

(別添3)



医薬品規制調和国際会議

ICH E2B 実装作業部会

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

バージョン 1.02 2016年11月10日

(別添3)

文書の履歴

最終版 確定日	文書の標題	バージョン	発表	WG
2013年 4月	個別症例安全性報告 (ICSR) の電子的伝送 実装ガイドの付録I (G) 技術的情報	1.00	Step 4 文書	E2B EWG
2014年 11月	校正実施。変更履歴の詳細は別添のシート 参照。	1.01	Step 4 文書	E2B IWG
2016年 11月	M5 参照を ISO IDMP 参照へ変更。	1.02	Step 4 文書	E2B IWG

目次

I.	序.....	4
II.	技術的情報.....	4
1.	ICH データ型、HL7 データ型及び E2B (R3) データ項目の XPATH.....	4
2.	複数の XML 表現に関する XML 断片.....	86
2.1	開始日、終了日及び持続期間.....	86
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.....	86
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.....	86
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.....	87
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.....	88
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.....	88
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.r.7又は G.k.4.r.6のいずれかに入力する.....	89
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.....	89
2.2.	F 検査結果.....	90
2.2.1.	Fr.3.2 値及び限定子.....	90
2.2.1.1.	値 (例: "10 mg/dL").....	90
2.2.1.2.	値より大きい (例: "> 10 mg/dL").....	90
2.2.1.3.	値より小さい (例: "< 10 mg/dL").....	91
2.2.1.4.	値以上 (例: "≥ 10 mg/dL").....	91
2.2.1.5.	値以下 (例: "≤ 10 mg/dL").....	91
2.2.2.	Fr.3.2 及び Fr.3.3.....	91
2.2.3.	Fr.3.1.....	92
2.2.4.	Fr.3.4.....	92
2.3.	G.k.4 投与量の例.....	92
2.3.1.	1日当たり 1/回.....	92
2.3.2.	1日当たり 1錠/回.....	93
2.3.3.	1日1回、1/4錠/回.....	93

(別添3)

2.3.4.	週1回、6錠/回.....	94
2.3.5.	1日2回、1錠/回.....	94
2.3.6.	1日4回、7.5 mg/回.....	95
2.3.7.	1日1回、15 mL/回.....	96
2.3.8.	2日に1回、1錠/回.....	96
2.3.9.	頓用、1錠/回、開始日、終了日.....	97
2.3.10.	頓用、20 mg/回.....	97
2.3.11.	周期的、500 mg/回、開始日、終了日.....	98
2.3.12.	周期的、500 mg/回.....	98
2.3.13.	総投与量 20,000 mg、開始日、終了日.....	98
2.4.	電話、Fax、電子メール (C.3.4.6、C.3.4.7、及びC.3.4.8).....	99
2.5.	報告者の電話番号に対して"Privacy"を示す (C.2.r.2.7).....	99
2.6.	トライメスターを使用した妊娠期間 (D.2.2.1b).....	99
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 (G.k.2.3.r.1).....	99
2.8.	各副作用に関する因果関係情報の例.....	100
III.	参照インスタンスについての注意事項.....	101
IV.	参考.....	102
	ICSR メッセージにおける E2B (R3) データ項目構造.....	102

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、その代わりに、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伝送し、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='2.16.840.1.113883.3.989.2.1.1.1']/@code
		バッチ内のメッセージの種 類に関する ICH コードリス トのバージョン					/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/name[@codeSystem='2.16.840.1.113883.3.989.2.1.1.1']@codeSystem Version
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='2.16.840.1.113883.3.989.2.1.3.22']/@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='2.16.840.1.113883.3.989.2.1.3.13'][1]/@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='2.16.840.1.113883.3.989.2.1.3.14'][1]/@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[r]/id[@root='2.16.840.1.113883.3.989.2.1.3.1'] [1]/@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[r]/sender[@typeCode='SND']/device[@classCode= 'DEV'][@determinerCode='INSTANCE']/id[@root='2.16.840.1.113883.3.989.2.1.3.11'] [1]/@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[r]/receiver[@typeCode='RCV']/device[@classCode ='DEV'][@determinerCode='INSTANCE']/id[@root='2.16.840.1.113883.3.989.2.1.3.12'] [1]/@extensio n
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[r]/creationTime/@value
h	C.1	症例安全性報告の識別					

(別添3)

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 (I)	extension=Character String (ST)	値	/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='INVSTG'][@moodCode='EVN']/id[@root='2.16.840.1.113883.3.989.2.1.3.1']][1]/@extension
e	C.1.2	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[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/effectiveTime/@value
e	C.1.3	報告の種類	1N	Coded With Equivalents (CE)	code=Character String (ST)	値	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subjectOf2[@typeCode='SUBJ'][1]/investigationCharacteristic/code[@code='1'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.23']][1]/investigationCharacteristic[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='CE'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.2']/@code
		報告の種類に関する ICH コードリストのバージョン					/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subjectOf2[@typeCode='SUBJ'][1]/investigationCharacteristic/code[@code='1'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.23']][1]/investigationCharacteristic[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='CE'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.2']/@codeSystemVersion
e	C.1.4	情報源から最初に報告が入手された日	日付/時間	Interval of Point in Time (IVL<TS>)	low=Interval Boundary (VXB)	値	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subjectOf2[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/effectiveTime/low/@value
e	C.1.5	本報告の最新情報入手日	日付/時間	Point in Time (TS)		値	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subjectOf2[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/availabilityTime/@value
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?	ブール型	Boolean (BL)		値	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subjectOf2[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP']/observationEvent/code[@code='1'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']][1]/observationEvent[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='BL']/@value
h	C.1.6.1.r	送信者が保有している資料(必要に応じ繰り返す)				繰り返しノード	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subjectOf2[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/reference[@typeCode='REFR'][@document/code[@code='1']][@codeSystem='2.16.840.1.113883.3.989.2.1.1.27']]
e	C.1.6.1.r.1	送信者が保有している資料	2000AN	Character String (ST)		値	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subjectOf2[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/reference[@typeCode='REFR'][@document/code[@code='1']][@codeSystem='2.16.840.1.113883.3.989.2.1.1.27']][r]/document[@classCode='DOC'][@moodCode='EVN']/title/text()

(別添3)

e	C.1.6.1.r.2	含まれる資料	N/A	Encapsulated Data (ED)		値	/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="INVSTG"][@moodCode="EVN"]/reference[@typeCode="REFR"][@document/code[@code="1"][@codeSystem="2.16.840.1.113883.3.989.2.1.1.27"]][r]/document[@classCode="DOC"][@moodCode="EVN"]/text/text()
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	/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="INVSTG"][@moodCode="EVN"]/component[@typeCode="COMP"][@observationEvent/code[@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	/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="INVSTG"][@moodCode="EVN"]/component[@typeCode="COMP"][@observationEvent/code[@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 (II)	extension=Character String (ST)	値	/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="INVSTG"][@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)	値	/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="INVSTG"][@moodCode="EVN"]/outboundRelationship[@typeCode="SPRT"][@relatedInvestigation/code[@code="1"][@codeSystem="2.16.840.1.113883.3.989.2.1.1.22"]][1]/relatedInvestigation[@classCode="INVSTG"][@moodCode="EVN"]/subjectOf2[@typeCode="SUBJ"][1]/controlActEvent[@classCode="CACT"][@moodCode="EVN"]/author[@typeCode="AUT"]/assignedEntity[@classCode="ASSIGNED"]/code[@codeSystem="2.16.840.1.113883.3.989.2.1.1.3"]/@code
		本症例の第一送信者に関する ICH コードリストのバージョン					/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="INVSTG"][@moodCode="EVN"]/outboundRelationship[@typeCode="SPRT"][@relatedInvestigation/code[@code="1"][@codeSystem="2.16.840.1.113883.3.989.2.1.1.22"]][1]/relatedInvestigation[@classCode="INVSTG"][@moodCode="EVN"]/subjectOf2[@typeCode="SUBJ"][1]/controlActEvent[@classCode="CACT"][@moodCode="EVN"]/author[@typeCode="AUT"]/assignedEntity[@classCode="ASSIGNED"]/code[@codeSystem="2.16.840.1.113883.3.989.2.1.1.3"]/@codeSystemVersion
h	C.1.9	その他の症例識別子					
e	C.1.9.1	過去の伝送で記載されたその他の症例識別子はあるか？	ブール型	Boolean (BL)		値	/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="INVSTG"][@moodCode="EVN"]/subjectOf2[@typeCode="SUBJ"]/investigationCharacteristic/code[@code="2"][@codeSystem="2.16.840.1.113883.3.989.2.1.1.23"]][1]/investigationCharacteristic[@classCode="OBS"][@moodCode="EVN"]/value[@xsi:type="BL"]/@value

(別添3)

h	C.2.r	第一次情報源 (必要に応じ繰り返す)				繰り返しノード	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/outboundRelationship[@typeCode='SPRT'][@relatedInvestigation/code[@code='2']][@codeSystem='2.16.840.1.113883.3.989.2.1.1.22']
h	C.2.r.1	報告者の氏名					
e	C.2.r.1.1	報告者の職名	50AN	Person Name (PN)	prefix=Entity Name Part (ENXP)	値	/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='INVSTG'][@moodCode='EVN']/outboundRelationship[@typeCode='SPRT'][@relatedInvestigation/code[@code='2']][@codeSystem='2.16.840.1.113883.3.989.2.1.1.22']][r]/relatedInvestigation[@classCode='INVSTG'][@moodCode='EVN']/subjectOf2[@typeCode='SUBJ']/controlActEvent[@classCode='CACT'][@moodCode='EVN']/author[@typeCode='AUT']/assignedEntity[@classCode='ASSIGNED']/assignedPerson[@classCode='PSN'][@determinerCode='INSTANCE']/name/prefix[1]/text()
e						NullFlavor	/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='INVSTG'][@moodCode='EVN']/outboundRelationship[@typeCode='SPRT'][@relatedInvestigation/code[@code='2']][@codeSystem='2.16.840.1.113883.3.989.2.1.1.22']][r]/relatedInvestigation[@classCode='INVSTG'][@moodCode='EVN']/subjectOf2[@typeCode='SUBJ']/controlActEvent[@classCode='CACT'][@moodCode='EVN']/author[@typeCode='AUT']/assignedEntity[@classCode='ASSIGNED']/assignedPerson[@classCode='PSN'][@determinerCode='INSTANCE']/name/prefix[1]/@nullFlavor
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:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/outboundRelationship[@typeCode='SPRT'][@relatedInvestigation/code[@code='2']][@codeSystem='2.16.840.1.113883.3.989.2.1.1.22']][r]/relatedInvestigation[@classCode='INVSTG'][@moodCode='EVN']/subjectOf2[@typeCode='SUBJ']/controlActEvent[@classCode='CACT'][@moodCode='EVN']/author[@typeCode='AUT']/assignedEntity[@classCode='ASSIGNED']/assignedPerson[@classCode='PSN'][@determinerCode='INSTANCE']/name/given[1]/text()
e						NullFlavor	/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='INVSTG'][@moodCode='EVN']/outboundRelationship[@typeCode='SPRT'][@relatedInvestigation/code[@code='2']][@codeSystem='2.16.840.1.113883.3.989.2.1.1.22']][r]/relatedInvestigation[@classCode='INVSTG'][@moodCode='EVN']/subjectOf2[@typeCode='SUBJ']/controlActEvent[@classCode='CACT'][@moodCode='EVN']/author[@typeCode='AUT']/assignedEntity[@classCode='ASSIGNED']/assignedPerson[@classCode='PSN'][@determinerCode='INSTANCE']/name/given[1]/@nullFlavor
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:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/outboundRelationship[@typeCode='SPRT'][@relatedInvestigation/code[@code='2']][@codeSystem='2.16.840.1.113883.3.989.2.1.1.22']][r]/relatedInvestigation[@classCode='INVSTG'][@moodCode='EVN']/subjectOf2[@typeCode='SUBJ']/controlActEvent[@classCode='CACT'][@moodCode='EVN']/author[@typeCode='AUT']/assignedEntity[@classCode='ASSIGNED']/assignedPerson[@classCode='PSN'][@determinerCode='INSTANCE']/name/given[2]/text()

(別添3)

e						NullFlavor	/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=INVSTG][@moodCode=EVN]/outboundRelationship[@typeCode=SPRT][relatedInvestigation/code[@code=2][@codeSystem=2.16.840.1.113883.3.989.2.1.1.22]][r]/relatedInvestigation[@classCode=INVSTG][@moodCode=EVN]/subjectOf2[@typeCode=SUBJ]/controlActEvent[@classCode=CACT][@moodCode=EVN]/author[@typeCode=AUT]/assignedEntity[@classCode=ASSIGNED]/assignedPerson[@classCode=PSN][@determinerCode=INSTANCE]/name/given[2]/@nullFlavor
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:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UV[r]/controlActProcess[@classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUBJ][1]/investigationEvent[@classCode=INVSTG][@moodCode=EVN]/outboundRelationship[@typeCode=SPRT][relatedInvestigation/code[@code=2][@codeSystem=2.16.840.1.113883.3.989.2.1.1.22]][r]/relatedInvestigation[@classCode=INVSTG][@moodCode=EVN]/subjectOf2[@typeCode=SUBJ]/controlActEvent[@classCode=CACT][@moodCode=EVN]/author[@typeCode=AUT]/assignedEntity[@classCode=ASSIGNED]/assignedPerson[@classCode=PSN][@determinerCode=INSTANCE]/name/family[1]/text()
e						NullFlavor	/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=INVSTG][@moodCode=EVN]/outboundRelationship[@typeCode=SPRT][relatedInvestigation/code[@code=2][@codeSystem=2.16.840.1.113883.3.989.2.1.1.22]][r]/relatedInvestigation[@classCode=INVSTG][@moodCode=EVN]/subjectOf2[@typeCode=SUBJ]/controlActEvent[@classCode=CACT][@moodCode=EVN]/author[@typeCode=AUT]/assignedEntity[@classCode=ASSIGNED]/assignedPerson[@classCode=PSN][@determinerCode=INSTANCE]/name/family[1]/@nullFlavor
h	C.2.r.2	報告者の住所及び電話番号					
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]/PORR_IN049016UV[r]/controlActProcess[@classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUBJ][1]/investigationEvent[@classCode=INVSTG][@moodCode=EVN]/outboundRelationship[@typeCode=SPRT][relatedInvestigation/code[@code=2][@codeSystem=2.16.840.1.113883.3.989.2.1.1.22]][r]/relatedInvestigation[@classCode=INVSTG][@moodCode=EVN]/subjectOf2[@typeCode=SUBJ]/controlActEvent[@classCode=CACT][@moodCode=EVN]/author[@typeCode=AUT]/assignedEntity[@classCode=ASSIGNED]/representedOrganization[@classCode=ORG][@determinerCode=INSTANCE]/assignedEntity[@classCode=ASSIGNED]/representedOrganization[@classCode=ORG][@determinerCode=INSTANCE]/name/text()
e						NullFlavor	/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=INVSTG][@moodCode=EVN]/outboundRelationship[@typeCode=SPRT][relatedInvestigation/code[@code=2][@codeSystem=2.16.840.1.113883.3.989.2.1.1.22]][r]/relatedInvestigation[@classCode=INVSTG][@moodCode=EVN]/subjectOf2[@typeCode=SUBJ]/controlActEvent[@classCode=CACT][@moodCode=EVN]/author[@typeCode=AUT]/assignedEntity[@classCode=ASSIGNED]/representedOrganization[@classCode=ORG][@determinerCode=INSTANCE]/assignedEntity[@classCode=ASSIGNED]/representedOrganization[@classCode=ORG][@determinerCode=INSTANCE]/name/@nullFlavor

