]/outboundRelationship2[@typeCode=COMP]/substanceAdministration[1]/substanceAdministration[@classCode=SBADM][@moodCode=EVN]/effectiveTime[@xsi:type=SXPР_TS]/comp[@xsi:type=PVL_TS]/period/@value </pre>
		<p>2.以下の子データ項目の2つを超える値が表示される場合： 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</p> <p>Parenthetic Set Expression of Time (SXPР_TS) [Periodic Interval of Time (PVL_TS)]</p>	<p>値</p>	<pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=um:hl7-019:v3 MCCL_IN200100UV01.xsd]/PORR_IN049016UV/r/controlAct/process[@classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUBJ]/investigationEvent[@classCode=INVSTG][@moodCode=EVN]/component[@typeCode=COMP]/adverseEventAssessment[1]/adverseEventAssessment[@classCode=INVSTG][@moodCode=EVN]/subject1[@typeCode=SBJ][1]/primaryRole[@classCode=INVSBJ/subjectOf2][@typeCode=SBJ][organizer/code/@code=4][@codeSystem=2.16.840.1.113883.3.989.2.1.1.20][1]/organizer[@classCode=CATEGORY][@moodCode=EVN]/component[1]/typeCode=COMP/substanceAdministration[id]/substanceAdministration[@classCode=SBADM][@moodCode=EVN]/outboundRelationship2[@typeCode=COMP]/substanceAdministration[1]/substanceAdministration[@classCode=SBADM][@moodCode=EVN]/effectiveTime[@xsi:type=SXPР_TS]/comp[@xsi:type=PVL_TS]/operator/@value </pre>

<p>3.以下の子ータ項目の1つの値のみが表示される場合</p> <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>/MCCI_IN200100UV01[@ITSVersion='XML_1.0']/@xsi:schemaLocation='urn:hi7-org:v3 MCCI_IN200100UV01.xsd'/PARR_IN049016UV/r/controlAct/process[@classCode='CACT']/@moodCode='EVN'/subject/@typeCode='SUBJ'[/investigationEvent/@classCode='INVESTG']/@moodCode='EVN'/component/@typeCode='COMP'[/adverseEventAssessment[/adverseEventAssessment/@classCode='INVESTG']/@moodCode='EVN']/subject/@typeCode='SBJ'[/primaryRole/@classCode='INVSBJ']/subject/@typeCode='SBJ'[/organizer/@code='4']/@codeSystem='2,16,840,113883,3,989,2,1,1,20'][/organizer/@classCode='CATEGORY']/@moodCode='EVN']/component/@typeCode='COMP'[/substanceAdministration/r/substanceAdministration/@classCode='SBADM']/@moodCode='COMP'[/substanceAdministration/@xsi:type='PVL_TS']/period/@value</pre>
<p>1.以下の子ータ項目の2つの値が表示される場合</p> <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>子ータ型 SXPР を伴う最初の comp 項目</p> <p>Parenthetic Set Expression of Time (SXPР_TS) [Periodic Interval of Time (PVL_TS)]</p>	<p>値</p> <p>period/units=Coded Simple Value (CS)</p>	<pre>/MCCI_IN200100UV01[@ITSVersion='XML_1.0']/@xsi:schemaLocation='urn:hi7-org:v3 MCCI_IN200100UV01.xsd'/PARR_IN049016UV/r/controlAct/process[@classCode='CACT']/@moodCode='EVN'/subject/@typeCode='SUBJ'[/investigationEvent/@classCode='INVESTG']/@moodCode='EVN'/component/@typeCode='COMP'[/adverseEventAssessment[/adverseEventAssessment/@classCode='INVESTG']/@moodCode='EVN']/subject/@typeCode='SBJ'[/organizer/@code='4']/@codeSystem='2,16,840,113883,3,989,2,1,1,20'][/organizer/@classCode='CATEGORY']/@moodCode='EVN']/component/@typeCode='COMP'[/substanceAdministration/r/substanceAdministration/@classCode='SBADM']/@moodCode='COMP'[/substanceAdministration/@xsi:type='SXPР_TS']/comp/@xsi:type='PVL_TS']/period/@unit</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 を伴う 2 番目の comp 項目</p> <p>Parenthetic Set Expression of Time (SXPR_TS) [Periodic Interval of Time (PVL_TS)]</p>	<p>値</p> <pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/PORR_IN049016UV1/controlAcipProcess[@classCode=CACTI][@moodCode=EVN]/subject[@typeCode=SUBJ][@investigationEvent[@classCode=INVESTG][@moodCode=EVN]/component[@typeCode=COMP][adverseEventAssessment[1]adverseEventAssessment[@classCode=INVESTG][@typeCode=EVN]/subject1[@typeCode=SBJ][1]primaryRole[@classCode=INVSBJ]/subjectOr2[@typeCode=SBJ][organizerCode=4][@codesSystem=2.16.840.1.113883.3.988.2.1.1.20][1]organizer[@classCode=CATEGORY][@moodCode=EVN]/component[1]@typeCode=COMP][substanceAdministration[id][k]/substanceAdministration[@classCode=SBADM][@moodCode=EVN]/outboundRelationship2[@typeCode=COMP][substanceAdministration][j]/substanceAdministration[@classCode=SBADM][@moodCode=EVN]/effectiveTime[@xsi:type=SXPR_TS]/comp[@xsi:type=PVL_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 (PVL_TS)</p>	<p>値</p> <pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/PORR_IN049016UV1/controlAcipProcess[@classCode=CACTI][@moodCode=EVN]/subject[@typeCode=SUBJ][@investigationEvent[@classCode=INVESTG][@moodCode=EVN]/component[@typeCode=COMP][adverseEventAssessment[1]adverseEventAssessment[@classCode=INVESTG][@typeCode=EVN]/subject1[@typeCode=SBJ][1]primaryRole[@classCode=INVSBJ]/subjectOr2[@typeCode=SBJ][organizerCode=4][@codesSystem=2.16.840.1.113883.3.988.2.1.1.20][1]organizer[@classCode=CATEGORY][@moodCode=EVN]/component[1]@typeCode=COMP][substanceAdministration[id][k]/substanceAdministration[@classCode=SBADM][@moodCode=EVN]/outboundRelationship2[@typeCode=COMP][substanceAdministration][j]/substanceAdministration[@classCode=SBADM][@moodCode=EVN]/effectiveTime[@xsi:type=PVL_TS]/period/@unit </pre> <p>period/unit=Coded Simple Value (CS)</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>値</p> <p>low=Interval Boundary (VXB)</p>	<p>日付/時間</p> <p>医薬品の投与開始日</p>	<p>G.k.4.r.4</p>	<pre> /MCCI_IN200100UV01/@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UV/r/controlActProcess[@classCode=CACT][@moodCode=EYN]/subject[@typeCode=SUBJ/1]/investigationEvent[@classCode=INVESTC][@moodCode=EYN]/component[@typeCode=COMP/1]/adverseEventAssessment[1]/adverseEventAssessment[@classCode=INVESTC][@moodCode=EVN]/subject[1]/primaryRole[@classCode=SBJ/1]/organizer[@code=4][@codeSystem=2,16,840.113883.3.989.2.1.1.20][1]/organization[@classCode=CATEGORY][@moodCode=EVN]/component[1]/typeCode=COMP/1/substanceAdministration[@classCode=SBADM][@moodCode=EVN]/outboundRelationship2[@typeCode=COMP/1/substanceAdministration][r/substanceAdministration[@classCode=SBADM][@moodCode=EVN]/effectiveTime[@xsi:type=XPRTS]/comp[@xsi:type=IVL_TS]/low/@value </pre>
<p>データ型 SXPRT を伴う最初の comp 項目</p> <p>Parenthetic Set Expression of Time (SXPRTS) [Interval of Point in Time (IVL_TS)]</p>	<p>NullFlavor</p>	<p>日付/時間</p>	<p>G.k.4.r.4</p>	<pre> /MCCI_IN200100UV01/@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UV/r/controlActProcess[@classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUBJ/1]/investigationEvent[@classCode=INVESTC][@moodCode=EYN]/component[@typeCode=COMP/1]/adverseEventAssessment[1]/adverseEventAssessment[@classCode=INVESTC][@moodCode=EVN]/subject[1]/primaryRole[@classCode=SBJ/1]/organizer[@code=4][@codeSystem=2,16,840.113883.3.989.2.1.1.20][1]/organization[@classCode=CATEGORY][@moodCode=EVN]/component[1]/typeCode=COMP/1/substanceAdministration[@classCode=SBADM][@moodCode=EVN]/outboundRelationship2[@typeCode=COMP/1/substanceAdministration][r/substanceAdministration[@classCode=SBADM][@moodCode=EVN]/effectiveTime[@xsi:type=XPRTS]/comp[@xsi:type=IVL_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.8a, G.k.4.r.8b <p>データ型 SXPР を伴う 2 項目の comp 項目</p> <p>Parenthetic Set Expression of Time (SXPР_TS) [interval of Point in Time (IVL_TS)]</p>	<p>値</p>	<pre> /MCCI_IN200100UV01[@ITSVersion='XML_1.0']/@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd'/PORR_IN049016UV1/controlActProcess[@classCode='CACT']/@moodCode='EVN']/subject[@typeCode='SUBJ']/investigationEvent[@classCode='INVTG']/@moodCode='EVN']/component[@typeCode='COMP']/adverseEventAssessment[1]/adverseEventAssessment[@classCode='INVTG']/@moodCode='EVN']/subject1[@typeCode='SBJ']/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ']/organizer/code=4'[@codesSystem='2.16.840.1.113883.3.989.2.1.1.20']/organizer/@classCode='CATEGORY'[@moodCode='EVN']/component[1]/typeCode='COMP']/substanceAdministration[id]/substanceAdministration/@classCode='SBADM'[@moodCode='EVN']/effectiveTime/@xsi:type='SXPР_TS']/comp[@xsi:type='IVL_TS']/@operator='A'/low/@value </pre>
		<pre> /MCCI_IN200100UV01[@ITSVersion='XML_1.0']/@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd'/PORR_IN049016UV1/controlActProcess[@classCode='CACT']/@moodCode='EVN']/subject[@typeCode='SUBJ']/investigationEvent[@classCode='INVTG']/@moodCode='EVN']/component[@typeCode='COMP']/adverseEventAssessment[1]/adverseEventAssessment[@classCode='INVTG']/@moodCode='EVN']/subject1[@typeCode='SBJ']/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ']/organizer/code=4'[@codesSystem='2.16.840.1.113883.3.989.2.1.1.20']/organizer/@classCode='CATEGORY'[@moodCode='EVN']/component[1]/typeCode='COMP']/substanceAdministration[id]/substanceAdministration/@classCode='SBADM'[@moodCode='EVN']/effectiveTime/@xsi:type='SXPР_TS']/comp[@xsi:type='IVL_TS']/@operator='A'/low/@nullFlavor </pre> <p>NullFlavor</p>