(別添3)

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']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/outboundRelationship[@typeCode='SPRT'][@relatedInvestigation/code[@code='2']][@codeSystem='2.16.840.1.113883.3.989.2.1.1.22']][r]/relatedInvestigation[@classCode='INVSTG'][@moodCode='EVN']/subjectOf2[@typeCode='SUBJ']/controlActEvent[@classCode='CACT'][@moodCode='EVN']/author[@typeCode='AUT']/assignedEntity[@classCode='ASSIGNED']/representedOrganization[@classCode='ORG'][@determinerCode='INSTANCE']/name/text()
e						NullFlavor	/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='INVSTG'][@moodCode='EVN']/outboundRelationship[@typeCode='SPRT'][@relatedInvestigation/code[@code='2']][@codeSystem='2.16.840.1.113883.3.989.2.1.1.22']][r]/relatedInvestigation[@classCode='INVSTG'][@moodCode='EVN']/subjectOf2[@typeCode='SUBJ']/controlActEvent[@classCode='CACT'][@moodCode='EVN']/author[@typeCode='AUT']/assignedEntity[@classCode='ASSIGNED']/representedOrganization[@classCode='ORG'][@determinerCode='INSTANCE']/name/@nullFlavor
e	C.2.r.2.3	報告者の住所 (番地)	100AN	Postal Address (AD)	streetAddressLine=Address Part (ADXP)	値	/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='INVSTG'][@moodCode='EVN']/outboundRelationship[@typeCode='SPRT'][@relatedInvestigation/code[@code='2']][@codeSystem='2.16.840.1.113883.3.989.2.1.1.22']][r]/relatedInvestigation[@classCode='INVSTG'][@moodCode='EVN']/subjectOf2[@typeCode='SUBJ']/controlActEvent[@classCode='CACT'][@moodCode='EVN']/author[@typeCode='AUT']/assignedEntity[@classCode='ASSIGNED']/addr[1]/streetAddressLine[1]/text()
e						NullFlavor	/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='INVSTG'][@moodCode='EVN']/outboundRelationship[@typeCode='SPRT'][@relatedInvestigation/code[@code='2']][@codeSystem='2.16.840.1.113883.3.989.2.1.1.22']][r]/relatedInvestigation[@classCode='INVSTG'][@moodCode='EVN']/subjectOf2[@typeCode='SUBJ']/controlActEvent[@classCode='CACT'][@moodCode='EVN']/author[@typeCode='AUT']/assignedEntity[@classCode='ASSIGNED']/addr[1]/streetAddressLine[1]/@nullFlavor
e	C.2.r.2.4	報告者の住所 (市町村等)	35AN	Postal Address (AD)	city=Address Part (ADXP)	値	/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='INVSTG'][@moodCode='EVN']/outboundRelationship[@typeCode='SPRT'][@relatedInvestigation/code[@code='2']][@codeSystem='2.16.840.1.113883.3.989.2.1.1.22']][r]/relatedInvestigation[@classCode='INVSTG'][@moodCode='EVN']/subjectOf2[@typeCode='SUBJ']/controlActEvent[@classCode='CACT'][@moodCode='EVN']/author[@typeCode='AUT']/assignedEntity[@classCode='ASSIGNED']/addr[1]/city[1]/text()
e						NullFlavor	/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='INVSTG'][@moodCode='EVN']/outboundRelationship[@typeCode='SPRT'][@relatedInvestigation/code[@code='2']][@codeSystem='2.16.840.1.113883.3.989.2.1.1.22']][r]/relatedInvestigation[@classCode='INVSTG'][@moodCode='EVN']/subjectOf2[@typeCode='SUBJ']/controlActEvent[@classCode='CACT'][@moodCode='EVN']/author[@typeCode='AUT']/assignedEntity[@classCode='ASSIGNED']/addr[1]/city[1]/@nullFlavor

(別添3)

e	C.2.r.2.5	報告者の住所（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_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/outboundRelationship[@typeCode='SPRT'][@relatedInvestigation/code[@code='2']][@codeSystem='2.16.840.1.113883.3.989.2.1.1.22']]/relatedInvestigation[@classCode='INVSTG'][@moodCode='EVN']/subjectOf2[@typeCode='SUBJ']/controlActEvent[@classCode='CACT'][@moodCode='EVN']/author[@typeCode='AUT']/assignedEntity[@classCode='ASSIGNED']/addr[1]/state[1]/text()
e						NullFlavor	/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='INVSTG'][@moodCode='EVN']/outboundRelationship[@typeCode='SPRT'][@relatedInvestigation/code[@code='2']][@codeSystem='2.16.840.1.113883.3.989.2.1.1.22']]/relatedInvestigation[@classCode='INVSTG'][@moodCode='EVN']/subjectOf2[@typeCode='SUBJ']/controlActEvent[@classCode='CACT'][@moodCode='EVN']/author[@typeCode='AUT']/assignedEntity[@classCode='ASSIGNED']/addr[1]/state[1]/nullFlavor
e	C.2.r.2.6	報告者の住所（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_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/outboundRelationship[@typeCode='SPRT'][@relatedInvestigation/code[@code='2']][@codeSystem='2.16.840.1.113883.3.989.2.1.1.22']]/relatedInvestigation[@classCode='INVSTG'][@moodCode='EVN']/subjectOf2[@typeCode='SUBJ']/controlActEvent[@classCode='CACT'][@moodCode='EVN']/author[@typeCode='AUT']/assignedEntity[@classCode='ASSIGNED']/addr[1]/postalCode[1]/text()
e						NullFlavor	/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='INVSTG'][@moodCode='EVN']/outboundRelationship[@typeCode='SPRT'][@relatedInvestigation/code[@code='2']][@codeSystem='2.16.840.1.113883.3.989.2.1.1.22']]/relatedInvestigation[@classCode='INVSTG'][@moodCode='EVN']/subjectOf2[@typeCode='SUBJ']/controlActEvent[@classCode='CACT'][@moodCode='EVN']/author[@typeCode='AUT']/assignedEntity[@classCode='ASSIGNED']/addr[1]/postalCode[1]/@nullFlavor
e	C.2.r.2.7	報告者の電話番号	33AN	Telecommunication Address (TEL)		値	substring(/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/outboundRelationship[@typeCode='SPRT'][@relatedInvestigation/code[@code='2']][@codeSystem='2.16.840.1.113883.3.989.2.1.1.22']]/relatedInvestigation[@classCode='INVSTG'][@moodCode='EVN']/subjectOf2[@typeCode='SUBJ']/controlActEvent[@classCode='CACT'][@moodCode='EVN']/author[@typeCode='AUT']/assignedEntity[@classCode='ASSIGNED']/telecom[starts-with(@value,'tel:')][1]/@value, 5)
e						NullFlavor	/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='INVSTG'][@moodCode='EVN']/outboundRelationship[@typeCode='SPRT'][@relatedInvestigation/code[@code='2']][@codeSystem='2.16.840.1.113883.3.989.2.1.1.22']]/relatedInvestigation[@classCode='INVSTG'][@moodCode='EVN']/subjectOf2[@typeCode='SUBJ']/controlActEvent[@classCode='CACT'][@moodCode='EVN']/author[@typeCode='AUT']/assignedEntity[@classCode='ASSIGNED']/telecom[starts-with(@value,'tel:')][1]/@nullFlavor

(別添3)

e	C.2.r.3	報告者の国コード	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_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/outboundRelationship[@typeCode='SPRT'][@relatedInvestigation/code[@code='2']][@codeSystem='2.16.840.1.113883.3.989.2.1.1.22']][r]/relatedInvestigation[@classCode='INVSTG'][@moodCode='EVN']/subjectOf2[@typeCode='SUBJ']/controlActEvent[@classCode='CACT'][@moodCode='EVN']/author[@typeCode='AUT']/assignedEntity[@classCode='ASSIGNED']/assignedPerson[@classCode='PSN'][@determinerCode='INSTANCE']/asLocatedEntity[@classCode='LOCE'][1]/location[@classCode='COUNTRY'][@determinerCode='INSTANCE']/code[@codeSystem='1.0.3166.1.2.2']/code
e						NullFlavor	/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='INVSTG'][@moodCode='EVN']/outboundRelationship[@typeCode='SPRT'][@relatedInvestigation/code[@code='2']][@codeSystem='2.16.840.1.113883.3.989.2.1.1.22']][r]/relatedInvestigation[@classCode='INVSTG'][@moodCode='EVN']/subjectOf2[@typeCode='SUBJ']/controlActEvent[@classCode='CACT'][@moodCode='EVN']/author[@typeCode='AUT']/assignedEntity[@classCode='ASSIGNED']/assignedPerson[@classCode='PSN'][@determinerCode='INSTANCE']/asLocatedEntity[@classCode='LOCE'][1]/location[@classCode='COUNTRY'][@determinerCode='INSTANCE']/code[@codeSystem='1.0.3166.1.2.2']/nullFlavor
e	C.2.r.4	資格	1N	Coded With Equivalents (CE)	code=Character String (ST)	値	/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='INVSTG'][@moodCode='EVN']/outboundRelationship[@typeCode='SPRT'][@relatedInvestigation/code[@code='2']][@codeSystem='2.16.840.1.113883.3.989.2.1.1.22']][r]/relatedInvestigation[@classCode='INVSTG'][@moodCode='EVN']/subjectOf2[@typeCode='SUBJ']/controlActEvent[@classCode='CACT'][@moodCode='EVN']/author[@typeCode='AUT']/assignedEntity[@classCode='ASSIGNED']/assignedPerson[@classCode='PSN'][@determinerCode='INSTANCE']/asQualifiedEntity[@classCode='QUAL'][1]/code[@codeSystem='2.16.840.1.113883.3.989.2.1.1.6']/code
		資格に関する ICH コードリストのバージョン					/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='INVSTG'][@moodCode='EVN']/outboundRelationship[@typeCode='SPRT'][@relatedInvestigation/code[@code='2']][@codeSystem='2.16.840.1.113883.3.989.2.1.1.22']][r]/relatedInvestigation[@classCode='INVSTG'][@moodCode='EVN']/subjectOf2[@typeCode='SUBJ']/controlActEvent[@classCode='CACT'][@moodCode='EVN']/author[@typeCode='AUT']/assignedEntity[@classCode='ASSIGNED']/assignedPerson[@classCode='PSN'][@determinerCode='INSTANCE']/asQualifiedEntity[@classCode='QUAL'][1]/code[@codeSystem='2.16.840.1.113883.3.989.2.1.1.6']/@codeSystemVersion
e						NullFlavor	/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='INVSTG'][@moodCode='EVN']/outboundRelationship[@typeCode='SPRT'][@relatedInvestigation/code[@code='2']][@codeSystem='2.16.840.1.113883.3.989.2.1.1.22']][r]/relatedInvestigation[@classCode='INVSTG'][@moodCode='EVN']/subjectOf2[@typeCode='SUBJ']/controlActEvent[@classCode='CACT'][@moodCode='EVN']/author[@typeCode='AUT']/assignedEntity[@classCode='ASSIGNED']/assignedPerson[@classCode='PSN'][@determinerCode='INSTANCE']/asQualifiedEntity[@classCode='QUAL'][1]/code[@codeSystem='2.16.840.1.113883.3.989.2.1.1.6']/@nullFlavor

(別添 3)

e	C.2.r.5	規制目的上の第一次情報源	1N	Real Number (REAL)		値	/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='INVSTG'][@moodCode='EVN']/outboundRelationship[@typeCode='SPRT'][@relatedInvestigation/code[@code='2']][@codeSystem='2.16.840.1.113883.3.989.2.1.1.22']][r]/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	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subjectOf1[@typeCode='SUBJ'][1]/controlActEvent/author/assignedEntity/code/@codeSystem='2.16.840.1.113883.3.989.2.1.1.7']][1]/controlActEvent[@classCode='CACT'][@moodCode='EVN']/author[@typeCode='AUT']/assignedEntity[@classCode='ASSIGNED']/code/@codeSystem='2.16.840.1.113883.3.989.2.1.1.7']/@code
		送信者の種類に関する ICH コードリストのバージョン					/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subjectOf1[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/subjectOf1[@typeCode='SUBJ'][1]/controlActEvent/author/assignedEntity/code/@codeSystem='2.16.840.1.113883.3.989.2.1.1.7']][1]/controlActEvent[@classCode='CACT'][@moodCode='EVN']/author[@typeCode='AUT']/assignedEntity[@classCode='ASSIGNED']/code/@codeSystemVersion
e	C.3.2	送信者の組織	100AN	Organization Name (ON)	name=Entity Name Part (ENXP)	値	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subjectOf1[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/subjectOf1[@typeCode='SUBJ'][1]/controlActEvent/author/assignedEntity/code/@codeSystem='2.16.840.1.113883.3.989.2.1.1.7']][1]/controlActEvent[@classCode='CACT'][@moodCode='EVN']/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	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subjectOf1[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/subjectOf1[@typeCode='SUBJ'][1]/controlActEvent/author/assignedEntity/code/@codeSystem='2.16.840.1.113883.3.989.2.1.1.7']][1]/controlActEvent[@classCode='CACT'][@moodCode='EVN']/author[@typeCode='AUT']/assignedEntity[@classCode='ASSIGNED']/representedOrganization[@classCode='ORG'][@determinerCode='INSTANCE']/name/text()
e	C.3.3.2	送信者の職名	50AN	Person Name (PN)	prefix=Entity Name Part (ENXP)	値	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subjectOf1[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/subjectOf1[@typeCode='SUBJ'][1]/controlActEvent/author/assignedEntity/code/@codeSystem='2.16.840.1.113883.3.989.2.1.1.7']][1]/controlActEvent[@classCode='CACT'][@moodCode='EVN']/author[@typeCode='AUT']/assignedEntity[@classCode='ASSIGNED']/assignedPerson[@classCode='PSN'][@determinerCode='INSTANCE']/name/prefix[1]/text()

(別添 3)

e	C.3.3.3	送信者の名前	60AN	Person Name (PN)	given=Entity Name Part (ENXP)	値	/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='INVSTG'][@moodCode='EVN']/subjectOf1[@typeCode='SUBJ'][controlActEvent/author/assignedEntity/code[@codeSystem='2.16.840.1.113883.3.989.2.1.1.7']][1]/controlActEvent[@classCode='CACT'][@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	/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='INVSTG'][@moodCode='EVN']/subjectOf1[@typeCode='SUBJ'][controlActEvent/author/assignedEntity/code[@codeSystem='2.16.840.1.113883.3.989.2.1.1.7']][1]/controlActEvent[@classCode='CACT'][@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	/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='INVSTG'][@moodCode='EVN']/subjectOf1[@typeCode='SUBJ'][controlActEvent/author/assignedEntity/code[@codeSystem='2.16.840.1.113883.3.989.2.1.1.7']][1]/controlActEvent[@classCode='CACT'][@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	/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='INVSTG'][@moodCode='EVN']/subjectOf1[@typeCode='SUBJ'][controlActEvent/author/assignedEntity/code[@codeSystem='2.16.840.1.113883.3.989.2.1.1.7']][1]/controlActEvent[@classCode='CACT'][@moodCode='EVN']/author[@typeCode='AUT']/assignedEntity[@classCode='ASSIGNED']/addr[1]/streetAddressLine[1]/text()
e	C.3.4.2	送信者の住所 (市町村等)	35AN	Postal Address (AD)	city=Address Part (ADXP)	値	/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='INVSTG'][@moodCode='EVN']/subjectOf1[@typeCode='SUBJ'][controlActEvent/author/assignedEntity/code[@codeSystem='2.16.840.1.113883.3.989.2.1.1.7']][1]/controlActEvent[@classCode='CACT'][@moodCode='EVN']/author[@typeCode='AUT']/assignedEntity[@classCode='ASSIGNED']/addr[1]/city[1]/text()
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_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/subjectOf1[@typeCode='SUBJ'][controlActEvent/author/assignedEntity/code[@codeSystem='2.16.840.1.113883.3.989.2.1.1.7']][1]/controlActEvent[@classCode='CACT'][@moodCode='EVN']/author[@typeCode='AUT']/assignedEntity[@classCode='ASSIGNED']/addr[1]/state[1]/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_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/subjectOf1[@typeCode='SUBJ']/controlActEvent/author/assignedEntity/code[@codeSystem='2.16.840.1.113883.3.989.2.1.1.7']][1]/controlActEvent[@classCode='CACT'][@moodCode='EVN']/author[@typeCode='AUT']/assignedEntity[@classCode='ASSIGNED']/addr[1]/postalCode[1]/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_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/subjectOf1[@typeCode='SUBJ']/controlActEvent/author/assignedEntity/code[@codeSystem='2.16.840.1.113883.3.989.2.1.1.7']][1]/controlActEvent[@classCode='CACT'][@moodCode='EVN']/author[@typeCode='AUT']/assignedEntity[@classCode='ASSIGNED']/assignedPerson[@classCode='PSN'][@determinerCode='INSTANCE']/asLocatedEntity[@classCode='LOCE'][@moodCode='EVN']/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_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/subjectOf1[@typeCode='SUBJ']/controlActEvent/author/assignedEntity/code[@codeSystem='2.16.840.1.113883.3.989.2.1.1.7']][1]/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_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/subjectOf1[@typeCode='SUBJ']/controlActEvent/author/assignedEntity/code[@codeSystem='2.16.840.1.113883.3.989.2.1.1.7']][1]/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_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/subjectOf1[@typeCode='SUBJ']/controlActEvent/author/assignedEntity/code[@codeSystem='2.16.840.1.113883.3.989.2.1.1.7']][1]/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）				繰り返しノード	/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='INVSTG'][@moodCode='EVN']/reference[@typeCode='REFR'][document/code[@code='2']][@codeSystem='2.16.840.1.113883.3.989.2.1.1.27']]
e	C.4.r.1	引用文献	500AN	Encapsulated Data (ED)		値	/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='INVSTG'][@moodCode='EVN']/reference[@typeCode='REFR'][document/code[@code='2']][@codeSystem='2.16.840.1.113883.3.989.2.1.1.27']][r]/document[@classCode='DOC'][@moodCode='EVN']/bibliographicDesignationText/text()

(別添3)

e						NullFlavor	/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='INVSTG'][@moodCode='EVN']/reference[@typeCode='REFR']/document/code[@code='2'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.27']]/r]/document[@classCode='DOC'][@moodCode='EVN']/bibliographicDesignationText/@nullFlavor
e	C.4.r.2	含まれる資料	N/A	Encapsulated Data (ED)		値	/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='INVSTG'][@moodCode='EVN']/reference[@typeCode='REFR']/document/code[@code='2'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.27']]/r]/document[@classCode='DOC'][@moodCode='EVN']/text/text()
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)				繰り返しノード	/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='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment[1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject[1]/primaryRole[@classCode='INVSBJ']/subjectOf1[@typeCode='SBJ'][1]/researchStudy[@classCode='CLNTRL'][@moodCode='EVN']/authorization[@typeCode='AUTH']
e	C.5.1.r.1	試験の登録番号	50AN	Instance Identifier (I)	extension=Character String (ST)	値	/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='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment[1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject[1]/primaryRole[@classCode='INVSBJ']/subjectOf1[@typeCode='SBJ'][1]/researchStudy[@classCode='CLNTRL'][@moodCode='EVN']/authorization[@typeCode='AUTH']]/r]/studyRegistration[@classCode='ACT'][@moodCode='EVN']/id[@root='2.16.840.1.113883.3.989.2.1.3.6']]/extension
e						NullFlavor	/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='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment[1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject[1]/primaryRole[@classCode='INVSBJ']/subjectOf1[@typeCode='SBJ'][1]/researchStudy[@classCode='CLNTRL'][@moodCode='EVN']/authorization[@typeCode='AUTH']]/r]/studyRegistration[@classCode='ACT'][@moodCode='EVN']/id[@root='2.16.840.1.113883.3.989.2.1.3.6']]/nullFlavor
e	C.5.1.r.2	試験の登録国	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_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment[1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject[1]/primaryRole[@classCode='INVSBJ']/subjectOf1[@typeCode='SBJ'][1]/researchStudy[@classCode='CLNTRL'][@moodCode='EVN']/authorization[@typeCode='AUTH']]/r]/studyRegistration[@classCode='ACT'][@moodCode='EVN']/author[@typeCode='AUT']/territorialAuthority[@classCode='TERR']/governingPlace[@classCode='COUNTRY'][@determinerCode='INSTANCE']/code[@codeSystem='1.0.3166.1.2.2']]/code

e						NullFlavor	/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='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment[1]/adverseEventAssessment[@classCode='INVSTG']@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf1[@typeCode='SBJ'][1]/researchStudy[@classCode='CLNTRL'][@moodCode='EVN']/authorization[@typeCode='AUTH'][r]/studyRegistration[@classCode='ACT'][@moodCode='EVN']/author[@typeCode='AUT']/territorialAuthority[@classCode='TERR']/governingPlace[@classCode='COUNTRY'][@determinerCode='INSTANCE']/code[@codeSystem='1.0.3166.1.2.2']@nullFlavor
e	C.5.2	試験名	2000AN	Character String (ST)		値	/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='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment[1]/adverseEventAssessment[@classCode='INVSTG']@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf1[@typeCode='SBJ'][1]/researchStudy[@classCode='CLNTRL'][@moodCode='EVN']/title/text()
e						NullFlavor	/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='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment[1]/adverseEventAssessment[@classCode='INVSTG']@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf1[@typeCode='SBJ'][1]/researchStudy[@classCode='CLNTRL'][@moodCode='EVN']/title/@nullFlavor
e	C.5.3	試験依頼者(スポンサー)の試験番号	50AN	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[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment[1]/adverseEventAssessment[@classCode='INVSTG']@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf1[@typeCode='SBJ'][1]/researchStudy[@classCode='CLNTRL'][@moodCode='EVN']/id[@root='2.16.840.1.113883.3.989.2.1.3.5']@extension
e						NullFlavor	/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='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment[1]/adverseEventAssessment[@classCode='INVSTG']@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf1[@typeCode='SBJ'][1]/researchStudy[@classCode='CLNTRL'][@moodCode='EVN']/id[@root='2.16.840.1.113883.3.989.2.1.3.5']@nullFlavor
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	/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='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment[1]/adverseEventAssessment[@classCode='INVSTG']@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf1[@typeCode='SBJ'][1]/researchStudy[@classCode='CLNTRL'][@moodCode='EVN']/code[@codeSystem='2.16.840.1.113883.3.989.2.1.1.8']@code

(別添3)

		副作用／有害事象が観察された試験の種類に関するICH コードリストのバージョン					/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf1[@typeCode='SBJ'][1]/researchStudy[@classCode='CLNTRL'][@moodCode='EVN']/code[@codeSystem='2.16.840.1.113883.3.989.2.1.1.8'][@codeSystemVersion]
h	D	患者特性					
e	D.1	患者 (名前又はイニシャル)	60AN	Entity Name (EN)	name=Entity Name Part (ENXP)	値	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/player1[@classCode='PSN'][@determinerCode='INSTANCE']/name[1]/text()
e						NullFlavor	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/player1[@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	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/player1[@classCode='PSN'][@determinerCode='INSTANCE']/asIdentifiedEntity[@classCode='IDENT'][@code='1'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.4'][@id/@root='2.16.840.1.113883.3.989.2.1.3.7'][1]/@extension
e						NullFlavor	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/player1[@classCode='PSN'][@determinerCode='INSTANCE']/asIdentifiedEntity[@classCode='IDENT'][@code='1'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.4'][@id/@root='2.16.840.1.113883.3.989.2.1.3.7'][1]/@nullFlavor
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	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/player1[@classCode='PSN'][@determinerCode='INSTANCE']/asIdentifiedEntity[@classCode='IDENT'][@code='2'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.4'][@id/@root='2.16.840.1.113883.3.989.2.1.3.8'][@extension]

e						NullFlavor	/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='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment[1]/adverseEventAssessment[1][@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/player1[@classCode='PSN'][@determinerCode='INSTANCE']/asIdentifiedEntity[@classCode='IDENT'][code[@code='2']][@codeSystem='2.16.840.1.113883.3.989.2.1.1.4']][1]/id[@root='2.16.840.1.113883.3.989.2.1.3.8']][1]/@nullFlavor
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	/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='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment[1]/adverseEventAssessment[1][@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/player1[@classCode='PSN'][@determinerCode='INSTANCE']/asIdentifiedEntity[@classCode='IDENT'][code[@code='3']][@codeSystem='2.16.840.1.113883.3.989.2.1.1.4']][1]/id[@root='2.16.840.1.113883.3.989.2.1.3.9']][1]/@extension
e						NullFlavor	/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='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment[1]/adverseEventAssessment[1][@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/player1[@classCode='PSN'][@determinerCode='INSTANCE']/asIdentifiedEntity[@classCode='IDENT'][code[@code='3']][@codeSystem='2.16.840.1.113883.3.989.2.1.1.4']][1]/id[@root='2.16.840.1.113883.3.989.2.1.3.9']][1]/@nullFlavor
e	D.1.1.4	患者の診療記録番号及びその情報源 (試験の中での患者識別番号)	20AN	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[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment[1]/adverseEventAssessment[1][@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/player1[@classCode='PSN'][@determinerCode='INSTANCE']/asIdentifiedEntity[@classCode='IDENT'][code[@code='4']][@codeSystem='2.16.840.1.113883.3.989.2.1.1.4']][1]/id[@root='2.16.840.1.113883.3.989.2.1.3.10']][1]/@extension
e						NullFlavor	/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='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment[1]/adverseEventAssessment[1][@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/player1[@classCode='PSN'][@determinerCode='INSTANCE']/asIdentifiedEntity[@classCode='IDENT'][code[@code='4']][@codeSystem='2.16.840.1.113883.3.989.2.1.1.4']][1]/id[@root='2.16.840.1.113883.3.989.2.1.3.10']][1]/@nullFlavor
h	D.2	年齢情報					
e	D.2.1	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']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment[1]/adverseEventAssessment[1][@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/player1[@classCode='PSN'][@determinerCode='INSTANCE']/birthTime/@value

(別添 3)

		患者の年齢群 (報告者の表現による)に関する ICH コードリストのバージョン					/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='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment[1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][@observation/code[@code='4']][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']][1]/observation[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='CE'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.9']][1]/@codeSystemVersion
e	D.3	体重 (kg)	6N	Physical Quantity (PQ)	value=Real Number (REAL)	値	/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='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment[1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][@observation/code[@code='7']][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']][1]/observation[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='PQ'][@unit='kg'][1]/@value
e	D.4	身長 (cm)	3N	Physical Quantity (PQ)	value=Real Number (REAL)	値	/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='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment[1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][@observation/code[@code='17']][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']][1]/observation[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='PQ'][@unit='cm'][1]/@value
e	D.5	性別	1N	Coded With Equivalents (CE)	code=Character String (ST)	値	/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='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment[1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/player1[@classCode='PSN'][@determinerCode='INSTANCE']/administrativeGenderCode[@codeSystem='1.0.5218']/@code
e						NullFlavor	/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='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment[1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/player1[@classCode='PSN'][@determinerCode='INSTANCE']/administrativeGenderCode[@codeSystem='1.0.5218']/@nullFlavor
e	D.6	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']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/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'][@observation/code[@code='22']][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']][1]/observation[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='TS'][1]/@value

(別添 3)

e						NullFlavor	/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='INVSTG']{1}[@moodCode='EVN']/component[@typeCode='COMP']{1}/adverseEventAssessment{1}/adverseEventAssessment{1}[@classCode='INVSTG']{1}[@moodCode='EVN']/subject1[@typeCode='SBJ']{1}/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ']{1}/organizer/code[@code='1']{1}[@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']{1}/organizer[@classCode='CATEGORY']{1}[@moodCode='EVN']/component[@typeCode='COMP']{1}/observation/code[@codeSystem='2.16.840.1.113883.6.163']{1}/observation[@classCode='OBS']{1}[@moodCode='EVN']/effectiveTime[@xsi:type='IVL_TS']/low/@nullFlavor
e	D.7.1.r.3	継続	ブール型	Boolean (BL)		値	/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='INVSTG']{1}[@moodCode='EVN']/component[@typeCode='COMP']{1}/adverseEventAssessment{1}/adverseEventAssessment{1}[@classCode='INVSTG']{1}[@moodCode='EVN']/subject1[@typeCode='SBJ']{1}/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ']{1}/organizer/code[@code='1']{1}[@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']{1}/organizer[@classCode='CATEGORY']{1}[@moodCode='EVN']/component[@typeCode='COMP']{1}/observation/code[@codeSystem='2.16.840.1.113883.6.163']{1}/observation[@classCode='OBS']{1}[@moodCode='EVN']/inboundRelationship[@typeCode='REFR']{1}/observation/code[@code='13']{1}[@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']{1}/observation[@classCode='OBS']{1}[@moodCode='EVN']/value[@xsi:type='BL']{1}/value
e						NullFlavor	/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='INVSTG']{1}[@moodCode='EVN']/component[@typeCode='COMP']{1}/adverseEventAssessment{1}/adverseEventAssessment{1}[@classCode='INVSTG']{1}[@moodCode='EVN']/subject1[@typeCode='SBJ']{1}/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ']{1}/organizer/code[@code='1']{1}[@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']{1}/organizer[@classCode='CATEGORY']{1}[@moodCode='EVN']/component[@typeCode='COMP']{1}/observation/code[@codeSystem='2.16.840.1.113883.6.163']{1}/observation[@classCode='OBS']{1}[@moodCode='EVN']/inboundRelationship[@typeCode='REFR']{1}/observation/code[@code='13']{1}[@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']{1}/observation[@classCode='OBS']{1}[@moodCode='EVN']/value[@xsi:type='BL']{1}/nullFlavor
e	D.7.1.r.4	終了日	日付/時間	Interval of Point in Time (IVL<TS>)	high=Interval Boundary (IVXB)	値	/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='INVSTG']{1}[@moodCode='EVN']/component[@typeCode='COMP']{1}/adverseEventAssessment{1}/adverseEventAssessment{1}[@classCode='INVSTG']{1}[@moodCode='EVN']/subject1[@typeCode='SBJ']{1}/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ']{1}/organizer/code[@code='1']{1}[@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']{1}/organizer[@classCode='CATEGORY']{1}[@moodCode='EVN']/component[@typeCode='COMP']{1}/observation/code[@codeSystem='2.16.840.1.113883.6.163']{1}/observation[@classCode='OBS']{1}[@moodCode='EVN']/effectiveTime[@xsi:type='IVL_TS']/high/@value
e						NullFlavor	/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='INVSTG']{1}[@moodCode='EVN']/component[@typeCode='COMP']{1}/adverseEventAssessment{1}/adverseEventAssessment{1}[@classCode='INVSTG']{1}[@moodCode='EVN']/subject1[@typeCode='SBJ']{1}/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ']{1}/organizer/code[@code='1']{1}[@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']{1}/organizer[@classCode='CATEGORY']{1}[@moodCode='EVN']/component[@typeCode='COMP']{1}/observation/code[@codeSystem='2.16.840.1.113883.6.163']{1}/observation[@classCode='OBS']{1}[@moodCode='EVN']/effectiveTime[@xsi:type='IVL_TS']/high/@nullFlavor