(別添 3)

<pre> /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UVJr/control/ActProcess[@classCode=CACT][@moo dCode=EVN]/subject/@typeCode=SUBJ[1]/investigationEvent/@classCode=INVSTG[1]/moodCo de=EVN/component/@typeCode=COMP[1]/adverseEventAssessment[1]/adverseEventAssessment [@classCode=INVSTG][@moodCode=EVN]/subject/@typeCode=SBJ[1]/primaryRole/@classC ode=INVSBJ[1]/subjectOf/@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]/@moodCode=COMP[1]/substanceAdministration[id]/substanceAdministration[@classCode=SBADM][@typeCode=EVN]/outboundRelationship2[1]/typeCode=COMP[1]/substanceAdministration[1]/sub stanceAdministration[@classCode=SBADM][@moodCode=EVN]/effectiveTime/@xsi:type=SXP R_ TS/comp/@xsi:type=IVL_TS/high/@nullFlavor </pre>	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:</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 SXP R を伴 う 2 番目の comp 目</p> <p>Parenthetic Set Expression of Time (SXP_TS) [Interval of Point in Time (IVL_TS)]</p>	<pre> /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UVJr/control/ActProcess[@classCode=CACT][@moo dCode=EVN]/subject/@typeCode=SUBJ[1]/investigationEvent/@classCode=INVSTG[1]/moodCo de=EVN/component/@typeCode=COMP[1]/adverseEventAssessment[1]/adverseEventAssessment [@classCode=INVSTG][@moodCode=EVN]/subject/@typeCode=SBJ[1]/primaryRole/@classC ode=INVSBJ[1]/subjectOf/@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]/@moodCode=COMP[1]/substanceAdministration[id]/substanceAdministration[@classCode=SBADM][@typeCode=EVN]/outboundRelationship2[1]/typeCode=COMP[1]/substanceAdministration[1]/sub stanceAdministration[@classCode=SBADM][@moodCode=EVN]/effectiveTime/@xsi:type=SXP R_ TS/comp/@xsi:type=IVL_TS][@operator=A]/high/@value </pre>	NullFlavor
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<p>e</p>	<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>high=Interval Boundary (IVXB)</p>	<p>値</p> <pre> /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PDRR_IN049016UV/r/controlActProcess[@classCode=CACT][@moodCode=EVN]/subject/@typeCode="SUBJ"/investigationEvent[@classCode=INVTG][@moodCode=EVN]/component/@typeCode="SBJ"/adverseEventAssessment[1]/adverseEventAssessment[@classCode=INVTG][@moodCode="EVN"]/subject1/@typeCode="SBJ"/primaryRole/@classCode=INVSBJ/subjectC2/@typeCode="SBJ"/organizer/@code="4"/@codeSystem="2.16.840.1.113883.3.988.2.1.1.20"/organizer/@classCode="CATEGORY"/@moodCode="EVN"/component1/@typeCode="COMP"/substanceAdministration[id][K]/substanceAdministration[@classCode=SBADM][@moodCode="EVN"]/outboundRelationship2[@typeCode="COMP"/substanceAdministration]/substanceAdministration[@classCode=SBADM][@moodCode="EVN"]/effectiveTime/@xsi:type="IVL_TS"/high/@value </pre>
<p>e</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"> 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>width/value=Real Number (REAL)</p>	<p>NullFlavor</p> <pre> /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PDRR_IN049016UV/r/controlActProcess[@classCode=CACT][@moodCode=EVN]/subject/@typeCode="SUBJ"/investigationEvent[@classCode=INVTG][@moodCode=EVN]/component/@typeCode="COMP"/adverseEventAssessment[1]/adverseEventAssessment[@classCode=INVTG][@moodCode="EVN"]/subject1/@typeCode="SBJ"/primaryRole/@classCode=INVSBJ/subjectC2/@typeCode="SBJ"/organizer/@code="4"/@codeSystem="2.16.840.1.113883.3.988.2.1.1.20"/organizer/@classCode="CATEGORY"/@moodCode="EVN"/component1/@typeCode="COMP"/substanceAdministration[id][K]/substanceAdministration[@classCode=SBADM][@moodCode="EVN"]/outboundRelationship2[@typeCode="COMP"/substanceAdministration]/substanceAdministration[@classCode=SBADM][@moodCode="EVN"]/effectiveTime/@xsi:type="IVL_TS"/high/@nullFlavor </pre>
<p>e</p>	<p>5N 医薬品投与期間 (数)</p>	<p>Interval of Point in Time (IVL_TS)</p>	<p>width/value=Real Number (REAL)</p>	<p>値</p> <pre> /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PDRR_IN049016UV/r/controlActProcess[@classCode=CACT][@moodCode=EVN]/subject/@typeCode="SUBJ"/investigationEvent[@classCode=INVTG][@moodCode=EVN]/component/@typeCode="COMP"/adverseEventAssessment[1]/adverseEventAssessment[@classCode=INVTG][@moodCode="EVN"]/subject1/@typeCode="SBJ"/primaryRole/@classCode=INVSBJ/subjectC2/@typeCode="SBJ"/organizer/@code="4"/@codeSystem="2.16.840.1.113883.3.988.2.1.1.20"/organizer/@classCode="CATEGORY"/@moodCode="EVN"/component1/@typeCode="COMP"/substanceAdministration[id][K]/substanceAdministration[@classCode=SBADM][@moodCode="EVN"]/outboundRelationship2[@typeCode="COMP"/substanceAdministration]/substanceAdministration[@classCode=SBADM][@moodCode="EVN"]/effectiveTime/@xsi:type="SXPR_TS"/comp/@xsi:type="IVL_TS"/width/@value </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"> G.k.4.r.2, G.k.4.r.3 G.k.4.r.4 G.k.4.r.5 G.k.4.r.6a, G.k.4.r.6b <p>データ型 SXPР を伴う 2 番目の comp 項目</p> <p>Parenthetic Set Expression of Time (SXPР_TS) [Intervale of Point in Time {VL_TS}]</p>			<p>値</p> <pre> /MCCLI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCLI_IN200100UV01.xsd]/p/OPRR_IN049016UV1/p/controlActProcess[@classCode=CACTI][@mooodCode=EVN]/subject/@typeCode=SUBJ1/1/inverseEvent[@classCode=INVSTG1][@mooodCode=EVN]/component/@typeCode=COMP1/adverseEventAssessment[1]/adverseEventAssessment[@classCode=COMP1][@mooodCode=EVN]/subject1/@typeCode=SBJ1/1/primaryRole/@classCode=INVSBJ1/subjectOr2/@typeCode=SBJ1/organizer/code[@code=4][@codeSystem=2.16.840.1.113883.3.989.2.1.1.20][1]/organizer/@classCode=CATEGORY1/@mooodCode=EVN/component1/@classCode=COMP1/substanceAdministration[id][k]/substanceAdministration[@classCode=SBADM][@mooodCode=EVN]/outboundRelationship2/@typeCode=COMP1/substanceAdministration[id][r]/substanceAdministration[@classCode=SBADM][@mooodCode=EVN]/effectiveTime/@xsi:type=SXPР_TS/comp1/@xsi:type=VL_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"> 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 {VL_TS}</p>	<p>width/value=Real Number (REAL)</p>		<p>値</p> <pre> /MCCLI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCLI_IN200100UV01.xsd]/p/OPRR_IN049016UV1/p/controlActProcess[@classCode=CACTI][@mooodCode=EVN]/subject/@typeCode=SUBJ1/1/inverseEvent[@classCode=INVSTG1][@mooodCode=EVN]/component/@typeCode=COMP1/adverseEventAssessment[1]/adverseEventAssessment[@classCode=COMP1][@mooodCode=EVN]/subject1/@typeCode=SBJ1/1/primaryRole/@classCode=INVSBJ1/subjectOr2/@typeCode=SBJ1/organizer/code[@code=4][@codeSystem=2.16.840.1.113883.3.989.2.1.1.20][1]/organizer/@classCode=CATEGORY1/@mooodCode=EVN/component1/@classCode=COMP1/substanceAdministration[id][k]/substanceAdministration[@classCode=SBADM][@mooodCode=EVN]/outboundRelationship2/@typeCode=COMP1/substanceAdministration[id][r]/substanceAdministration[@classCode=SBADM][@mooodCode=EVN]/effectiveTime/@xsi:type=VL_TS/width/@value </pre>

<p>e</p> <p>G.k.4.r.6b</p>	<p>医薬品投与期間 (単位)</p> <p>50AN</p>	<p>1.以下の子一タ項目の2つを超える値が表示される場合:</p> <ol style="list-style-type: none"> 1) G.k.4.r.2, G.k.4.r.3 2) G.k.4.r.4 3) G.k.4.r.5 4) G.k.4.r.6a, G.k.4.r.6b <p>子一タ型 SXPР を伴う最初の comp 項目</p> <p>Parenthetic Set Expression of Time (SXPР_TS) [Interval of Point in Time (VL_TS)]</p>	<p>値</p> <p>width/unit=Coded Simple Value (CS)</p>	<pre> /MCCLI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCLI_IN200100UV01.xsd]/PDRR_IN049016UV[controlActProcess/@classCode=CACT][@mo dCode=EVN]/subject/@typeCode=SUBJ[investigationEvent/@classCode=INVTG][@mo dCode=EVN]/component/@typeCode=COMP[adverseEventAssessment[1]/adverseEventAssessm ent/@classCode=INVTG][@moodCode=EVN]/subject1/@typeCode=SBJ[1]/primaryRole/@class Code=INVSBJ/subjectO2/@typeCode=SBJ[organizer/code/@code=4][@codeSystem=2.16.840.1 13883.3.988.2.1.1.20][1]/organizer/@classCode=CATEGORY[1]/moodCode=EVN/component[1]/typeCode=COMP[1]/substanceAdministration[id][k]/substanceAdministration[1]/sub stanceAdministration/@classCode=SBADM[1]/moodCode=EVN[1]/effectiveTime/@xsi:type=SXPР_ TS/comp[1][@xsi:type=VL_TS]/width/@unit </pre>
		<p>2.以下の子一タ項目の2つを超える値が表示される場合:</p> <ol style="list-style-type: none"> 1) G.k.4.r.2, G.k.4.r.3 2) G.k.4.r.4 3) G.k.4.r.5 4) G.k.4.r.6a, G.k.4.r.6b <p>子一タ型 SXPР を伴う2番目の comp 項目</p> <p>Parenthetic Set Expression of Time (SXPР_TS) [Interval of Point in Time (VL_TS)]</p>	<p>値</p>	<pre> /MCCLI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCLI_IN200100UV01.xsd]/PDRR_IN049016UV[controlActProcess/@classCode=CACT][@mo dCode=EVN]/subject/@typeCode=SUBJ[1]/investigationEvent/@classCode=INVTG][@mo dCode=EVN]/component/@typeCode=COMP[1]/adverseEventAssessment[1]/adverseEventAssessm ent/@classCode=INVTG][@moodCode=EVN]/subject1/@typeCode=SBJ[1]/primaryRole/@class Code=INVSBJ/subjectO2/@typeCode=SBJ[organizer/code/@code=4][@codeSystem=2.16.840.1 13883.3.988.2.1.1.20][1]/organizer/@classCode=CATEGORY[1]/moodCode=EVN/component[1]/typeCode=COMP[1]/substanceAdministration[id][k]/substanceAdministration[1]/sub stanceAdministration/@classCode=SBADM[1]/moodCode=EVN[1]/effectiveTime/@xsi:type=SXPР_ TS/comp[2][@xsi:type=VL_TS]/operator/@width/@unit </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"> 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>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]/PORR_IN049016UV/r/controlActProcess/@classCode=CACT][@moodCode=EVN]/component/@typeCode=SUBJ[1]/investigationEvent/@classCode=INVESTG][@moodCode=EVN]/component/@typeCode=COMP[1]/adverseEventAssessment[1]/adverseEventAssessment/@classCode=INVESTG][@moodCode=EVN]/subject/@typeCode=SBJ[1]/primaryRole/@classCode=INVSBJ[1]/subject/@typeCode=SBJ[1]/organizer/@code=4][@codeSystem=2.16.840.1.113883.3.989.2.1.1.20][1]/organizer/@classCode=CATEGORY][@moodCode=EVN]/component/@typeCode=COMP[1]/substanceAdministration[id]/[K]/substanceAdministration/@classCode=SBADM][@moodCode=EVN]/outboundRelationship2/@typeCode=COMP[1]/substanceAdministration[1]/substanceAdministration/@classCode=SBADM][@moodCode=EVN]/effectiveTime/@xsi:type=IVL_TS][width/@unit</pre>
<p>Character String (ST)</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/r/controlActProcess/@classCode=CACT][@moodCode=EVN]/component/@typeCode=SUBJ[1]/investigationEvent/@classCode=INVESTG][@moodCode=EVN]/component/@typeCode=COMP[1]/adverseEventAssessment[1]/adverseEventAssessment/@classCode=INVSBJ[1]/subject/@typeCode=SBJ[1]/organizer/@code=4][@codeSystem=2.16.840.1.113883.3.989.2.1.1.20][1]/organizer/@classCode=CATEGORY][@moodCode=EVN]/component/@typeCode=COMP[1]/substanceAdministration[id]/[K]/substanceAdministration/@classCode=SBADM][@moodCode=EVN]/outboundRelationship2/@typeCode=COMP[1]/substanceAdministration[1]/substanceAdministration/@classCode=SBADM][@moodCode=EVN]/consumable/@typeCode=CSM][1]/instanceOfKind/@classCode=INST[1]/productInstance/@classCode=MMAA][@determineCode=INSTANCE]/ofNumber/text()</pre>
<p>Batch/Lot Number</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/r/controlActProcess/@classCode=CACT][@moodCode=EVN]/component/@typeCode=SUBJ[1]/investigationEvent/@classCode=INVESTG][@moodCode=EVN]/component/@typeCode=COMP[1]/adverseEventAssessment[1]/adverseEventAssessment/@classCode=INVSBJ[1]/subject/@typeCode=SBJ[1]/organizer/@code=4][@codeSystem=2.16.840.1.113883.3.989.2.1.1.20][1]/organizer/@classCode=CATEGORY][@moodCode=EVN]/component/@typeCode=COMP[1]/substanceAdministration[id]/[K]/substanceAdministration/@classCode=SBADM][@moodCode=EVN]/outboundRelationship2/@typeCode=COMP[1]/substanceAdministration[1]/substanceAdministration/@classCode=SBADM][@moodCode=EVN]/text/text()</pre>
<p>G.k.4.r.8</p>	<p>投与量を表す記述情報</p>	<p>2000AN</p>	<p>Encapsulated Data (ED)</p>
<p>G.k.4.r.9</p>	<p>医薬品剤形</p>		