(別添3)

e	D.7.1.r.5	備考	2000AN	Encapsulated Data (ED)	値	/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=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=1][@codeSystem=2.16.840.1.113883.3.989.2.1.1.20]][1]/organizer[@classCode=CATEGORY][@moodCode=EVN]/component[@typeCode=COMP][observation/code[@codeSystem=2.16.840.1.113883.6.163]][r]/observation[@classCode=OBS][@moodCode=EVN]/outboundRelationship2[@typeCode=COMP][observation/code[@code=10][@codeSystem=2.16.840.1.113883.3.989.2.1.1.19]][1]/observation[@classCode=OBS][@moodCode=EVN]/value[@xsi:type=ED][1]/text()
e	D.7.1.r.6	家族歴	ブール型	Boolean (BL)	値	/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=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=1][@codeSystem=2.16.840.1.113883.3.989.2.1.1.20]][1]/organizer[@classCode=CATEGORY][@moodCode=EVN]/component[@typeCode=COMP][observation/code[@codeSystem=2.16.840.1.113883.6.163]][r]/observation[@classCode=OBS][@moodCode=EVN]/outboundRelationship2[@typeCode=EXPL][observation/code[@code=38][@codeSystem=2.16.840.1.113883.3.989.2.1.1.19]][1]/observation[@classCode=OBS][@moodCode=EVN]/value[@xsi:type=BL][1]/@value
e	D.7.2	関連する治療歴及び随伴症状（副作用／有害事象を除く）の記述情報	10000AN	Encapsulated Data (ED)	値	/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=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=1][@codeSystem=2.16.840.1.113883.3.989.2.1.1.20]][1]/organizer[@classCode=CATEGORY][@moodCode=EVN]/component[@typeCode=COMP][observation/code[@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()
e					NullFlavor	/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=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=1][@codeSystem=2.16.840.1.113883.3.989.2.1.1.20]][1]/organizer[@classCode=CATEGORY][@moodCode=EVN]/component[@typeCode=COMP][observation/code[@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
e	D.7.3	併用療法	ブール型	Boolean (BL)	値	/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=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=1][@codeSystem=2.16.840.1.113883.3.989.2.1.1.20]][1]/organizer[@classCode=CATEGORY][@moodCode=EVN]/component[@typeCode=COMP][observation/code[@code=11][@codeSystem=2.16.840.1.113883.3.989.2.1.1.19]][1]/observation[@classCode=OBS][@moodCode=EVN]/value[@xsi:type=BL][1]/@value

h	D.8.r	関連する過去の医薬品使用歴 (必要に応じ繰り返す)			繰り返しノード	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP']
e	D.8.r.1	医薬品名 (報告された表現)	250AN	Entity Name (EN)	値	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT']
e					NullFlavor	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT']
e	D.8.r.2a	MPID バージョン日付/番号	ISO IDMP のとおり	Coded With Equivalents (CE)	値	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT']
e	D.8.r.2b	医薬品製品識別子 (MPID)	ISO IDMP のとおり	Coded With Equivalents (CE)	値	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT']

e	D.8.r.3a	PhPID バージョン日付/番号	ISO IDMP のとおり	Coded With Equivalents (CE)	codeSystemVersion=Character String (ST)	値	/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='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='2'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][substanceAdministration][r]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/consumable[@typeCode='CSM'][1]/instanceOfKind[@classCode='INST']/kindOfProduct[@classCode='MMAT'][@determinerCode='KIND']/code[@codeSystem='TBD-PhPID']/@code
e	D.8.r.3b	製剤識別子 (PhPID)	ISO IDMP のとおり	Coded With Equivalents (CE)	code=Character String (ST)	値	/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='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='2'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][substanceAdministration][r]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/consumable[@typeCode='CSM'][1]/instanceOfKind[@classCode='INST']/kindOfProduct[@classCode='MMAT'][@determinerCode='KIND']/code[@codeSystem='TBD-PhPID']/@code
e	D.8.r.4	開始日	日付/時間	Interval of Point in Time (IVL<TS>)	low=Interval Boundary (IVXB)	値	/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='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='2'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][substanceAdministration][r]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/effectiveTime[@xsi:type='IVL_TS']/low/@value
e						NullFlavor	/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='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='2'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][substanceAdministration][r]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/effectiveTime[@xsi:type='IVL_TS']/low/@nullFlavor
e	D.8.r.5	終了日	日付/時間	Interval of Point in Time (IVL<TS>)	high=Interval Boundary (IVXB)	値	/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='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='2'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][substanceAdministration][r]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/effectiveTime[@xsi:type='IVL_TS']/high/@value

e						NullFlavor	/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='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='2']@codeSystem='2.16.840.1.113883.3.989.2.1.1.20'[1]organizer[@classCode='CATEGORY']@moodCode='EVN'/component[@typeCode='COMP']substanceAdministration[r]/substanceAdministration[@classCode='SBADM']@moodCode='EVN'/effectiveTime@xsi:type='IVL_TS'/high@nullFlavor
e	D.8.r.6a	使用理由の MedDRA バージョン	4AN	Coded With Equivalents (CE)	codeSystemVersion= Character String (ST)	値	/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='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='2']@codeSystem='2.16.840.1.113883.3.989.2.1.1.20'[1]organizer[@classCode='CATEGORY']@moodCode='EVN'/component[@typeCode='COMP']substanceAdministration[r]/substanceAdministration[@classCode='SBADM']@moodCode='EVN'/outboundRelationship2[@typeCode='RSON']observation/code[@code='19']@codeSystem='2.16.840.1.113883.3.989.2.1.1.19'[1]observation[@classCode='OBS']@moodCode='EVN'/value[@xsi:type='CE']@codeSystem='2.16.840.1.113883.6.163'[1]@codeSystemVersion
e	D.8.r.6b	使用理由 (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'/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT']@moodCode='EVN'/subject[@typeCode='SUBJ'][1]/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='2']@codeSystem='2.16.840.1.113883.3.989.2.1.1.20'[1]organizer[@classCode='CATEGORY']@moodCode='EVN'/component[@typeCode='COMP']substanceAdministration[r]/substanceAdministration[@classCode='SBADM']@moodCode='EVN'/outboundRelationship2[@typeCode='RSON']observation/code[@code='19']@codeSystem='2.16.840.1.113883.3.989.2.1.1.19'[1]observation[@classCode='OBS']@moodCode='EVN'/value[@xsi:type='CE']@codeSystem='2.16.840.1.113883.6.163'[1]@code
e	D.8.r.7a	副作用の MedDRA バージョン	4AN	Coded With Equivalents (CE)	codeSystemVersion= Character String (ST)	値	/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='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='2']@codeSystem='2.16.840.1.113883.3.989.2.1.1.20'[1]organizer[@classCode='CATEGORY']@moodCode='EVN'/component[@typeCode='COMP']substanceAdministration[r]/substanceAdministration[@classCode='SBADM']@moodCode='EVN'/outboundRelationship2[@typeCode='CAUS']observation/code[@code='29']@codeSystem='2.16.840.1.113883.3.989.2.1.1.19'[1]observation[@classCode='OBS']@moodCode='EVN'/value[@xsi:type='CE']@codeSystem='2.16.840.1.113883.6.163'[1]@codeSystemVersion

(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	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVTG'][@moodCode='EVN']/component[@typeCode='COMP']/adverseEventAssessment[1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@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[r]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/outboundRelationship2[@typeCode='CAUS'][@observation/code[@code='29']][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']][1]/observation[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='CE'][@codeSystem='2.16.840.1.113883.6.163']][1]/@code
h	D.9	死亡の場合					
e	D.9.1	死亡日	日付/時間	Point in Time (TS)		値	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVTG'][@moodCode='EVN']/component[@typeCode='COMP']/adverseEventAssessment[1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/player1[@classCode='PSN'][@determinerCode='INSTANCE']/deceasedTime/@value
e						NullFlavor	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVTG'][@moodCode='EVN']/component[@typeCode='COMP']/adverseEventAssessment[1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/player1[@classCode='PSN'][@determinerCode='INSTANCE']/deceasedTime/@nullFlavor
h	D.9.2.r	報告された死因 (必要に応じ繰り返す)				繰り返しノード	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVTG'][@moodCode='EVN']/component[@typeCode='COMP']/adverseEventAssessment[1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][@observation/code[@code='32']][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']]
e	D.9.2.r.1a	報告された死因の MedDRA バージョン	4AN	Coded With Equivalents (CE)	codeSystemVersion=Character String (ST)	値	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVTG'][@moodCode='EVN']/component[@typeCode='COMP']/adverseEventAssessment[1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][@observation/code[@code='32']][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']][r]/observation[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='CE'][@codeSystem='2.16.840.1.113883.6.163']][1]/@codeSystemVersion
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	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVTG'][@moodCode='EVN']/component[@typeCode='COMP']/adverseEventAssessment[1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][@observation/code[@code='32']][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']][r]/observation[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='CE'][@codeSystem='2.16.840.1.113883.6.163']][1]/@code

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	/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='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment[1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][observation/code[@code='32']@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']][r]/observation[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='CE'][@codeSystem='2.16.840.1.113883.6.163'][1]/originalText/text()
e	D.9.3	剖検は実施されたか?	ブール型	Boolean (BL)		値	/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='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment[1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][observation/code[@code='5']@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']][1]/observation[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='BL'][@codeSystem='2.16.840.1.113883.6.163'][1]/value
e						NullFlavor	/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='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment[1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][observation/code[@code='5']@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']][1]/observation[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='BL'][@codeSystem='2.16.840.1.113883.6.163'][1]/nullFlavor
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	/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='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment[1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][observation/code[@code='5']@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']][1]/observation[@classCode='OBS'][@moodCode='EVN']/outboundRelationship2[@typeCode='DRIV'][observation/code[@code='8']@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']]
e	D.9.4.r.1a	剖検による死因の MedDRA バージョン	4AN	Coded With Equivalents (CE)	codeSystemVersion = Character String (ST)	値	/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='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment[1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][observation/code[@code='5']@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']][1]/observation[@classCode='OBS'][@moodCode='EVN']/outboundRelationship2[@typeCode='DRIV'][observation/code[@code='8']@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']][r]/observation[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='CE'][@codeSystem='2.16.840.1.113883.6.163'][1]/codeSystemVersion

(別添3)

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']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/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']/observation/code[@code='5'][@codeSystem='2.16.84.0.1.113883.3.989.2.1.1.19']][1]/observation[@classCode='OBS'][@moodCode='EVN']/outboundRelationship2[@typeCode='DRIV']/observation/code[@code='8'][@codeSystem='2.16.84.0.1.113883.3.989.2.1.1.19']][r]/observation[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='CE'][@codeSystem='2.16.84.0.1.113883.6.163']][1]/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']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/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']/observation/code[@code='5'][@codeSystem='2.16.84.0.1.113883.3.989.2.1.1.19']][1]/observation[@classCode='OBS'][@moodCode='EVN']/outboundRelationship2[@typeCode='DRIV']/observation/code[@code='8'][@codeSystem='2.16.84.0.1.113883.3.989.2.1.1.19']][r]/observation[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='CE'][@codeSystem='2.16.84.0.1.113883.6.163']][1]/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']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment[1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/player1[@classCode='PSN'][@determinerCode='INSTANCE']/role[@classCode='PRS'][1]/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']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment[1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/player1[@classCode='PSN'][@determinerCode='INSTANCE']/role[@classCode='PRS'][1]/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']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment[1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/player1[@classCode='PSN'][@determinerCode='INSTANCE']/role[@classCode='PRS'][1]/associatedPerson[@classCode='PSN'][@determinerCode='INSTANCE']/birthTime/@value

(別添3)

e	D.10.4	親の体重 (kg)	6N	Physical Quantity (PQ)	value=Real Number (REAL)	値	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/player1[@classCode='PSN'][@determinerCode='INSTANCE']/role[@classCode='PRS'][1]/subjectOf2[@typeCode='SBJ'][observation/code[@code='7']][@codeSystem='2.16.840.1.11388.3.3.989.2.1.1.19'][1]/observation[@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	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/player1[@classCode='PSN'][@determinerCode='INSTANCE']/role[@classCode='PRS'][1]/subjectOf2[@typeCode='SBJ'][observation/code[@code='17']][@codeSystem='2.16.840.1.11388.3.3.989.2.1.1.19'][1]/observation[@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	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/player1[@classCode='PSN'][@determinerCode='INSTANCE']/role[@classCode='PRS'][1]/associatedPerson[@classCode='PSN'][@determinerCode='INSTANCE']/administrativeGenderCode[@codeSystem='1.0.5218']/@code
e						NullFlavor	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/player1[@classCode='PSN'][@determinerCode='INSTANCE']/role[@classCode='PRS'][1]/associatedPerson[@classCode='PSN'][@determinerCode='INSTANCE']/administrativeGenderCode[@codeSystem='1.0.5218']/@nullFlavor
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[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/player1[@classCode='PSN'][@determinerCode='INSTANCE']/role[@classCode='PRS'][1]/subjectOf2[@typeCode='SBJ'][organizer/code[@code='1']][@codeSystem='2.16.840.1.11388.3.3.989.2.1.1.20'][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][observation/code[@codeSystem='2.16.840.1.11388.6.163']]