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e	G.k.4.r.9.1	医薬品剤形の (自由記載)	60AN	Coded With Equivalents (CE)	originalText=Encapsulated Data (ED)	値	<pre> /MCCL_IN200100UV01[ITSVersion=XML_1.0][xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]PDRR_IN049016UV[controlActProcess[classCode=CACT][moo dCode=EVN]/subject[typeCode=SUBJ]/investigationEvent[classCode=INVTG][moodCo de=EVN]/component[typeCode=COMP]/adverseEventAssessment[1]/adverseEventAssessm ent[1]/primaryRole[classCode=INVSBJ]/subject[1]/organizer[1]/code=4][codeSystem=2.16.840.1 13883.3.989.2.1.1.20][1]/organizer[1]/code=CATGORY][moodCode=EVN]/component[1]/code=SBADM][moodCode=EVN]/substanceAdministration[1]/sub stanceAdministration[1]/code=SBADM][moodCode=EVN]/consumable[typeCode=CSM][1]/instanceOfKind[classCode=INST]/kindOfProduct[classCode=MMAT][1]/determinerCode=KI ND]/formCode[1]/codeSystem=TBDDoseForm]/originalText/text() </pre>
e	G.k.4.r.9.2a	医薬品剤形の ID ハーブ 日付/番号	M5 ガイド ラインを参 照	Coded With Equivalents (CE)	codeSystemVersion= Character String (ST)	値	<pre> /MCCL_IN200100UV01[ITSVersion=XML_1.0][xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]PDRR_IN049016UV[controlActProcess[classCode=CACT][moo dCode=EVN]/subject[typeCode=SUBJ]/investigationEvent[classCode=INVTG][moodCo de=EVN]/component[typeCode=COMP]/adverseEventAssessment[1]/adverseEventAssessm ent[1]/primaryRole[classCode=INVSBJ]/subject[1]/organizer[1]/code=4][codeSystem=2.16.840.1 13883.3.989.2.1.1.20][1]/organizer[1]/code=CATGORY][moodCode=EVN]/component[1]/code=SBADM][moodCode=EVN]/substanceAdministration[1]/sub stanceAdministration[1]/code=SBADM][moodCode=EVN]/consumable[typeCode=CSM][1]/instanceOfKind[classCode=INST]/kindOfProduct[classCode=MMAT][1]/determinerCode=KI ND]/formCode[1]/codeSystem=TBDDoseForm]/originalText/text() </pre>
e	G.k.4.r.9.2b	医薬品剤形の ID	M5 ガイド ラインを参 照	Coded With Equivalents (CE)	code=Character String (ST)	値	<pre> /MCCL_IN200100UV01[ITSVersion=XML_1.0][xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]PDRR_IN049016UV[controlActProcess[classCode=CACT][moo dCode=EVN]/subject[typeCode=SUBJ]/investigationEvent[classCode=INVTG][moodCo de=EVN]/component[typeCode=COMP]/adverseEventAssessment[1]/adverseEventAssessm ent[1]/primaryRole[classCode=INVSBJ]/subject[1]/organizer[1]/code=4][codeSystem=2.16.840.1 13883.3.989.2.1.1.20][1]/organizer[1]/code=CATGORY][moodCode=EVN]/component[1]/code=SBADM][moodCode=EVN]/substanceAdministration[1]/sub stanceAdministration[1]/code=SBADM][moodCode=EVN]/consumable[typeCode=CSM][1]/instanceOfKind[classCode=INST]/kindOfProduct[classCode=MMAT][1]/determinerCode=KI ND]/formCode[1]/codeSystem=TBDDoseForm]/originalText/text() </pre>
h	G.k.4.r.10	投与経路					

e	G.k.4.r.10.1	投与経路 (自由記載)	60AN	Coded With Equivalents (CE)	originalText=Encapsulated Data (ED)	値	<pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/PDRR_IN049016UV1[controlActProcess/@classCode=CACT][@moo dCode=EVN]/subject/@typeCode=SUBJ1[investigationEvent/@classCode=INVTG][@moodCo de=EVN]/component/@typeCode=COMP1[adverseEventAssessment[1]/adverseEventAssessment /@classCode=INVTG][@moodCode=EVN]/subject[1]/primaryRole/@classC ode=INVSBJ/subjectOr2/@typeCode=SBJ1[organizer/@code=4][@codeSystem=2.16.840.1 .113883.3.989.2.1.1.20][1]/organizer/@classCode=CATEGORY1[moodCode=EVN/jcomponent /@typeCode=COMP1/substanceAdministration/djK/substanceAdministration/@classCode=SBADM][@moodCode=EVN]/yboundRelationship2/@typeCode=COMP1[substanceAdministration]/sub stanceAdministration/@classCode=SBADM][@moodCode=EVN]/routeCode/@codeSystem=2.16. 840.1.1.13883.3.989.2.1.1.14/originalText/@nullFlavor </pre>
e						NullFlavor	<pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/PDRR_IN049016UV1[controlActProcess/@classCode=CACT][@moo dCode=EVN]/subject/@typeCode=SUBJ1[investigationEvent/@classCode=INVTG][@moodCo de=EVN]/component/@typeCode=COMP1[adverseEventAssessment[1]/adverseEventAssessment /@classCode=INVTG][@moodCode=EVN]/subject[1]/primaryRole/@classC ode=INVSBJ/subjectOr2/@typeCode=SBJ1[organizer/@code=4][@codeSystem=2.16.840.1 .113883.3.989.2.1.1.20][1]/organizer/@classCode=CATEGORY1[moodCode=EVN/jcomponent /@typeCode=COMP1/substanceAdministration/djK/substanceAdministration/@classCode=SBADM][@moodCode=EVN]/yboundRelationship2/@typeCode=COMP1[substanceAdministration]/sub stanceAdministration/@classCode=SBADM][@moodCode=EVN]/routeCode/@codeSystem=2.16. 840.1.1.13883.3.989.2.1.1.14/originalText/@nullFlavor </pre>
e	G.k.4.r.10.2a	投与経路の ID 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	<pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/PDRR_IN049016UV1[controlActProcess/@classCode=CACT][@moo dCode=EVN]/subject/@typeCode=SUBJ1[investigationEvent/@classCode=INVTG][@moodCo de=EVN]/component/@typeCode=COMP1[adverseEventAssessment[1]/adverseEventAssessment /@classCode=INVTG][@moodCode=EVN]/subject[1]/primaryRole/@classC ode=INVSBJ/subjectOr2/@typeCode=SBJ1[organizer/@code=4][@codeSystem=2.16.840.1 .113883.3.989.2.1.1.20][1]/organizer/@classCode=CATEGORY1[moodCode=EVN/jcomponent /@typeCode=COMP1/substanceAdministration/djK/substanceAdministration/@classCode=SBADM][@moodCode=EVN]/yboundRelationship2/@typeCode=COMP1[substanceAdministration]/sub stanceAdministration/@classCode=SBADM][@moodCode=EVN]/routeCode/@codeSystem=2.16. 840.1.1.13883.3.989.2.1.1.14]/@codeSystemVersion </pre>
e	G.k.4.r.10.2b	投与経路の ID	M5 ガイドライン (3N) を参照	Coded With Equivalents (CE)	code=Character String (ST)	値	<pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/PDRR_IN049016UV1[controlActProcess/@classCode=CACT][@moo dCode=EVN]/subject/@typeCode=SUBJ1[investigationEvent/@classCode=INVTG][@moodCo de=EVN]/component/@typeCode=COMP1[adverseEventAssessment[1]/adverseEventAssessment /@classCode=INVTG][@moodCode=EVN]/subject[1]/primaryRole/@classC ode=INVSBJ/subjectOr2/@typeCode=SBJ1[organizer/@code=4][@codeSystem=2.16.840.1 .113883.3.989.2.1.1.20][1]/organizer/@classCode=CATEGORY1[moodCode=EVN/jcomponent /@typeCode=COMP1/substanceAdministration/djK/substanceAdministration/@classCode=SBADM][@moodCode=EVN]/yboundRelationship2/@typeCode=COMP1[substanceAdministration]/sub stanceAdministration/@classCode=SBADM][@moodCode=EVN]/routeCode/@codeSystem=2.16. 840.1.1.13883.3.989.2.1.1.14]/@code </pre>
h	G.k.4.r.11	薬への投与経路 (親子/胎児報告の場合)					

(別添 3)

<p>e</p> <p>G.k.4.r.11.1</p>	<p>親への投与経路 (自由記載)</p> <p>60AN</p>	<p>Coded With Equivalents (CE)</p>	<p>originalText=Encapsulated Data (ED)</p>	<p>値</p> <pre> /MCCL_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCL_IN200100UV01.xsd']/PDRR_IN049016UV1/controlActProcess/@classCode=CACTT[@moo dCode='EVN']/subject/@typeCode=SUBJ1[investigationEvent/@classCode=INVESTG][@moodCo de='EVN']/component/@typeCode=COMP1[adverseEventAssessment1/adverseEventAssessment /@classCode=INVESTG][@moodCode='EVN']/subject1/@typeCode=SBJ1[primaryRole/@classC ode=INVSBJ/subjectO2/@typeCode=SBJ1/organizer/code/@code=4][@codeSystem=2.16.840.1 13883.3.989.2.1.1.20][1]/organizer/@classCode=CATEGORY1[@moodCode='EVN']/component /@typeCode=COMP1[substanceAdministration1/id1/substanceAdministration/@classCode=SBADM][@moodCode='EVN']/outboundRelationship2/@typeCode=COMP1[substanceAdministration]/sub stanceAdministration/@classCode=SBADM][@moodCode='EVN']/inboundRelationship/@typeCode =REFR1[observation/code/@code=28][@codeSystem=2.16.840.1.13883.3.989.2.1.1.19][1]/obse rvation/@classCode=OBS1[@moodCode='EVN']/value[@xsi:type='CE'][@codeSystem=2.16.840.1. 13883.3.989.2.1.1.14][1]/originalText/text() </pre>
<p>e</p>	<p>NullFlavor</p>	<p>NullFlavor</p>	<p>値</p>	<pre> /MCCL_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCL_IN200100UV01.xsd']/PDRR_IN049016UV1/controlActProcess/@classCode=CACTT[@moo dCode='EVN']/subject/@typeCode=SUBJ1[investigationEvent/@classCode=INVESTG][@moodCo de='EVN']/component/@typeCode=COMP1[adverseEventAssessment1/adverseEventAssessment /@classCode=INVESTG][@moodCode='EVN']/subject1/@typeCode=SBJ1[primaryRole/@classC ode=INVSBJ/subjectO2/@typeCode=SBJ1/organizer/code/@code=4][@codeSystem=2.16.840.1 13883.3.989.2.1.1.20][1]/organizer/@classCode=CATEGORY1[@moodCode='EVN']/component /@typeCode=COMP1[substanceAdministration1/id1/substanceAdministration/@classCode=SBADM][@moodCode='EVN']/outboundRelationship2/@typeCode=COMP1[substanceAdministration]/sub stanceAdministration/@classCode=SBADM][@code='28'][@codeSystem=2.16.840.1.13883.3.989.2.1.1.19][1]/obse rvation/@classCode=OBS1[@moodCode='EVN']/value[@xsi:type='CE'][@codeSystem=2.16.840.1. 13883.3.989.2.1.1.14][1]/originalText/@nullFlavor </pre>
<p>e</p> <p>G.k.4.r.11.2a</p>	<p>親への投与経路の ID バージョン日付/番号</p> <p>M5 ガイドラインを参照</p>	<p>Coded With Equivalents (CE)</p>	<p>codeSystemVersion=Character String (ST)</p>	<p>値</p> <pre> /MCCL_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCL_IN200100UV01.xsd']/PDRR_IN049016UV1/controlActProcess/@classCode=CACTT[@moo dCode='EVN']/subject/@typeCode=SUBJ1[investigationEvent/@classCode=INVESTG][@moodCo de='EVN']/component/@typeCode=COMP1[adverseEventAssessment1/adverseEventAssessment /@classCode=INVESTG][@moodCode='EVN']/subject1/@typeCode=SBJ1[primaryRole/@classC ode=INVSBJ/subjectO2/@typeCode=SBJ1/organizer/code/@code=4][@codeSystem=2.16.840.1 13883.3.989.2.1.1.20][1]/organizer/@classCode=CATEGORY1[@moodCode='EVN']/component /@typeCode=COMP1[substanceAdministration1/id1/substanceAdministration/@classCode=SBADM][@moodCode='EVN']/outboundRelationship2/@typeCode=COMP1[substanceAdministration]/sub stanceAdministration/@classCode=SBADM][@code='28'][@codeSystem=2.16.840.1.13883.3.989.2.1.1.19][1]/obse rvation/@classCode=OBS1[@moodCode='EVN']/value[@xsi:type='CE'][@codeSystem=2.16.840.1. 13883.3.989.2.1.1.14][1]/originalText/@nullFlavor </pre>

<p>e</p>	<p>G.k.4.r.11.2b 親への投与経路の 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> /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PDRR_IN049016UVJr/controlAct/process[@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[1]/organizer/code[@code=4][@codeSystem=2,16,840,1 13883,3,989,2,1,1,20][1]/organizer[@classCode=CATEGORY][@moodCode=EVN]/component[1]/@moodCode=EVN/youboundRelationship2[@typeCode=COMP][substanceAdministration][1]/sub stanceAdministration[@classCode=SBADM][@moodCode=EVN]/inboundRelationship[@typeCode =REFR][observation/code[@code=28][@codeSystem=2,16,840,1,13883,3,989,2,1,1,19][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 副作用／有害事象発現まで の累積投与量 (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]/PDRR_IN049016UVJr/controlAct/process[@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[1]/organizer/code[@code=4][@codeSystem=2,16,840,1 13883,3,989,2,1,1,20][1]/organizer[@classCode=CATEGORY][@moodCode=EVN]/component[1]/@moodCode=EVN/youboundRelationship2[@typeCode=SUMM][observation/code[@code=14][@codeSystem=2,16,840,1,13883,3,989,2,1,1,19][1]/observation[@classCode=OBS][@moodCod e=EVN]/value[@xsi:type=PQ][1]/@value </pre>
<p>e</p>	<p>G.k.5b 副作用／有害事象発現まで の累積投与量 (単位)</p>	<p>50AN</p>	<p>Physical Quantity (PQ)</p>	<p>unit=Coded Simple- Value (CS)</p>	<p>値</p>	<pre> /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PDRR_IN049016UVJr/controlAct/process[@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[1]/organizer/code[@code=4][@codeSystem=2,16,840,1 13883,3,989,2,1,1,20][1]/organizer[@classCode=CATEGORY][@moodCode=EVN]/component[1]/@moodCode=EVN/youboundRelationship2[@typeCode=SUMM][observation/code[@code=14][@codeSystem=2,16,840,1,13883,3,989,2,1,1,19][1]/observation[@classCode=OBS][@moodCod e=EVN]/value[@xsi:type=PQ][1]/@unit </pre>
<p>e</p>	<p>G.k.6a 曝露時の妊娠期間 (数)</p>	<p>3N</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_IN049016UVJr/controlAct/process[@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[1]/organizer/code[@code=4][@codeSystem=2,16,840,1 13883,3,989,2,1,1,20][1]/organizer[@classCode=CATEGORY][@moodCode=EVN]/component[1]/@moodCode=EVN/youboundRelationship2[@typeCode=PERT][observation/code[@code=16][@codeSystem=2,16,840,1,13883,3,989,2,1,1,19][1]/observation[@classCode=OBS][@moodCod e=EVN]/value[@xsi:type=PQ][1]/@value </pre>

(別添3)

e	G.k.6b	曝露時の延滞期間 (単位)	50AN	Physical Quantity (PQ)	unit=Coded Simple Value (CS)	値
h	G.k.7.r	医薬品使用理由 (必要に応じ繰り返す)		Coded With Equivalents (CE)	originalText=Encapsulated Data (ED)	繰り返しノード
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			値
e						Null Flavor

(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>Coded With Equivalents (CE)</p>	<p>code=SystemVersion= Character String (ST)</p>	<p>値</p> <pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd][@typeCode=SUBJ][@investigationEvent/@classCode=CACT][@moo dCode=EVN]/subject[@typeCode=SUBJ][@investigationEvent/@classCode=INVSIG][@moodCo de=EVN]/component[@typeCode=COMP][@adverseEventAssessment[1]/adverseEventAssessment [@classCode=INVSIG][@moodCode=EVN]/subject[1][@typeCode=SBJ][@primaryRole/@classC ode=INVSBJ]/subjectCf2[@typeCode=SBJ][@organizerCode/@code=4][@codeSystem=2.16.840.1 .113883.3.989.2.1.1.20][1][@typeCode=CATEGORY][@moodCode=EVN]/component[1][@moodCode=EVN]/substanceAdministration[id][@substanceAdministration/@classCode=SBADM][@typeCode=COMP][@substanceAdministration/@typeCode=RSON][@observationCode/@code=19][@c odeSystem=2.16.840.1.113883.3.989.2.1.1.19][r/observation/@classCode=ASSIGNED][code=3][@c odeSystem=2.16.840.1.113883.3.989.2.1.1.21][1][value/@xsi:type=CE][@codeSystem=2.16.840. 1.113883.6.163][1][@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>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][@typeCode=SUBJ][@investigationEvent/@classCode=CACT][@moo dCode=EVN]/subject[@typeCode=SUBJ][@investigationEvent/@classCode=INVSIG][@moodCo de=EVN]/component[@typeCode=COMP][@adverseEventAssessment[1]/adverseEventAssessment [@classCode=INVSIG][@moodCode=EVN]/subject[1][@typeCode=SBJ][@primaryRole/@classC ode=INVSBJ]/subjectCf2[@typeCode=SBJ][@organizerCode/@code=4][@codeSystem=2.16.840.1 .113883.3.989.2.1.1.20][1][@typeCode=CATEGORY][@moodCode=EVN]/component[1][@moodCode=EVN]/substanceAdministration[id][@substanceAdministration/@classCode=SBADM][@typeCode=COMP][@substanceAdministration/@typeCode=RSON][@observationCode/@code=19][@c odeSystem=2.16.840.1.113883.3.989.2.1.1.19][r/observation/@classCode=OBS][@moodCode= EVN][performer/@typeCode=PRF][assignedEntity/@classCode=ASSIGNED][code=3][@c odeSystem=2.16.840.1.113883.3.989.2.1.1.21][1][value/@xsi:type=CE][@codeSystem=2.16.840. 1.113883.6.163][1][@code </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>Concept Descriptor (CD)</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][@typeCode=SUBJ][@investigationEvent/@classCode=CACT][@moo dCode=EVN]/subject[@typeCode=SUBJ][@investigationEvent/@classCode=INVSIG][@moodCo de=EVN]/component[@typeCode=COMP][@adverseEventAssessment[1]/adverseEventAssessment [@classCode=INVSIG][@moodCode=EVN]/subject[1][@typeCode=SBJ][@primaryRole/@classC ode=INVSBJ]/subjectCf2[@typeCode=SBJ][@organizerCode/@code=4][@codeSystem=2.16.840.1 .113883.3.989.2.1.1.20][1][@typeCode=CATEGORY][@moodCode=EVN]/component[1][@moodCode=EVN]/substanceAdministration[id][@substanceAdministration/@classCode=SBADM][@typeCode=COMP][@substanceAdministration/@typeCode=CAUS][@act/@classCode=ACT][@code System=2.16.840.1.113883.3.989.2.1.1.15][1][act/@classCode=ACT][@moodCode=EVN]/code/@codeSystem=2. 16.840.1.113883.6.163][1][@code </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.i.1</p> <p>評価対象の副作用/有害事 象</p>				<p>N/A</p>