(別添3)

e	D.10.7.1.r.1a	親の関連する治療歴及び随伴症状の MedDRA バージョン	4AN	Concept Descriptor (CD)	codeSystemVersion=Character String (ST)	値	/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='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment[1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/player1[@classCode='PSN'][@determinerCode='INSTANCE']/role[@classCode='PRS'][1]/subjectOf2[@typeCode='SBJ']/organizer/code[@code='1'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP']/observation/code[@codeSystem='2.16.840.1.113883.6.163']]/r/observation[@classCode='OBS'][@moodCode='EVN']/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)	値	/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='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment[1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/player1[@classCode='PSN'][@determinerCode='INSTANCE']/role[@classCode='PRS'][1]/subjectOf2[@typeCode='SBJ']/organizer/code[@code='1'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP']/observation/code[@codeSystem='2.16.840.1.113883.6.163']]/r/observation[@classCode='OBS'][@moodCode='EVN']/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 (IVXB)	値	/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='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment[1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/player1[@classCode='PSN'][@determinerCode='INSTANCE']/role[@classCode='PRS'][1]/subjectOf2[@typeCode='SBJ']/organizer/code[@code='1'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP']/observation/code[@codeSystem='2.16.840.1.113883.6.163']]/r/observation[@classCode='OBS'][@moodCode='EVN']/effectiveTime[@xsi:type='IVL_TS']/low/@value
e						NullFlavor	/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='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment[1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/player1[@classCode='PSN'][@determinerCode='INSTANCE']/role[@classCode='PRS'][1]/subjectOf2[@typeCode='SBJ']/organizer/code[@code='1'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP']/observation/code[@codeSystem='2.16.840.1.113883.6.163']]/r/observation[@classCode='OBS'][@moodCode='EVN']/effectiveTime[@xsi:type='IVL_TS']/low/@nullFlavor

e	D.10.7.1.r.3	継続	ブール型	Boolean (BL)		値	/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='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment[1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/player1[@classCode='PSN'][@determinerCode='INSTANCE']/role[@classCode='PRS'][1]/subjectOf2[@typeCode='SBJ'][organizer/code[@code='1']][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][@codeSystem='2.16.840.1.113883.6.163']][r]/observation[@classCode='OBS'][@moodCode='EVN']/inboundRelationship[@typeCode='REFR'][@code='13'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']][1]/observation[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='BL'][1]/@value
e	D.10.7.1.r.4	終了日	日付/時間	Interval of Point in Time (IVL<TS>)	high=Interval Boundary (IVXB)	値	/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='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment[1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/player1[@classCode='PSN'][@determinerCode='INSTANCE']/role[@classCode='PRS'][1]/subjectOf2[@typeCode='SBJ'][organizer/code[@code='1']][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][@codeSystem='2.16.840.1.113883.6.163']][r]/observation[@classCode='OBS'][@moodCode='EVN']/effectiveTime[@xsi:type='IVL_TS']/high/@value
e						NullFlavor	/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='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment[1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/player1[@classCode='PSN'][@determinerCode='INSTANCE']/role[@classCode='PRS'][1]/subjectOf2[@typeCode='SBJ'][organizer/code[@code='1']][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][@codeSystem='2.16.840.1.113883.6.163']][r]/observation[@classCode='OBS'][@moodCode='EVN']/effectiveTime[@xsi:type='IVL_TS']/high/@nullFlavor
e	D.10.7.1.r.5	備考	2000AN	Encapsulated Data (ED)		値	/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='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment[1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/player1[@classCode='PSN'][@determinerCode='INSTANCE']/role[@classCode='PRS'][1]/subjectOf2[@typeCode='SBJ'][organizer/code[@code='1']][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][@codeSystem='2.16.840.1.113883.6.163']][r]/observation[@classCode='OBS'][@moodCode='EVN']/outboundRelationship2[@typeCode='COMP'][@code='10'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']][1]/observation[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='ED'][1]/text()

e	D.10.7.2	親の関連する治療歴及び随伴症状の記述情報	10000AN	Encapsulated Data (ED)		値	/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='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'] adverseEventAssessment[1] adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/player1[@classCode='PSN'][@determinerCode='INSTANCE']/role[@classCode='PRS'][1]/subjectOf2[@typeCode='SBJ'] organizer/code[@code='1'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20'] organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'] observation/code[@code='18'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19'] observation[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='ED'][1]/text()
h	D.10.8.r	親の関連する過去の医薬品使用歴 (必要に応じ繰り返す)				繰り返しノード	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'] adverseEventAssessment[1] adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/player1[@classCode='PSN'][@determinerCode='INSTANCE']/role[@classCode='PRS'][1]/subjectOf2[@typeCode='SBJ'] organizer/code[@code='2'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20'] organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'] substanceAdministration
e	D.10.8.r.1	医薬品名 (報告された表現)	250AN	Entity Name (EN)	name=Entity Name Part (ENXP)	値	/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='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'] adverseEventAssessment[1] adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/player1[@classCode='PSN'][@determinerCode='INSTANCE']/role[@classCode='PRS'][1]/subjectOf2[@typeCode='SBJ'] organizer/code[@code='2'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20'] organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'] substanceAdministration[r]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/consumable[@typeCode='CSM'][1]/instanceOfKind[@classCode='INST']/kindOfProduct[@classCode='MMAT'][@determinerCode='KIND']/name[1]/text()
e	D.10.8.r.2a	MPID バージョン日付/番号	ISO IDMP のとおり	Coded With Equivalents (CE)	codeSystemVersion=Character String (ST)	値	/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='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'] adverseEventAssessment[1] adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/player1[@classCode='PSN'][@determinerCode='INSTANCE']/role[@classCode='PRS'][1]/subjectOf2[@typeCode='SBJ'] organizer/code[@code='2'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20'] organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'] substanceAdministration[r]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/consumable[@typeCode='CSM'][1]/instanceOfKind[@classCode='INST']/kindOfProduct[@classCode='MMAT'][@determinerCode='KIND']/code[@codeSystem='TBD-MPID']/codeSystemVersion

(別添3)

e	D.10.8.r.2b	医薬品製品識別子 (MPID)	ISO IDMP のとおり	Coded With Equivalents (CE)	code=Character String (ST)	値	/MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UV[r]/controlActProcess[@classCode=CACT][@mood Code=EVN]/subject[@typeCode=SUBJ][1]/investigationEvent[@classCode=INVSTG][@moodCo de=EVN]/component[@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment [@classCode=INVSTG][@moodCode=EVN]/subject1[@typeCode=SBJ][1]/primaryRole[@classC ode=INVSBJ]/player1[@classCode=PSN][@determinerCode=INSTANCE]/role[@classCode=PR S][1]/subjectOf2[@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[@typeC ode=COMP][substanceAdministration][r]/substanceAdministration[@classCode=SBADM][@mood Code=EVN]/consumable[@typeCode=CSM][1]/instanceOfKind[@classCode=INST]/kindOfProduc t[@classCode=MMAT][@determinerCode=KIND]/code[@codeSystem=TBD-MPID]/@code
e	D.10.8.r.3a	PhPID バージョン日付/番 号	ISO IDMP のとおり	Coded With Equivalents (CE)	codeSystemVersion= Character String (ST)	値	/MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UV[r]/controlActProcess[@classCode=CACT][@mood Code=EVN]/subject[@typeCode=SUBJ][1]/investigationEvent[@classCode=INVSTG][@moodCo de=EVN]/component[@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment [@classCode=INVSTG][@moodCode=EVN]/subject1[@typeCode=SBJ][1]/primaryRole[@classC ode=INVSBJ]/player1[@classCode=PSN][@determinerCode=INSTANCE]/role[@classCode=PR S][1]/subjectOf2[@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[@typeC ode=COMP][substanceAdministration][r]/substanceAdministration[@classCode=SBADM][@mood Code=EVN]/consumable[@typeCode=CSM][1]/instanceOfKind[@classCode=INST]/kindOfProduc t[@classCode=MMAT][@determinerCode=KIND]/code[@codeSystem=TBD-PhPID]/@codeSyste mVersion
e	D.10.8.r.3b	製剤識別子 (PhPID)	ISO IDMP のとおり	Coded With Equivalents (CE)	code=Character String (ST)	値	/MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UV[r]/controlActProcess[@classCode=CACT][@mood Code=EVN]/subject[@typeCode=SUBJ][1]/investigationEvent[@classCode=INVSTG][@moodCo de=EVN]/component[@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment [@classCode=INVSTG][@moodCode=EVN]/subject1[@typeCode=SBJ][1]/primaryRole[@classC ode=INVSBJ]/player1[@classCode=PSN][@determinerCode=INSTANCE]/role[@classCode=PR S][1]/subjectOf2[@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[@typeC ode=COMP][substanceAdministration][r]/substanceAdministration[@classCode=SBADM][@mood Code=EVN]/consumable[@typeCode=CSM][1]/instanceOfKind[@classCode=INST]/kindOfProduc t[@classCode=MMAT][@determinerCode=KIND]/code[@codeSystem=TBD-PhPID]/@code
e	D.10.8.r.4	開始日	日付/時間	Interval of Point in Time (IVL<TS>)	low=Interval Boundary (IVXB)	値	/MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UV[r]/controlActProcess[@classCode=CACT][@mood Code=EVN]/subject[@typeCode=SUBJ][1]/investigationEvent[@classCode=INVSTG][@moodCo de=EVN]/component[@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment [@classCode=INVSTG][@moodCode=EVN]/subject1[@typeCode=SBJ][1]/primaryRole[@classC ode=INVSBJ]/player1[@classCode=PSN][@determinerCode=INSTANCE]/role[@classCode=PR S][1]/subjectOf2[@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[@typeC ode=COMP][substanceAdministration][r]/substanceAdministration[@classCode=SBADM][@mood Code=EVN]/effectiveTime[@xsi:type=IVL_TS]/low/@value

e						NullFlavor	/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='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'] adverseEventAssessment[1] adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/player1[@classCode='PSN'][@determinerCode='INSTANCE']/role[@classCode='PRS'][1]/subjectOf2[@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[r]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/effectiveTime[@xsi:type='IVL_TS']/low/@nullFlavor
e	D.10.8.r.5	終了日	日付/時間	Interval of Point in Time (IVL<TS>)	high=Interval Boundary (IVXB)	値	/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='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'] adverseEventAssessment[1] adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/player1[@classCode='PSN'][@determinerCode='INSTANCE']/role[@classCode='PRS'][1]/subjectOf2[@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[r]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/effectiveTime[@xsi:type='IVL_TS']/high/@value
e						NullFlavor	/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='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'] adverseEventAssessment[1] adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/player1[@classCode='PSN'][@determinerCode='INSTANCE']/role[@classCode='PRS'][1]/subjectOf2[@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[r]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/effectiveTime[@xsi:type='IVL_TS']/high/@nullFlavor
e	D.10.8.r.6a	使用理由の MedDRA パー ジョン	4AN	Coded With Equivalents (CE)	codeSystemVersion= Character String (ST)	値	/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='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'] adverseEventAssessment[1] adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/player1[@classCode='PSN'][@determinerCode='INSTANCE']/role[@classCode='PRS'][1]/subjectOf2[@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[r]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/outboundRelationship2[@typeCode='RSON'] [observation/code[@code='19'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19'] [1] observation[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='CE'][@codeSystem='2.16.840.1.113883.6.163'] [1] /@codeSystemVersion

e	D.10.8.r.6b	使用理由 (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']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ']{1}/investigationEvent[@classCode='INVSTG']{1}[@moodCode='EVN']/component[@typeCode='COMP']{1}/adverseEventAssessment{1}/adverseEventAssessment[@classCode='INVSTG']{1}[@moodCode='EVN']/subject1[@typeCode='SBJ']{1}/primaryRole[@classCode='INVSBJ']/player1[@classCode='PSN']{1}/determinerCode='INSTANCE']/role[@classCode='PRS']{1}/subjectOf2[@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']{1}[@moodCode='EVN']/outboundRelationship2[@typeCode='RSON']{1}/observation/code[@code='19']{1}[@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']{1}/observation[@classCode='OBS']{1}[@moodCode='EVN']/value[@xsi:type='CE']{1}[@codeSystem='2.16.840.1.113883.6.163']{1}/@code
e	D.10.8.r.7a	副作用の MedDRA バージョン	4AN	Coded With Equivalents (CE)	codeSystemVersion=Character String (ST)	値	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT']{1}[@moodCode='EVN']/subject[@typeCode='SUBJ']{1}/investigationEvent[@classCode='INVSTG']{1}[@moodCode='EVN']/component[@typeCode='COMP']{1}/adverseEventAssessment{1}/adverseEventAssessment[@classCode='INVSTG']{1}[@moodCode='EVN']/subject1[@typeCode='SBJ']{1}/primaryRole[@classCode='INVSBJ']/player1[@classCode='PSN']{1}/determinerCode='INSTANCE']/role[@classCode='PRS']{1}/subjectOf2[@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']{1}[@moodCode='EVN']/outboundRelationship2[@typeCode='CAUS']{1}/observation/code[@code='29']{1}[@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']{1}/observation[@classCode='OBS']{1}[@moodCode='EVN']/value[@xsi:type='CE']{1}[@codeSystem='2.16.840.1.113883.6.163']{1}/@codeSystemVersion
e	D.10.8.r.7b	副作用 (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']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT']{1}[@moodCode='EVN']/subject[@typeCode='SUBJ']{1}/investigationEvent[@classCode='INVSTG']{1}[@moodCode='EVN']/component[@typeCode='COMP']{1}/adverseEventAssessment{1}/adverseEventAssessment[@classCode='INVSTG']{1}[@moodCode='EVN']/subject1[@typeCode='SBJ']{1}/primaryRole[@classCode='INVSBJ']/player1[@classCode='PSN']{1}/determinerCode='INSTANCE']/role[@classCode='PRS']{1}/subjectOf2[@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']{1}[@moodCode='EVN']/outboundRelationship2[@typeCode='CAUS']{1}/observation/code[@code='29']{1}[@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']{1}/observation[@classCode='OBS']{1}[@moodCode='EVN']/value[@xsi:type='CE']{1}[@codeSystem='2.16.840.1.113883.6.163']{1}/@code
h	E.i	副作用/有害事象 (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[r]/controlActProcess[@classCode='CACT']{1}[@moodCode='EVN']/subject[@typeCode='SUBJ']{1}/investigationEvent[@classCode='INVSTG']{1}[@moodCode='EVN']/component[@typeCode='COMP']{1}/adverseEventAssessment{1}/adverseEventAssessment[@classCode='INVSTG']{1}[@moodCode='EVN']/subject1[@typeCode='SBJ']{1}/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ']{1}/observation[id]{1}[@code='29']{1}[@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']{1}
h	E.1.1	第一次情報源により報告された副作用/有害事象					

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	/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='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment[1]/adverseEventAssessment[@classCode='INVSTG']@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][observation[id][code[@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'][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	/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='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment[1]/adverseEventAssessment[@classCode='INVSTG']@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][observation[id][code[@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'][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	/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='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment[1]/adverseEventAssessment[@classCode='INVSTG']@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][observation[id][code[@code='29']][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']]]/observation[@classCode='OBS'][@moodCode='EVN']/outboundRelationship2[@typeCode='PERT']/observation/code[@code='30'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']]]/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 バージョン	4AN	Coded With Equivalents (CE)	codeSystemVersion = Character String (ST)	値	/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='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment[1]/adverseEventAssessment[@classCode='INVSTG']@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][observation[id][code[@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'][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	/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='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment[1]/adverseEventAssessment[@classCode='INVSTG']@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][observation[id][code[@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'][1]/@code