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h	G.k.9.i.2.r	医薬品と副作用/有害事象の因果関係 (必要に応じ繰り返し)		繰り返し ノード	<pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0' /MCCL_IN200100UV01.xsd/PORR_IN049016UV/r/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]/component/@typeCode=COMP[1]/adverseEventAssessment[1]/adverseEventAssessment[@classCode=COMP][causalityAssessment[1]/adverseEffectReference[@classCode=OBS][@moodCode=EVN]/id[@root=UUIID of k-th reaction][subject2/@typeCode=SUBJ/productUseReference[@classCode=SBADM][@moodCode=EVN]/id[@root=UUIID of k-th drug]]] </pre>
e	G.k.9.i.2.r.1	評価の情報源	60AN	Coded With Equivalents (CE) originalText=Encapsulated Data (ED)	<pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0' /MCCL_IN200100UV01.xsd/PORR_IN049016UV/r/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]/component/@typeCode=COMP[1]/adverseEventAssessment[1]/adverseEventAssessment[@classCode=COMP][causalityAssessment[1]/adverseEffectReference[@classCode=OBS][@moodCode=EVN]/id[@root=UUIID of k-th reaction][subject2/@typeCode=SUBJ/productUseReference[@classCode=SBADM][@moodCode=EVN]/id[@root=UUIID of k-th drug]]/assignedEntity[@classCode=ASSIGNED]/code/originalText/text() </pre>
e	G.k.9.i.2.r.2	評価方法	60AN	Coded With Equivalents (CE) originalText=Encapsulated Data (ED)	<pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0' /MCCL_IN200100UV01.xsd/PORR_IN049016UV/r/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]/component/@typeCode=COMP[1]/adverseEventAssessment[1]/adverseEventAssessment[@classCode=COMP][causalityAssessment[1]/adverseEffectReference[@classCode=OBS][@moodCode=EVN]/id[@root=UUIID of k-th reaction][subject2/@typeCode=SUBJ/productUseReference[@classCode=SBADM][@moodCode=EVN]/id[@root=UUIID of k-th drug]]/methodCode[1]/originalText/text() </pre>
e	G.k.9.i.2.r.3	評価結果	60AN	Character String (ST)	<pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0' /MCCL_IN200100UV01.xsd/PORR_IN049016UV/r/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]/component/@typeCode=COMP[1]/adverseEventAssessment[1]/adverseEventAssessment[@classCode=COMP][causalityAssessment[1]/adverseEffectReference[@classCode=OBS][@moodCode=EVN]/id[@root=UUIID of k-th reaction][subject2/@typeCode=SUBJ/productUseReference[@classCode=SBADM][@moodCode=EVN]/id[@root=UUIID of k-th drug]]/value[@xsi:type=ST]/text() </pre>

<p>e</p> <p>G.k.9.i.3.1a</p>	<p>医薬品の投与開始から副作 用／有害事象発現までの時 間間隔 (数)</p> <p>5N</p>	<p>Physical Quantity (PQ)</p>	<p>value=Real Number (REAL)</p>	<p>値</p>	<p>/MCC1_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCC1_IN200100UV01.xsd]PDRR_IN049016UV[controlActProcess/@classCode=CACT][@moo dCode=EVN]/subject/@typeCode=SUBJ[investigationEvent/@classCode=INVTG][@moodCo de=EVN]/component/@typeCode=COMP[adverseEventAssessment[1]/adverseEventAssessment /@classCode=INVTG][@moodCode=EVN]/subject[1]/typeCode=SBJ[1]/primaryRole/@classC ode=INVSBJ[subjectOf/@typeCode=SBJ]/organizer/@classCode=CATEGORY[1][@moodCode= EVN][code/@code=4][@codeSystem=2.16.840.1.113883.3.989.2.1.1.20][1]/component/@typeCo de=COMP[substanceAdministration[id][K]/substanceAdministration/@classCode=SBADM][@moo dCode=EVN]/outboundRelationship[1][@typeCode=SAE][actReference/@classCode=OBS][@moo dCode=EVN]/id[@root=UJID of I-th reaction]/pauseQuantity/@value</p>
<p>e</p> <p>G.k.9.i.3.1b</p>	<p>医薬品の投与開始から副作 用／有害事象発現までの時 間間隔 (単位)</p> <p>50AN</p>	<p>Physical Quantity (PQ)</p>	<p>unit=Coded Simple Value (CS)</p>	<p>値</p>	<p>/MCC1_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCC1_IN200100UV01.xsd]PDRR_IN049016UV[controlActProcess/@classCode=CACT][@moo dCode=EVN]/subject/@typeCode=SUBJ[investigationEvent/@classCode=INVTG][@moodCo de=EVN]/component/@typeCode=COMP[adverseEventAssessment[1]/adverseEventAssessment /@classCode=INVTG][@moodCode=EVN]/subject[1]/typeCode=SBJ[1]/primaryRole/@classC ode=INVSBJ[subjectOf/@typeCode=SBJ]/organizer/@classCode=CATEGORY[1][@moodCode= EVN][code/@code=4][@codeSystem=2.16.840.1.113883.3.989.2.1.1.20][1]/component/@typeCo de=COMP[substanceAdministration[id][K]/substanceAdministration/@classCode=SBADM][@moo dCode=EVN]/outboundRelationship[1][@typeCode=SAE][actReference/@classCode=OBS][@moo dCode=EVN]/id[@root=UJID of I-th reaction]/pauseQuantity/@unit</p>
<p>e</p> <p>G.k.9.i.3.2a</p>	<p>医薬品の最終投与から副作 用／有害事象発現までの時 間間隔 (数)</p> <p>5N</p>	<p>Physical Quantity (PQ)</p>	<p>value=Real Number (REAL)</p>	<p>値</p>	<p>/MCC1_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCC1_IN200100UV01.xsd]PDRR_IN049016UV[controlActProcess/@classCode=CACT][@moo dCode=EVN]/subject/@typeCode=SUBJ[investigationEvent/@classCode=INVTG][@moodCo de=EVN]/component/@typeCode=COMP[adverseEventAssessment[1]/adverseEventAssessment /@classCode=INVTG][@moodCode=EVN]/subject[1]/typeCode=SBJ[1]/primaryRole/@classC ode=INVSBJ[subjectOf/@typeCode=SBJ]/organizer/@classCode=CATEGORY[1][@moodCode= EVN][code/@code=4][@codeSystem=2.16.840.1.113883.3.989.2.1.1.20][1]/component/@typeCo de=COMP[substanceAdministration[id][K]/substanceAdministration/@classCode=SBADM][@moo dCode=EVN]/outboundRelationship[1][@typeCode=SAE][actReference/@classCode=OBS][@moo dCode=EVN]/id[@root=UJID of I-th reaction]/pauseQuantity/@value</p>
<p>e</p> <p>G.k.9.i.3.2b</p>	<p>医薬品の最終投与から副作 用／有害事象発現までの時 間間隔 (単位)</p> <p>50AN</p>	<p>Physical Quantity (PQ)</p>	<p>unit=Coded Simple Value (CS)</p>	<p>値</p>	<p>/MCC1_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCC1_IN200100UV01.xsd]PDRR_IN049016UV[controlActProcess/@classCode=CACT][@moo dCode=EVN]/subject/@typeCode=SUBJ[investigationEvent/@classCode=INVTG][@moodCo de=EVN]/component/@typeCode=COMP[adverseEventAssessment[1]/adverseEventAssessment /@classCode=INVTG][@moodCode=EVN]/subject[1]/typeCode=SBJ[1]/primaryRole/@classC ode=INVSBJ[subjectOf/@typeCode=SBJ]/organizer/@classCode=CATEGORY[1][@moodCode= EVN][code/@code=4][@codeSystem=2.16.840.1.113883.3.989.2.1.1.20][1]/component/@typeCo de=COMP[substanceAdministration[id][K]/substanceAdministration/@classCode=SBADM][@moo dCode=EVN]/outboundRelationship[1][@typeCode=SAE][actReference/@classCode=OBS][@moo dCode=EVN]/id[@root=UJID of I-th reaction]/pauseQuantity/@unit</p>