(別添3)

e	E.i.3.1	報告者によって重要とされた副作用/有害事象	1N	Coded With Equivalents (CE)	code=Character String (ST)	値	/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='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment[1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][observation[id][code[@code='29']][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']][1]/observation[@classCode='OBS'][@moodCode='EVN']/outboundRelationship2[@typeCode='PERT'][observation/code[@code='37']][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']][1]/observation[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='CE'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.10']][1]/@code
		報告者によって重要とされた副作用/有害事象に関する ICH コードリストのバージョン					/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='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment[1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][observation[id][code[@code='29']][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']][1]/observation[@classCode='OBS'][@moodCode='EVN']/outboundRelationship2[@typeCode='PERT'][observation/code[@code='37']][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']][1]/observation[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='CE'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.10']][1]/@codeSystemVersion
h	E.i.3.2	有害事象ごとの重篤性の基準					
e	E.i.3.2a	死に至るもの	ブール型	Boolean (BL)		値	/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='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment[1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][observation[id][code[@code='29']][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']][1]/observation[@classCode='OBS'][@moodCode='EVN']/outboundRelationship2[@typeCode='PERT'][observation/code[@code='34']][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']][1]/observation[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='BL']][1]/@value
e						NullFlavor	/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='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment[1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][observation[id][code[@code='29']][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']][1]/observation[@classCode='OBS'][@moodCode='EVN']/outboundRelationship2[@typeCode='PERT'][observation/code[@code='34']][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']][1]/observation[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='BL']][1]/@nullFlavor

e	E.i.3.2b	生命を脅かすもの	ブール型	Boolean (BL)	値	/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='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment[1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][observation[id][code[@code='29']][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']][1]/observation[@classCode='OBS'][@moodCode='EVN']/outboundRelationship2[@typeCode='PERT'][observation/code[@code='21']][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']][1]/observation[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='BL'][1]/@value
e					NullFlavor	/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='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment[1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][observation[id][code[@code='29']][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']][1]/observation[@classCode='OBS'][@moodCode='EVN']/outboundRelationship2[@typeCode='PERT'][observation/code[@code='21']][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']][1]/observation[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='BL'][1]/@nullFlavor
e	E.i.3.2c	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	ブール型	Boolean (BL)	値	/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='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment[1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][observation[id][code[@code='29']][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']][1]/observation[@classCode='OBS'][@moodCode='EVN']/outboundRelationship2[@typeCode='PERT'][observation/code[@code='33']][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']][1]/observation[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='BL'][1]/@value
e					NullFlavor	/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='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment[1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][observation[id][code[@code='29']][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']][1]/observation[@classCode='OBS'][@moodCode='EVN']/outboundRelationship2[@typeCode='PERT'][observation/code[@code='33']][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']][1]/observation[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='BL'][1]/@nullFlavor
e	E.i.3.2d	永続的又は顕著な障害・機能不全に陥るもの	ブール型	Boolean (BL)	値	/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='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment[1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][observation[id][code[@code='29']][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']][1]/observation[@classCode='OBS'][@moodCode='EVN']/outboundRelationship2[@typeCode='PERT'][observation/code[@code='35']][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']][1]/observation[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='BL'][1]/@value

e						NullFlavor	/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='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment[1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ']][observation[id][code[@code='29']][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']]]/observation[@classCode='OBS'][@moodCode='EVN']/outboundRelationship2[@typeCode='PERT']][observation/code[@code='35']][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']]]/observation[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='BL'][1]/@nullFlavor
e	E.i.3.2e	先天異常を来すもの	ブール型	Boolean (BL)		値	/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='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment[1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ']][observation[id][code[@code='29']][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']]]/observation[@classCode='OBS'][@moodCode='EVN']/outboundRelationship2[@typeCode='PERT']][observation/code[@code='12']][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']]]/observation[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='BL'][1]/@value
e						NullFlavor	/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='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment[1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ']][observation[id][code[@code='29']][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']]]/observation[@classCode='OBS'][@moodCode='EVN']/outboundRelationship2[@typeCode='PERT']][observation/code[@code='12']][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']]]/observation[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='BL'][1]/@nullFlavor
e	E.i.3.2f	その他の医学的に重要な状態	ブール型	Boolean (BL)		値	/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='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment[1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ']][observation[id][code[@code='29']][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']]]/observation[@classCode='OBS'][@moodCode='EVN']/outboundRelationship2[@typeCode='PERT']][observation/code[@code='26']][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']]]/observation[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='BL'][1]/@value
e						NullFlavor	/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='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment[1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ']][observation[id][code[@code='29']][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']]]/observation[@classCode='OBS'][@moodCode='EVN']/outboundRelationship2[@typeCode='PERT']][observation/code[@code='26']][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']]]/observation[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='BL'][1]/@nullFlavor

e	E.i.4	副作用／有害事象の発現日	日付／時間	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 HL7 データ型: Interval of Point in Time (IVL<TS>)	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 low=Interval Boundary (IVXB)	値	/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='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][1]/adverseEventAssessment[1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][observation[id][code[@code='29']][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']]][i]/observation[@classCode='OBS'][@moodCode='EVN']/effectiveTime[@xsi:type='IVL_TS']/low/@value
e						NullFlavor	/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='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][1]/adverseEventAssessment[1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][observation[id][code[@code='29']][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']]][i]/observation[@classCode='OBS'][@moodCode='EVN']/effectiveTime[@xsi:type='IVL_TS']/low/@nullFlavor
e				2.E.i.4、E.i.5 及び E.i.6 のすべての項目が表示される場合 データ型 SXPР を伴う最初の comp 項目 HL7 データ型: Parenthetic Set Expression of Point in Time (SXPР<TS>)	2.E.i.4、E.i.5 及び E.i.6 のすべての項目が表示される場合 データ型 SXPР を伴う最初の comp 項目 comp/low=Interval Boundary (IVXB)	値	/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='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][1]/adverseEventAssessment[1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][observation[id][code[@code='29']][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']]][i]/observation[@classCode='OBS'][@moodCode='EVN']/effectiveTime[@xsi:type='SXPР_TS']/comp[@xsi:type='IVL_TS']/low/@value
e						NullFlavor	/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='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][1]/adverseEventAssessment[1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][observation[id][code[@code='29']][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']]][i]/observation[@classCode='OBS'][@moodCode='EVN']/effectiveTime[@xsi:type='SXPР_TS']/comp[@xsi:type='IVL_TS']/low/@nullFlavor

				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 SXPR を伴う 2 番目の comp 項目 HL7 データ型: Parenthetic Set Expression of Point in Time (SXPR<TS>)	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 SXPR を伴う 2 番目の comp 項目 comp/low=Interval Boundary (IVXB)	値	/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='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment[1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][observation[id][code@code='29'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']]]/observation[@classCode='OBS'][@moodCode='EVN']/effectiveTime[@xsi:type='SXPR_TS']/comp[@xsi:type='IVL_TS'][@operator='A']/low/@value
						NullFlavor	/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='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment[1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][observation[id][code@code='29'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']]]/observation[@classCode='OBS'][@moodCode='EVN']/effectiveTime[@xsi:type='SXPR_TS']/comp[@xsi:type='IVL_TS'][@operator='A']/low/@nullFlavor
e	E.i.5	副作用/有害事象の終了日	日付/時間	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 HL7 データ型: Interval of Point in Time (IVL<TS>)	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 high=Interval Boundary (IVXB)	値	/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='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment[1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][observation[id][code@code='29'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']]]/observation[@classCode='OBS'][@moodCode='EVN']/effectiveTime[@xsi:type='IVL_TS']/high/@value
e						NullFlavor	/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='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment[1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][observation[id][code@code='29'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']]]/observation[@classCode='OBS'][@moodCode='EVN']/effectiveTime[@xsi:type='IVL_TS']/high/@nullFlavor

e			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 SXPR を伴う最初の comp 項目 HL7 データ型 : Parenthetic Set Expression of Point in Time (SXPR<TS>)	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 SXPR を伴う最初の comp 項目 comp/high=Interval Boundary (IVXB)	値	/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='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][observation[id][code][@code='29']][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']][]/observation[@classCode='OBS'][@moodCode='EVN']/effectiveTime[@xsi:type='SXPR_TS']/comp[@xsi:type='IVL_TS']/high/@value
e					NullFlavor	/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='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][observation[id][code][@code='29']][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']][]/observation[@classCode='OBS'][@moodCode='EVN']/effectiveTime[@xsi:type='SXPR_TS']/comp[@xsi:type='IVL_TS']/high/@nullFlavor
			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 SXPR を伴う 2 番目の comp 項目 HL7 データ型 : Parenthetic Set Expression of Point in Time (SXPR<TS>)	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 SXPR を伴う 2 番目の comp 項目 comp/high=Interval Boundary (IVXB)	値	/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='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][observation[id][code][@code='29']][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']][]/observation[@classCode='OBS'][@moodCode='EVN']/effectiveTime[@xsi:type='SXPR_TS']/comp[@xsi:type='IVL_TS'][@operator='A']/high/@value
					NullFlavor	/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='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][observation[id][code][@code='29']][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']][]/observation[@classCode='OBS'][@moodCode='EVN']/effectiveTime[@xsi:type='SXPR_TS']/comp[@xsi:type='IVL_TS'][@operator='A']/high/@nullFlavor

e	E.i.6a	副作用／有害事象の持続期間 (数)	5N	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 HL7 データ型: Interval of Point in Time (IVL<TS>)	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 width/value=Real Number (REAL)	値	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVTG'][@moodCode='EVN']/component[@typeCode='COMP'][1]/adverseEventAssessment[@classCode='INVTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ']/observation[id][code][code='29'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']]/observation[@classCode='OBS'][@moodCode='EVN']/effectiveTime[@xsi:type='IVL_TS']/width/@value
e				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 SXPR を伴う最初の comp 項目 HL7 データ型: Parenthetic Set Expression of Point in Time (SXPR<TS>)	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 SXPR を伴う最初の comp 項目 comp/width/value=Real Number (REAL)	値	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVTG'][@moodCode='EVN']/component[@typeCode='COMP'][1]/adverseEventAssessment[@classCode='INVTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ']/observation[id][code][code='29'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']]/observation[@classCode='OBS'][@moodCode='EVN']/effectiveTime[@xsi:type='SXPR_TS']/comp[@xsi:type='IVL_TS']/width/@value
				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 SXPR を伴う 2 番目の comp 項目 HL7 データ型: Parenthetic Set Expression of Point in Time (SXPR<TS>)	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 SXPR を伴う 2 番目の comp 項目 comp/width/value=Real Number (REAL)	値	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVTG'][@moodCode='EVN']/component[@typeCode='COMP'][1]/adverseEventAssessment[@classCode='INVTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ']/observation[id][code][code='29'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']]/observation[@classCode='OBS'][@moodCode='EVN']/effectiveTime[@xsi:type='SXPR_TS']/comp[@xsi:type='IVL_TS']/@operator='A']/width/@value
e	E.i.6b	副作用／有害事象の持続期間 (単位)	50AN	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 HL7 データ型: Interval of Point in Time (IVL<TS>)	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 width/unit=Coded Simple Value (CS)	値	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVTG'][@moodCode='EVN']/component[@typeCode='COMP'][1]/adverseEventAssessment[@classCode='INVTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ']/observation[id][code][code='29'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']]/observation[@classCode='OBS'][@moodCode='EVN']/effectiveTime[@xsi:type='IVL_TS']/width/@unit

e				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 SXPR を伴う最初の comp 項目 HL7 データ型： Parenthetic Set Expression of Point in Time (SXPR<TS>)	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 SXPR を伴う最初の comp 項目 comp/width/unit=Coded Simple Value (CS)	値	/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='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment[1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][observation[id][code][@code='29']][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']][i]/observation[@classCode='OBS'][@moodCode='EVN']/effectiveTime[@xsi:type='SXPR_TS']/comp[@xsi:type='IVL_TS']/width/@unit
				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 SXPR を伴う 2 番目の comp 項目 HL7 データ型： Parenthetic Set Expression of Point in Time (SXPR<TS>)	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 SXPR を伴う 2 番目の comp 項目 comp/width/unit=Coded Simple Value (CS)	値	/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='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment[1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][observation[id][code][@code='29']][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']][i]/observation[@classCode='OBS'][@moodCode='EVN']/effectiveTime[@xsi:type='SXPR_TS']/comp[@xsi:type='IVL_TS'][@operator='A']/width/@unit
e	E.i.7	最終観察時の副作用／有害事象の転帰	1N	Coded With Equivalents (CE)	code=Character String (ST)	値	/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='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment[1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][observation[id][code][@code='29']][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']][i]/observation[@classCode='OBS'][@moodCode='EVN']/outboundRelationship2[@typeCode='PERT']][i]/observation/code[@code='27']][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']][1]/observation[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='CE'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.11']][1]/@code
		最終観察時の副作用／有害事象の転帰の ICH コードリストのバージョン					/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='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment[1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][observation[id][code][@code='29']][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']][i]/observation[@classCode='OBS'][@moodCode='EVN']/outboundRelationship2[@typeCode='PERT']][i]/observation/code[@code='27']][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']][1]/observation[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='CE'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.11']][1]/@codeSystemVersion

(別添3)

e	E.i.8	医療専門家による医学的確認	ブール型	Boolean (BL)		値	/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='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ']/observation[id][code][@code='29'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']][1]/observation[@classCode='OBS'][@moodCode='EVN']/outboundRelationship2[@typeCode='PERT']/observation/code[@code='24'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']][1]/observation[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='BL']/@value
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	/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='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ']/observation[id][code][@code='29'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']][1]/observation[@classCode='OBS'][@moodCode='EVN']/location[@typeCode='LOC'][1]/locatedEntity[@classCode='LOCE']/locatedPlace[@classCode='COUNTRY'][@determinerCode='INSTANCE']/code[@codeSystem='1.0.3166.1.2.2']/@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[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/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='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']]
e	F.r.1	日付 (検査)	日付／時間	Point in Time (TS)		値	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/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='3'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP']/observation/code[@codeSystem='2.16.840.1.113883.6.163']][r]/observation[@classCode='OBS'][@moodCode='EVN']/effectiveTime/@value
e						NullFlavor	/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='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='3'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP']/observation/code[@codeSystem='2.16.840.1.113883.6.163']][r]/observation[@classCode='OBS'][@moodCode='EVN']/effectiveTime/@nullFlavor
h	F.r.2	検査名					

(別添 3)

e	F.r.2.1	検査名 (自由記載)	250AN	Concept Descriptor (CD)	originalText=Encapsulated Data (ED)	値	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/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='3']][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][@observation/code[@codeSystem='2.16.840.1.113883.6.163']][r]/observation[@classCode='OBS'][@moodCode='EVN']/code/originalText/text()
e	F.r.2.2a	検査名の MedDRA バージョン	4AN	Concept Descriptor (CD)	codeSystemVersion=Character String (ST)	値	/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='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='3']][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][@observation/code[@codeSystem='2.16.840.1.113883.6.163']][r]/observation[@classCode='OBS'][@moodCode='EVN']/code/@codeSystemVersion
e	F.r.2.2b	検査名 (MedDRA コード)	8N	Concept Descriptor (CD)	code=Character String (ST)	値	/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='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='3']][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][@observation/code[@codeSystem='2.16.840.1.113883.6.163']][r]/observation[@classCode='OBS'][@moodCode='EVN']/code/@code
h	F.r.3	検査結果					
e	F.r.3.1	検査結果 (コード)	1N	Coded With Equivalents (CE)	code=Character String (ST)	値	/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='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='3']][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][@observation/code[@codeSystem='2.16.840.1.113883.6.163']][r]/observation[@classCode='OBS'][@moodCode='EVN']/interpretationCode[@codeSystem='2.16.840.1.113883.3.989.2.1.1.12']][1]/@code
		検査結果 (コード) に関する ICH コードリストのバージョン					/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='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='3']][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][@observation/code[@codeSystem='2.16.840.1.113883.6.163']][r]/observation[@classCode='OBS'][@moodCode='EVN']/interpretationCode[@codeSystem='2.16.840.1.113883.3.989.2.1.1.12']][1]/@codeSystemVersion