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e	G.k.9.1.4	再致与で副作用は再発したか？	1N	Coded With Equivalents (CE)	code=Character String (ST)	値	<pre> /MCCL_IN200100UV01[ITSVersion=XML_1.0][xsi:schemaLocation=urn:h7-org:v3 MCCL_IN200100UV01.xsd/PPORR_IN049016UV/]/controlActProcess[!classCode=CACT][!moodCo dCode=EVN]/subject[!typeCode=SUBJ][!investigationEvent[!classCode=INVESTG][!moodCo de=EVN]/component[!typeCode=COMP][!adverseEventAssessment[!adverseEventAssessment [classCode=INVESTG][!moodCode=EVN]/subject[!typeCode=SBJ][!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][!component[!typeCo de=COMP][!substanceAdministration[!K/substanceAdministration[!code=SBADM][!moo dCode=EVN]/outboundRelationship2[!typeCode=PERT][!observation[!code=3][!codeSy stem=2.16.840.1.113883.3.989.2.1.1.19][!observation[!classCode=OBS][!moodCode=EVN]/id boundRelationship1[!typeCode=REFR]/actReference[!classCode=OBS][!moodCode=EVN]/id of i-th reaction]/value[!xsi:type=CE][!codeSystem=2.16.840.1.113883.3.989.2.1.1.16][!]/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> /MCCL_IN200100UV01[ITSVersion=XML_1.0][xsi:schemaLocation=urn:h7-org:v3 MCCL_IN200100UV01.xsd/PPORR_IN049016UV/]/controlActProcess[!classCode=CACT][!moo dCode=EVN]/subject[!typeCode=SUBJ][!investigationEvent[!classCode=INVESTG][!moodCo de=EVN]/component[!typeCode=COMP][!adverseEventAssessment[!adverseEventAssessment [classCode=INVESTG][!moodCode=EVN]/subject[!typeCode=SBJ][!primaryRole[!classC ode=INVSBJ][subjectO2[!typeCode=SBJ]/organizer[!code=4][!codeSystem=2.16.840.1 13883.3.989.2.1.1.20][!]/organizer[!classCode=CATEGORY][!moodCode=EVN]/component[!typeCode=COMP][!substanceAdministration[!K/substanceAdministration[!code=SBADM][!moodCode=EVN]/outboundRelationship2[!typeCode=REFR][!observation[!code=3][!@ codeSystem=2.16.840.1.113883.3.989.2.1.1.19][!]/observation[!classCode=OBS][!moodCode= EVN]/value[!xsi:type=CE][!codeSystem=2.16.840.1.113883.3.989.2.1.1.17][!]/code </pre>
e						繰り返すノード	<pre> /MCCL_IN200100UV01[ITSVersion=XML_1.0][xsi:schemaLocation=urn:h7-org:v3 MCCL_IN200100UV01.xsd/PPORR_IN049016UV/]/controlActProcess[!classCode=CACT][!moo dCode=EVN]/subject[!typeCode=SUBJ][!investigationEvent[!classCode=INVESTG][!moodCo de=EVN]/component[!typeCode=COMP][!adverseEventAssessment[!adverseEventAssessment [classCode=INVESTG][!moodCode=EVN]/subject[!typeCode=SBJ][!primaryRole[!classC ode=INVSBJ][subjectO2[!typeCode=SBJ]/organizer[!code=4][!codeSystem=2.16.840.1 13883.3.989.2.1.1.20][!]/organizer[!classCode=CATEGORY][!moodCode=EVN]/component[!typeCode=COMP][!substanceAdministration[!K/substanceAdministration[!code=SBADM][!moodCode=EVN]/outboundRelationship2[!typeCode=REFR][!observation[!code=3][!@ codeSystem=2.16.840.1.113883.3.989.2.1.1.19][</pre>
e	G.k.11	医薬品に関するその他の情報 (自由記載)	2000AN	Character String (ST)		値	<pre> /MCCL_IN200100UV01[ITSVersion=XML_1.0][xsi:schemaLocation=urn:h7-org:v3 MCCL_IN200100UV01.xsd/PPORR_IN049016UV/]/controlActProcess[!classCode=CACT][!moo dCode=EVN]/subject[!typeCode=SUBJ][!investigationEvent[!classCode=INVESTG][!moodCo de=EVN]/component[!typeCode=COMP][!adverseEventAssessment[!adverseEventAssessment [classCode=INVESTG][!moodCode=EVN]/subject[!typeCode=SBJ][!primaryRole[!classC ode=INVSBJ][subjectO2[!typeCode=SBJ]/organizer[!code=4][!codeSystem=2.16.840.1 13883.3.989.2.1.1.20][!]/organizer[!classCode=CATEGORY][!moodCode=EVN]/component[!typeCode=COMP][!substanceAdministration[!K/substanceAdministration[!code=SBADM][!moodCode=EVN]/outboundRelationship2[!typeCode=REFR][!observation[!code=3][!@ codeSystem=2.16.840.1.113883.3.989.2.1.1.19][!]/text() </pre>
h	H	症例概要及びその他の情報の記述					

(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> /MCCI_IN200100UV01[@ITSVersion="XML_1.0"]/@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PERR_IN049016UV/r/controlActProcess[@classCode=CACT][@moodCode=EVN]/subject[@typeCode="SUBJ"]/investigationEvent[@classCode=INVTG][@moodCode=EVN]/text/text </pre>
e	H.2	報告者の意見	20000AN	Encapsulated Data (ED)	値	<pre> /MCCI_IN200100UV01[@ITSVersion="XML_1.0"]/@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PERR_IN049016UV/r/controlActProcess[@classCode=CACT][@moodCode=EVN]/subject[@typeCode="SUBJ"]/investigationEvent[@classCode=INVTG][@moodCode=EVN]/component[@typeCode=COMP]/adverseEventAssessment[1]/adverseEventAssessment[@classCode=INVTG][@moodCode=EVN]/component1[@typeCode=COMP]/observationEvent[1]/observationEvent[1]/code/@code="10"[@codeSystem="2.16.840.1.113883.3.989.2.1.19"]/author[@typeCode="AUT"]/asSignedEntity[@classCode=ASSIGNED]/code/@code="3"[@codeSystem="2.16.840.1.113883.3.989.2.1.1.21"]/observationEvent[@classCode=OBS][@moodCode=EVN]/value[@xsi:type=ED]/text </pre>
h	H.3.r	送信者による診断名（必要に応じて繰り返し）			繰り返しノード	<pre> /MCCI_IN200100UV01[@ITSVersion="XML_1.0"]/@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PERR_IN049016UV/r/controlActProcess[@classCode=CACT][@moodCode=EVN]/subject[@typeCode="SUBJ"]/investigationEvent[@classCode=INVTG][@moodCode=EVN]/component[@typeCode=COMP]/adverseEventAssessment[1]/adverseEventAssessment[@classCode=INVTG][@moodCode=EVN]/component1[@typeCode=COMP]/observationEvent[1]/observationEvent[1]/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> /MCCI_IN200100UV01[@ITSVersion="XML_1.0"]/@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PERR_IN049016UV/r/controlActProcess[@classCode=CACT][@moodCode=EVN]/subject[@typeCode="SUBJ"]/investigationEvent[@classCode=INVTG][@moodCode=EVN]/component[@typeCode=COMP]/adverseEventAssessment[1]/adverseEventAssessment[@classCode=INVTG][@moodCode=EVN]/component1[@typeCode=COMP]/observationEvent[1]/observationEvent[1]/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"]/observationEvent[@classCode=OBS][@moodCode=EVN]/value[@xsi:type=CE][@codeSystem="2.16.840.1.113883.6.163"]/@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> /MCCI_IN200100UV01[@ITSVersion="XML_1.0"]/@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PERR_IN049016UV/r/controlActProcess[@classCode=CACT][@moodCode=EVN]/subject[@typeCode="SUBJ"]/investigationEvent[@classCode=INVTG][@moodCode=EVN]/component[@typeCode=COMP]/adverseEventAssessment[1]/adverseEventAssessment[@classCode=INVTG][@moodCode=EVN]/component1[@typeCode=COMP]/observationEvent[1]/observationEvent[1]/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"]/observationEvent[@classCode=OBS][@moodCode=EVN]/value[@xsi:type=CE][@codeSystem="2.16.840.1.113883.6.163"]/@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_IN049016UV[controlActProcess/@classCode=CACTI][@moodCo dCode=EVN]/subject/@typeCode=SUBJ[investigationEvent/@classCode=INVTG][@moodCo dCode=EVN]/component/@typeCode=COMP[adverseEventAssessment[adverseEventAssessment /@classCode=INVTG][@moodCode=EVN]/component[1/@typeCode=COMP][observationEvent[code/@code=1][@codeSystem=2.16.840.1.113883.3.989.2.1.1.19][author/@typeCode=AUT][as signedEntity/@classCode=ASSIGNED][code=1][@codeSystem=2.16.840.1.113883.3.989. 2.1.1.21][1/observationEvent/@classCode=OBS][@moodCode=EVN]/value[@xsi:type=ED]/text 0 </pre>
h	H.5.r	母国語で記載された症例概 要及び報告者の意見 (必要に 応じ繰り返す)			繰り返 し ノ ー ド	<pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/PORR_IN049016UV[controlActProcess/@classCode=CACTI][@moodCo dCode=EVN]/subject/@typeCode=SUBJ[1/observationEvent[1/observationEvent[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_IN049016UV[controlActProcess/@classCode=CACTI][@moodCo dCode=EVN]/subject/@typeCode=SUBJ[1/observationEvent[1/observationEvent[36][@codeSystem=2. 16.840.1.113883.3.989.2.1.1.19][author/@typeCode=AUT][assignedEntity/@classCode=ASSIGN ED]/code/@code=2][@codeSystem=2.16.840.1.113883.3.989.2.1.1.21][1/observationEvent[cl assCode=OBS][@moodCode=EVN]/value[@xsi:type=ED]/text() </pre>
e	H.5.r.1b	症例概要及び報告者の意見 の記載言語	3A	Encapsulated Data (ED)	値	<pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/PORR_IN049016UV[controlActProcess/@classCode=CACTI][@moodCo dCode=EVN]/subject/@typeCode=SUBJ[1/observationEvent[1/observationEvent[36][@codeSystem=2. 16.840.1.113883.3.989.2.1.1.19][author/@typeCode=AUT][assignedEntity/@classCode=ASSIGN ED]/code/@code=2][@codeSystem=2.16.840.1.113883.3.989.2.1.1.21][1/observationEvent[cl assCode=OBS][@moodCode=EVN]/value[@xsi:type=ED]/@language </pre>

h:ヘッダ e:エン タイプ	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	HL7デー タ型 (下位構成要素)	分類	Xpath
h	ACK.M/A	ICH ICSR パッチ確認 応答						
e	ACK.M.1	確認応答パッチ番号		100AN	Instance Identifier (I)	extension=Character String (ST)	値	/MCCI_IN200101UV01[ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200101UV01.xsd]/id/@root=2.16.840.1.113883.3.989.2.1.3.201/@extension
e	ACK.M.2	確認応答パッチ送信 者識別子	N.1.4	60AN	Instance Identifier (I)	extension=Character String (ST)	値	/MCCI_IN200101UV01[ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200101UV01.xsd]/sender[typeCode=SND]/device[classCode=DEV][determiner Code=INSTANCE]/id/@root=2.16.840.1.113883.3.989.2.1.3.1711/@extension
e	ACK.M.3	確認応答パッチ受信 者識別子	N.1.3	60AN	Instance Identifier (I)	extension=Character String (ST)	値	/MCCI_IN200101UV01[ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200101UV01.xsd]/receiver[typeCode=RCV]/device[classCode=DEV][determiner Code=INSTANCE]/id/@root=2.16.840.1.113883.3.989.2.1.3.1811/@extension
e	ACK.M.4	パッチ伝送の確認応 答日		日付/時 間	Point in Time (TS)		値	/MCCI_IN200101UV01[ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200101UV01.xsd]/creationTime/@value
e	ACK.A.1	ICSR パッチ番号	N.1.2	100AN	Instance Identifier (I)	extension=Character String (ST)	値	/MCCI_IN200101UV01[ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200101UV01.xsd]/acknowledgement[typeCode=targetBatch]/id/@root=2.16.840.1.113 883.3.989.2.1.3.221/@extension
e	ACK.A.2	確認応答領域メッ セージ番号		100AN	Instance Identifier (I)	extension=Character String (ST)	値	/MCCI_IN200101UV01[ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200101UV01.xsd]/attentionLine[keyWordText@code=2][@codeSystem=2.16.840.1.11 3883.3.989.2.1.1.2411][value@xsi:type=11][@root=2.16.840.1.113883.3.989.2.1.3.211]/@extens ion
e	ACK.A.3	ICSR パッチ伝送日	N.1.5	日付/時 間	Point in Time (TS)		値	/MCCI_IN200101UV01[ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200101UV01.xsd]/attentionLine[keyWordText@code=3][@codeSystem=2.16.840.1.11 3883.3.989.2.1.1.2411][value@xsi:type=1511]/@value

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e	ACK.A.4	伝送確認応答コード	2A	Coded Value (CS)	値
e	ACK.A.5	パッチバリデーションエラー	250AN	Encapsulated Data (ED)	値
h	ACK.B.r	ICH ICSR メッセージ 確認応答			繰り返し ノード
e	ACK.B.r.1	ICSR メッセージ番号	100AN	Instance Identifier (II)	値
e	ACK.B.r.2	地域報告番号	100AN	Instance Identifier (II)	値
e	ACK.B.r.3	ICSR メッセージ確認 応答受信者	60AN	Instance Identifier (II)	値
e	ACK.B.r.4	ICSR メッセージ確認 応答送信者	60AN	Instance Identifier (II)	値
e	ACK.B.r.5	ICSR メッセージ作成 曜日	日付 / 時 間	Point in Time (TS)	値
e	ACK.B.r.6	ICSR メッセージの確認 応答コード	2A	Coded Value (CS)	値

2012年11月14日

(別添3)

e	ACK.B.r.7	エラー／警告メッセージ又は意見	250AN	Encapsulated Data (ED)	値	/MCCI_IN200101UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3-MCCI_IN200101UV01.xsd]/MCCI_IN000002UV01[?/acknowledgement[@typeCode][?/acknowledgementDetail[?/text/text()]]
---	-----------	-----------------	-------	------------------------	---	--

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

```

166 2.2. F 検査結果

167 2.2.1. F.r.3.2 値及び限定子

168 2.2.1.1. 値 (例: "10 mg/dL")

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

```

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

```

173 2.2.1.2. 値より大きい (例: "> 10 mg/dL")

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

```

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

```

182 2.2.1.3. 値より小さい (例: "<10 mg/dL")

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

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

191 2.2.1.4. 値以上 (例: ">= 10 mg/dL")

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

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

199 2.2.1.5. 値以下 (例: "<= 10 mg/dL")

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

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

207 2.2.2 F.r.3.2 及び F.r.3.3

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

```

217      <!-- F.r.1: Test Date -->
218      <value xsi:type="IVL_PQ">
219      <center value="10" unit="mg/dl"/>
220      <!-- F.r.3.2: Test Result (Value) -->
221      <!-- F.r.3.3: Unit -->
222      </value>

223  2.2.3.  F.r.3.1

224      <observation classCode="OBS" moodCode="EVN">
225      <code code="F.r.2.2b" codeSystem="2.16.840.1.113883.6.163" codeSystemVersion="F.r.2.2a">
226          <originalText>F.r.2</originalText>
227      </code>
228      <effectiveTime value="20090101"/>
229      <!-- F.r.1: Test Date -->
230      <interpretationCode code="Positive" codeSystem="2.16.840.1.113883.3.989.2.1.1.12"/>
231      <!-- F.r.3.1: Test Result (Code) -->

232  2.2.4.  F.r.3.4

233      <observation classCode="OBS" moodCode="EVN">
234      <code code="F.r.2.2b" codeSystem="2.16.840.1.113883.6.163" codeSystemVersion="F.r.2.2a">
235          <originalText>F.r.2</originalText>
236      </code>
237      <effectiveTime value="20090101"/>
238      <!-- F.r.1: Test Date -->
239      <value xsi:type="ED">F.r.3.4</value>
240      <!-- F.r.3.4: Result Unstructured Data (free text) -->

241  2.3.  G.k.4 投与量の例

242  2.3.1.  1日当たり1/回

243      <outboundRelationship2 typeCode="COMP">
244          <substanceAdministration classCode="SBADM" moodCode="EVN">
245              <text>1 per day</text>
246              <effectiveTime xsi:type="SXPRTS">
247                  <comp xsi:type="PIVLTST">
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="SXPRTS">
341             <comp xsi:type="PIVLTST">
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>
412

```

413 2.3.9. 頓用、1錠/回、開始日、終了日

```

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

```

427 2.3.10. 頓用、20 mg/回

```

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

```


435 2.3.11. 周期的、500 mg/回、開始日、終了日

```

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

```

448 2.3.12. 周期的、500 mg/回

```

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

```

455 2.3.13. 総投与量 20,000 mg、開始日、終了日

```

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

```

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

471 HL7 telecom データ型の構文 -

```

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

```

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

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

481 例 -

```

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

```

484 これは標準のHL7のnull flavorではないことに留意する。

485 2.6. トライメスターを使用した妊娠期間 (D.2.2.1b)

```

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

```

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

```

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

```

503 </ingredient>

504 2.8. 各副作用に関する因果関係情報の例

505 <component typeCode="COMP">

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

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

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

509 <methodCode>

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

511 </methodCode>

512 <author typeCode="AUT">

513 <assignedEntity classCode="ASSIGNED">

514 <code>

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

516 </code>

517 </assignedEntity>

518 </author>

519 <subject1 typeCode="SUBJ">

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

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

522 </adverseEffectReference>

523 </subject1>

524 <subject2 typeCode="SUBJ">

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

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

527 </productUseReference>

528 </subject2>

529 </causalityAssessment>

530 </component>

531

532 III. 参照インスタンスについての注意事項

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

547 例:

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

567 **IV. 参考**

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

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