(別添3)

e	F.r.3.3	検査結果 (単位)	50AN	Interval of Physical Quantity (IVL<PQ>)	1.EQ center/value/unit=Physical Quantity (PQ)	値	/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='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='3'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP']/observation/code[@codeSystem='2.16.840.1.113883.6.163']][r]/observation[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='IVL_PQ'][1]/center/@unit
e					2.GT low/value/unit=Coded Simple Value (CS)	値	/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='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='3'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP']/observation/code[@codeSystem='2.16.840.1.113883.6.163']][r]/observation[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='IVL_PQ'][high/@nullFlavor='PINF'][1]/low[@inclusive='false']/@unit
e					3.GE low/value/unit=Coded Simple Value (CS)	値	/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='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='3'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP']/observation/code[@codeSystem='2.16.840.1.113883.6.163']][r]/observation[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='IVL_PQ'][high/@nullFlavor='PINF'][1]/low[@inclusive='true']/@unit
e					4.LT high/value/unit=Coded Simple Value (CS)	値	/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='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='3'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP']/observation/code[@codeSystem='2.16.840.1.113883.6.163']][r]/observation[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='IVL_PQ'][low/@nullFlavor='NINF'][1]/high[@inclusive='false']/@unit

(別添3)

e					5.LE high/value/unit=Code d Simple Value (CS)	値	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT']@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVTG']@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVTG']@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ']/organizer/code[@code='3'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY']@moodCode='EVN']/component[@typeCode='COMP']/observation/code[@codeSystem='2.16.840.1.113883.6.163']][r]/observation[@classCode='OBS']@moodCode='EVN']/value[@xsi:type='IVL_PQ']@low/@nullFlavor='NINF'][1]/high[@inclusive='true']@unit
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	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT']@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVTG']@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVTG']@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ']/organizer/code[@code='3'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY']@moodCode='EVN']/component[@typeCode='COMP']/observation/code[@codeSystem='2.16.840.1.113883.6.163']][r]/observation[@classCode='OBS']@moodCode='EVN']/value[@xsi:type='ED']][1]/text()
e	F.r.4	正常範囲 低値	50AN	Physical Quantity (PQ)	value=Real Number (REAL)	値	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT']@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVTG']@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVTG']@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ']/organizer/code[@code='3'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY']@moodCode='EVN']/component[@typeCode='COMP']/observation/code[@codeSystem='2.16.840.1.113883.6.163']][r]/observation[@classCode='OBS']@moodCode='EVN']/referenceRange[@typeCode='REFV']@observationRange/interpretationCode[@code='L'][@codeSystem='2.16.840.1.113883.5.83']][1]/observationRange[@classCode='OBS']@moodCode='EVN.CRT']/value[@xsi:type='PQ']@value
e	F.r.5	正常範囲 高値	50AN	Physical Quantity (PQ)	value=Real Number (REAL)	値	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT']@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVTG']@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVTG']@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ']/organizer/code[@code='3'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY']@moodCode='EVN']/component[@typeCode='COMP']/observation/code[@codeSystem='2.16.840.1.113883.6.163']][r]/observation[@classCode='OBS']@moodCode='EVN']/referenceRange[@typeCode='REFV']@observationRange/interpretationCode[@code='H'][@codeSystem='2.16.840.1.113883.5.83']][1]/observationRange[@classCode='OBS']@moodCode='EVN.CRT']/value[@xsi:type='PQ']@value

e	F.r.6	備考	2000AN	Encapsulated Data (ED)		値	/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='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='3'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20'] [1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'] observation/code[@codeSystem='2.16.840.1.113883.6.163'] [r]/observation[@classCode='OBS'][@moodCode='EVN']/outboundRelationship2[@typeCode='PERT'] observation/code[@code='10'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19'] observation[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='ED'][1]/text()
e	F.r.7	その他の情報	ブール型	Boolean (BL)		値	/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='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='3'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20'] [1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'] observation/code[@codeSystem='2.16.840.1.113883.6.163'] [r]/observation[@classCode='OBS'][@moodCode='EVN']/outboundRelationship2[@typeCode='REFR'] observation/code[@code='25'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19'] observation[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='BL'][1]/@value
h	G.k	医薬品情報 (必要に応じ繰り返し)				繰り返しノード	/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='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[@typeCode='COMP'] substanceAdministration[id]
e	G.k.1	医薬品関与の位置付け	1N	Coded With Equivalents (CE)	code=Character String (ST)	値	/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='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'] adverseEventAssessment[1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'] causalityAssessment/code[@code='20'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19'] causalityAssessment[@classCode='OBS'][@moodCode='EVN']/subject2[@typeCode='SUBJ']/productUseReference[@classCode='SBADM'][@moodCode='EVN']/id[@root='UUID of k-th drug'] value[@xsi:type='CE'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.13']/@code

		医薬品関与の位置付けに関する ICH コードリストのバージョン					/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='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP']causalityAssessment/coef[@code='20'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']/causalityAssessment[@classCode='OBS'][@moodCode='EVN']/subject2[@typeCode='SUBJ']/productUseReference[@classCode='SBADM'][@moodCode='EVN']/id[@root='UUIID' of k-th drug]/value[@xsi:type='CE'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.13']/@codeSystemVersion
h	G.k.2	医薬品の識別					
h	G.k.2.1	医薬品の固有識別子/製剤の固有識別子					
e	G.k.2.1.1a	MPID バージョン日付/番号	ISO IDMP のとおり	Coded With Equivalents (CE)	codeSystemVersion= Character String (ST)	値	/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='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[@typeCode='COMP']/substanceAdministration[id]/k/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/consumable[@typeCode='CSM']][1]/instanceOfKind[@classCode='INST']/kindOfProduct[@classCode='MMAT'][@determinerCode='KIND']/coef[@codeSystem='TBD-MPID']/@codeSystemVersion
e	G.k.2.1.1b	医薬品製品識別子 (MPID)	ISO IDMP のとおり	Coded With Equivalents (CE)	code=Character String (ST)	値	/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='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[@typeCode='COMP']/substanceAdministration[id]/k/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/consumable[@typeCode='CSM']][1]/instanceOfKind[@classCode='INST']/kindOfProduct[@classCode='MMAT'][@determinerCode='KIND']/coef[@codeSystem='TBD-MPID']/@code
e	G.k.2.1.2a	PhPID バージョン日付/番号	ISO IDMP のとおり	Coded With Equivalents (CE)	codeSystemVersion= Character String (ST)	値	/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='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[@typeCode='COMP']/substanceAdministration[id]/k/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/consumable[@typeCode='CSM']][1]/instanceOfKind[@classCode='INST']/kindOfProduct[@classCode='MMAT'][@determinerCode='KIND']/coef[@codeSystem='TBD-PhPID']/@codeSystemVersion

e	G.k.2.1.2b	製剤識別子 (PhPID)	ISO IDMP のとおり	Coded With Equivalents (CE)	code=Character String (ST)	値	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moo dCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCo de='EVN']/component[@typeCode='COMP'] adverseEventAssessment[1] adverseEventAssessment [@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classC ode='INVSBJ']/subjectOf2[@typeCode='SBJ'] organizer/code[@code='4'][@codeSystem='2.16.840.1 .113883.3.989.2.1.1.20'] [1] organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'] substanceAdministration[id]/k/substanceAdministration[@classCode='SBADM '][@moodCode='EVN']/consumable[@typeCode='CSM'] [1] instanceOfKind[@classCode='INST']/kind OfProduct[@classCode='MMAT'][@determinerCode='KIND']/code[@codeSystem='TBD-PhPID']/@c ode
e	G.k.2.2	第一次情報源により報告さ れた医薬品名	250AN	Entity Name (EN)	name=Entity Name Part (ENXP)	値	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moo dCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCo de='EVN']/component[@typeCode='COMP'] adverseEventAssessment[1] adverseEventAssessment [@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classC ode='INVSBJ']/subjectOf2[@typeCode='SBJ'] organizer/code[@code='4'][@codeSystem='2.16.840.1 .113883.3.989.2.1.1.20'] [1] organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'] substanceAdministration[id]/k/substanceAdministration[@classCode='SBADM '][@moodCode='EVN']/consumable[@typeCode='CSM'] [1] instanceOfKind[@classCode='INST']/kind OfProduct[@classCode='MMAT'][@determinerCode='KIND']/name[1]/text()
h	G.k.2.3.r	成分/特定成分の識別子と 含量 (必要に応じ繰り返す)				繰り返し ノード	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moo dCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCo de='EVN']/component[@typeCode='COMP'] adverseEventAssessment[1] adverseEventAssessment [@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classC ode='INVSBJ']/subjectOf2[@typeCode='SBJ'] organizer/code[@code='4'][@codeSystem='2.16.840.1 .113883.3.989.2.1.1.20'] [1] organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'] substanceAdministration[id]/k/substanceAdministration[@classCode='SBADM '][@moodCode='EVN']/consumable[@typeCode='CSM'] [1] instanceOfKind[@classCode='INST']/kind OfProduct[@classCode='MMAT'][@determinerCode='KIND']/ingredient[@classCode='ACTI']
e	G.k.2.3.r.1	成分/特定成分名	250AN	Trivial Name (TN)	name=Entity Name Part (ENXP)	値	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moo dCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCo de='EVN']/component[@typeCode='COMP'] adverseEventAssessment[1] adverseEventAssessment [@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classC ode='INVSBJ']/subjectOf2[@typeCode='SBJ'] organizer/code[@code='4'][@codeSystem='2.16.840.1 .113883.3.989.2.1.1.20'] [1] organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'] substanceAdministration[id]/k/substanceAdministration[@classCode='SBADM '][@moodCode='EVN']/consumable[@typeCode='CSM'] [1] instanceOfKind[@classCode='INST']/kind OfProduct[@classCode='MMAT'][@determinerCode='KIND']/ingredient[@classCode='ACTI'] [r]/ingre dientSubstance[@classCode='MMAT'][@determinerCode='KIND']/name[1]/text()

(別添3)

e	G.k.2.3.r.2a	成分/特定成分の ID パー ジョン日付/番号	ISO IDMP のとおり	Coded With Equivalents (CE)	codeSystemVersion= Character String (ST)	値	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moo dCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCo de='EVN']/component[@typeCode='COMP'] adverseEventAssessment[1] adverseEventAssessment [@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classC ode='INVSBJ']/subjectOf2[@typeCode='SBJ']/organizer/code[@code='4'][@codeSystem='2.16.840.1 .113883.3.989.2.1.1.20'] [1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP']/substanceAdministration[id][k]/substanceAdministration[@classCode='SBADM '][@moodCode='EVN']/consumable[@typeCode='CSM'][1]/instanceOfKind[@classCode='INST']/kind OfProduct[@classCode='MMAT'][@determinerCode='KIND']/ingredient[@classCode='ACTI'][r]/ingre dientSubstance[@classCode='MMAT'][@determinerCode='KIND']/code[@codeSystem='TBD-Substa nce']/@codeSystemVersion
e	G.k.2.3.r.2b	成分/特定成分の ID	ISO IDMP のとおり	Coded With Equivalents (CE)	code=Character String (ST)	値	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moo dCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCo de='EVN']/component[@typeCode='COMP'] adverseEventAssessment[1] adverseEventAssessment [@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classC ode='INVSBJ']/subjectOf2[@typeCode='SBJ']/organizer/code[@code='4'][@codeSystem='2.16.840.1 .113883.3.989.2.1.1.20'] [1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP']/substanceAdministration[id][k]/substanceAdministration[@classCode='SBADM '][@moodCode='EVN']/consumable[@typeCode='CSM'][1]/instanceOfKind[@classCode='INST']/kind OfProduct[@classCode='MMAT'][@determinerCode='KIND']/ingredient[@classCode='ACTI'][r]/ingre dientSubstance[@classCode='MMAT'][@determinerCode='KIND']/code[@codeSystem='TBD-Substa nce']/@code
e	G.k.2.3.r.3a	含量 (数)	10N	Physical Quantity (PQ)	value=Real Number (REAL)	値	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moo dCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCo de='EVN']/component[@typeCode='COMP'] adverseEventAssessment[1] adverseEventAssessment [@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classC ode='INVSBJ']/subjectOf2[@typeCode='SBJ']/organizer/code[@code='4'][@codeSystem='2.16.840.1 .113883.3.989.2.1.1.20'] [1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP']/substanceAdministration[id][k]/substanceAdministration[@classCode='SBADM '][@moodCode='EVN']/consumable[@typeCode='CSM'][1]/instanceOfKind[@classCode='INST']/kind OfProduct[@classCode='MMAT'][@determinerCode='KIND']/ingredient[@classCode='ACTI'][r]/quant ity[denominator/@value='1']/numerator/@value
e	G.k.2.3.r.3b	含量 (単位)	50AN	Physical Quantity (PQ)	unit=Coded Simple Value (CS)	値	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moo dCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCo de='EVN']/component[@typeCode='COMP'] adverseEventAssessment[1] adverseEventAssessment [@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classC ode='INVSBJ']/subjectOf2[@typeCode='SBJ']/organizer/code[@code='4'][@codeSystem='2.16.840.1 .113883.3.989.2.1.1.20'] [1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP']/substanceAdministration[id][k]/substanceAdministration[@classCode='SBADM '][@moodCode='EVN']/consumable[@typeCode='CSM'][1]/instanceOfKind[@classCode='INST']/kind OfProduct[@classCode='MMAT'][@determinerCode='KIND']/ingredient[@classCode='ACTI'][r]/quant ity[denominator/@value='1']/numerator/@unit

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	/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='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[@typeCode='COMP'] substanceAdministration[id][k]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/consumable[@typeCode='CSM'] [1] instanceOfKind[@classCode='INST']/subjectOf[@typeCode='SBJ'] [1] productEvent[@classCode='ACT'][@moodCode='EVN'] 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='INST ANCE']/addr/country[1]/text()
e	G.k.2.5	治験薬の盲検状況	ブール型	Boolean (BL)		値	/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='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[@typeCode='COMP'] substanceAdministration[id][k]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/outboundRelationship2[@typeCode='PERT'] observation/code[@code='6'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19'] [1] observation[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='BL'] [1] @value
h	G.k.3	医薬品の承認の取得者及び承認/申請番号					
e	G.k.3.1	承認/申請番号	35AN	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[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'] [1] 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[@typeCode='COMP'] substanceAdministration[id][k]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/consumable[@typeCode='CSM'] [1] instanceOfKind[@classCode='INST']/kindOfProduct[@classCode='MMAT'][@determinerCode='KIND']/asManufacturedProduct[@classCode='MANU']/subjectOf[@typeCode='SBJ'] [1] approval[@classCode='CNTRCT'][@moodCode='EVN']/id[@root='2.16.840.1.113883.3.989.2.1.3.4'] @extension

e	G.k.3.2	承認/申請国	2A	Coded With Equivalents (CE)	code=Character String (ST)	値	/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='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[@typeCode='COMP'] substanceAdministration[id][k]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/consumable[@typeCode='CSM'] [1] instanceOfKind[@classCode='INST']/kindOfProduct[@classCode='MMAT'][@determinerCode='KIND']/asManufacturedProduct[@classCode='MANU']/subjectOf[@typeCode='SBJ'] [1] approval[@classCode='CTRCT'][@moodCode='EVN']/author[@typeCode='AUT']/territorialAuthority[@classCode='TERR']/territory[@classCode='NAT'][@determinerCode='INSTANCE']/code[@codeSystem='1.0.3166.1.2.2']/code
e	G.k.3.3	承認の取得者/申請者の名称	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']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'] [1] 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[@typeCode='COMP'] substanceAdministration[id][k]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/consumable[@typeCode='CSM'] [1] instanceOfKind[@classCode='INST']/kindOfProduct[@classCode='MMAT'][@determinerCode='KIND']/asManufacturedProduct[@classCode='MANU']/subjectOf[@typeCode='SBJ'] [1] approval[@classCode='CTRCT'][@moodCode='EVN']/holder[@typeCode='HLD'] [1] role[@classCode='HLD']/playingOrganization[@classCode='ORG'][@determinerCode='INSTANCE']/name/text()
h	G.k.4.r	投与量及び関連情報 (必要に応じ繰り返す)				繰り返しノード	/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='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[@typeCode='COMP'] substanceAdministration[id][k]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/outboundRelationship2[@typeCode='COMP'] substanceAdministration
e	G.k.4.r.1a	投与量 (数)	8N	Physical Quantity (PQ)	value=Real Number (REAL)	値	/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='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[@typeCode='COMP'] substanceAdministration[id][k]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/outboundRelationship2[@typeCode='COMP'] substanceAdministration[r]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/doseQuantity/@value

(別添3)

e				G.k.4.r.3 の単位が合計の場合 : Physical Quantity (PQ)	value=Real Number (REAL)	値	/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='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment[1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject[1]@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[@typeCode='COMP']/substanceAdministration[id][k]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/outboundRelationship2[@typeCode='COMP']/substanceAdministration[r]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/doseCheckQuantity[denominator[@xsi:type='PQ']@nullFlavor='UNK']/numerator[@xsi:type='PQ']@value
e	G.k.4.r.1b	投与量 (単位)	50AN	Physical Quantity (PQ)	unit=Coded Simple Value (CS)	値	/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='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment[1]/adverseEventAssessment[@classCode='INVSTG']@moodCode='EVN']/subject[1]@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[@typeCode='COMP']/substanceAdministration[id][k]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/outboundRelationship2[@typeCode='COMP']/substanceAdministration[r]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/doseQuantity/@unit
e				G.k.4.r.3 の単位が合計の場合 : Physical Quantity (PQ)	unit=Coded Simple Value (CS)	値	/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='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment[1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject[1]@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[@typeCode='COMP']/substanceAdministration[id][k]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/outboundRelationship2[@typeCode='COMP']/substanceAdministration[r]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/doseCheckQuantity[denominator[@xsi:type='PQ']@nullFlavor='UNK']/numerator[@xsi:type='PQ']@unit

e	G.k.4.r.2	投与間隔の単位数	4N	<p>1.以下のデータ項目の2つを超える値が表示される場合：</p> <p>1) G.k.4.r.2、 G.k.4.r.3 2) G.k.4.r.4 3) G.k.4.r.5 4) G.k.4.r.6a、 G.k.4.r.6b</p> <p>データ型 SXPR を伴う最初の comp 項目</p> <p>Parenthetic Set Expression of Time (SXPR_TS) [Periodic Interval of Time (PIVL_TS)]</p>	<p>period/value=Real Number (REAL)</p>	値	<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='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP']1/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']1/component[@typeCode='COMP']substanceAdministration/d[k]/substanceAdministration[@classCode='SBADM']1[@moodCode='EVN']/outboundRelationship2[@typeCode='COMP']substanceAdministration[r]/substanceAdministration[@classCode='SBADM']1[@moodCode='EVN']/effectiveTime[@xsi:type='SXPR_TS']/comp[@xsi:type='PIVL_TS']/period/@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> <p>1) G.k.4.r.2、 G.k.4.r.3 2) G.k.4.r.4 3) G.k.4.r.5 4) G.k.4.r.6a、 G.k.4.r.6b</p> <p>データ型 SXPR を伴う2番目の comp 項目</p> <p>Parenthetic Set Expression of Time (SXPR_TS) [Periodic Interval of Time (PIVL_TS)]</p>		値	<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='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP']1/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']1/component[@typeCode='COMP']substanceAdministration/d[k]/substanceAdministration[@classCode='SBADM']1[@moodCode='EVN']/outboundRelationship2[@typeCode='COMP']substanceAdministration[r]/substanceAdministration[@classCode='SBADM']1[@moodCode='EVN']/effectiveTime[@xsi:type='SXPR_TS']/comp[@xsi:type='PIVL_TS']1[@operator='A']/period/@value</pre>

e				<p>3.以下のデータ項目の1つの値のみが表示される場合</p> <p>1) G.k.4.r.2、 G.k.4.r.3 2) G.k.4.r.4 3) G.k.4.r.5 4) G.k.4.r.6a、 G.k.4.r.6b</p> <p>Periodic Interval of Time (PIVL_TS)</p>	<p>period/value=Real Number (REAL)</p>	<p>値</p>	<pre>/MCCI_IN200100UV01[@ITSVersion='XML_1.0']@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd'/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/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 [@typeCode='COMP'] substanceAdministration[id][k] substanceAdministration[@classCode='SBADM'] [@moodCode='EVN']/outboundRelationship2[@typeCode='COMP'] substanceAdministration[r] substanceAdministration[@classCode='SBADM'] [@moodCode='EVN']/effectiveTime[@xsi:type='PIVL_TS']/period/@value</pre>
e	G.k.4.r.3	投与間隔の定義	50AN	<p>1.以下のデータ項目の2つの値が表示される場合</p> <p>1) G.k.4.r.2、 G.k.4.r.3 2) G.k.4.r.4 3) G.k.4.r.5 4) G.k.4.r.6a、 G.k.4.r.6b</p> <p>データ型 SXPR を伴う最初の comp 項目</p> <p>Parenthetic Set Expression of Time (SXPR_TS) [Periodic Interval of Time (PIVL_TS)]</p>	<p>period/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']/subject[@typeCode='SUBJ'][1]/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 [@typeCode='COMP'] substanceAdministration[id][k] substanceAdministration[@classCode='SBADM'] [@moodCode='EVN']/outboundRelationship2[@typeCode='COMP'] substanceAdministration[r] substanceAdministration[@classCode='SBADM'] [@moodCode='EVN']/effectiveTime[@xsi:type='SXPR_TS']/comp[@xsi:type='PIVL_TS']/period/@unit</pre>

			<p>2.以下のデータ項目の2つを超える値が表示される場合:</p> <p>1) G.k.4.r.2、 G.k.4.r.3</p> <p>2) G.k.4.r.4</p> <p>3) G.k.4.r.5</p> <p>4) G.k.4.r.6a、 G.k.4.r.6b</p> <p>データ型 SXPTR を伴う 2 番目の comp 項目</p> <p>Parenthetic Set Expression of Time (SXPTR_TS) [Periodic Interval of Time (PIVL_TS)]</p>		値	<pre>/MCCL_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCL_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/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[@typeCode='COMP'] substanceAdministration/d[k]/substanceAdministration[@classCode='SBADM'] [@moodCode='EVN']/outboundRelationship2[@typeCode='COMP'] substanceAdministration[r]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/effectiveTime[@xsi:type='SXPTR_TS']/comp[@xsi:type='PIVL_TS'][@operator='A']/period/@unit</pre>
e			<p>3.以下のデータ項目の1つの値のみが表示される場合</p> <p>1) G.k.4.r.2、 G.k.4.r.3</p> <p>2) G.k.4.r.4</p> <p>3) G.k.4.r.5</p> <p>4) G.k.4.r.6a、 G.k.4.r.6b</p> <p>Periodic Interval of Time (PIVL_TS)</p>	period/unit=Coded Simple Value (CS)	値	<pre>/MCCL_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCL_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/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[@typeCode='COMP'] substanceAdministration/d[k]/substanceAdministration[@classCode='SBADM'] [@moodCode='EVN']/outboundRelationship2[@typeCode='COMP'] substanceAdministration[r]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/effectiveTime[@xsi:type='PIVL_TS']/period/@unit</pre>

e	G.k.4.r.4	医薬品の投与開始日	日付/時間	<p>1.以下のデータ項目の2つを超える値が表示される場合：</p> <p>1) G.k.4.r.2、G.k.4.r.3 2) G.k.4.r.4 3) G.k.4.r.5 4) G.k.4.r.6a、G.k.4.r.6b</p> <p>データ型 SXPR を伴う最初の comp 項目</p> <p>Parenthetic Set Expression of Time (SXPR_TS) [Intervale of Point in Time (IVL_TS)]</p>	low=Interval Boundary (IVXB)	値	<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='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[@typeCode='COMP']/substanceAdministration[id][k]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/outboundRelationship2[@typeCode='COMP']/substanceAdministration[r]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/effectiveTime[@xsi:type='SXPR_TS']/comp[@xsi:type='IVL_TS']/low/@value</pre>
e						NullFlavor	<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='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[@typeCode='COMP']/substanceAdministration[id][k]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/outboundRelationship2[@typeCode='COMP']/substanceAdministration[r]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/effectiveTime[@xsi:type='SXPR_TS']/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.6a、G.k.4.r.6b <p>データ型 SXPR を伴う 2 番目の comp 項目</p> <p>Parenthetic Set Expression of Time (SXPR_TS) [[Intervale of Point in Time (IVL_TS)]]</p>		値	<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='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[@typeCode='COMP'] substanceAdministration/d[k]/substanceAdministration[@classCode='SBADM'] [@moodCode='EVN']/outboundRelationship2[@typeCode='COMP'] substanceAdministration[r]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/effectiveTime[@xsi:type='SXPR_TS']/comp[@xsi:type='IVL_TS'][@operator='A']/ow/@value</pre>
					NullFlavor	<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='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[@typeCode='COMP'] substanceAdministration/d[k]/substanceAdministration[@classCode='SBADM'] [@moodCode='EVN']/outboundRelationship2[@typeCode='COMP'] substanceAdministration[r]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/effectiveTime[@xsi:type='SXPR_TS']/comp[@xsi:type='IVL_TS'][@operator='A']/ow/@nullFlavor</pre>

e				<p>3.以下のデータ項目の1つの値のみが表示される場合</p> <ol style="list-style-type: none"> G.k.4.r.2、 G.k.4.r.3 G.k.4.r.4 G.k.4.r.5 G.k.4.r.6a、 G.k.4.r.6b <p>Interval of Point in Time (IVL_TS)</p>	low=Interval Boundary (IVXB)	値	<pre>/MCCL_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='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[@typeCode='COMP']/substanceAdministration[id]/k/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/outboundRelationship2[@typeCode='COMP']/substanceAdministration[r]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/effectiveTime[@xsi:type='IVL_TS']/low/@value</pre>
e						NullFlavor	<pre>/MCCL_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='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[@typeCode='COMP']/substanceAdministration[id]/k/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/outboundRelationship2[@typeCode='COMP']/substanceAdministration[r]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/effectiveTime[@xsi:type='IVL_TS']/low/@nullFlavor</pre>
e	G.k.4.r.5	医薬品の投与終了日	日付/時間	<p>1.以下のデータ項目の2つを超える値が表示される場合：</p> <ol style="list-style-type: none"> G.k.4.r.2、 G.k.4.r.3 G.k.4.r.4 G.k.4.r.5 G.k.4.r.6a、 G.k.4.r.6b <p>データ型 SXPР を伴う最初の comp 項目</p> <p>Parenthetic Set Expression of Time (SXPР_TS)</p> <p>[Intervale of Point in Time (IVL_TS)]</p>	high=Interval Boundary (IVXB)	値	<pre>/MCCL_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='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[@typeCode='COMP']/substanceAdministration[id]/k/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/outboundRelationship2[@typeCode='COMP']/substanceAdministration[r]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/effectiveTime[@xsi:type='SXPР_TS']/comp[@xsi:type='IVL_TS']/high/@value</pre>

e					<p>NullFlavor</p> <pre>/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moo dCode='EVN']/subject[@typeCode='SUBJ']{1}/investigationEvent[@classCode='INVSTG'][@moodCo de='EVN']/component[@typeCode='COMP']{1}/adverseEventAssessment{1}/adverseEventAssessment [@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ']{1}/primaryRole[@classC ode='INVSBJ']/subjectOf2[@typeCode='SBJ']{1}/organizer/code[@code='4']{1}@codeSystem=2.16.840.1 .113883.3.989.2.1.1.20''{1}/organizer[@classCode='CATEGORY']{1}@moodCode='EVN'/component{ 1}/adverseEventAssessment[@typeCode='COMP']{1}/substanceAdministration[id][k]/substanceAdministration[@classCode='SBADM ']{1}@moodCode='EVN'/outboundRelationship2[@typeCode='COMP']{1}/substanceAdministration[r]/sub stanceAdministration[@classCode='SBADM']{1}@moodCode='EVN'/effectiveTime[@xsi:type='SXPR_ TS']/comp[@xsi:type='IVL_TS']/high/@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> <p>1) G.k.4.r.2, G.k.4.r.3</p> <p>2) G.k.4.r.4</p> <p>3) G.k.4.r.5</p> <p>4) G.k.4.r.6a, G.k.4.r.6b</p> <p>データ型 SXPR を伴 う 2 番目の comp 項 目</p> <p>Parenthetic Set Expression of Time (SXPR_TS) [Intervale of Point in Time (IVL_TS)]</p>	値	<pre>/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moo dCode='EVN']/subject[@typeCode='SUBJ']{1}/investigationEvent[@classCode='INVSTG'][@moodCo de='EVN']/component[@typeCode='COMP']{1}/adverseEventAssessment{1}/adverseEventAssessment [@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ']{1}/primaryRole[@classC ode='INVSBJ']/subjectOf2[@typeCode='SBJ']{1}/organizer/code[@code='4']{1}@codeSystem=2.16.840.1 .113883.3.989.2.1.1.20''{1}/organizer[@classCode='CATEGORY']{1}@moodCode='EVN'/component{ 1}/adverseEventAssessment[@typeCode='COMP']{1}/substanceAdministration[id][k]/substanceAdministration[@classCode='SBADM ']{1}@moodCode='EVN'/outboundRelationship2[@typeCode='COMP']{1}/substanceAdministration[r]/sub stanceAdministration[@classCode='SBADM']{1}@moodCode='EVN'/effectiveTime[@xsi:type='SXPR_ TS']/comp[@xsi:type='IVL_TS']{1}@operator='A'/high/@value</pre>
				NullFlavor	<pre>/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moo dCode='EVN']/subject[@typeCode='SUBJ']{1}/investigationEvent[@classCode='INVSTG'][@moodCo de='EVN']/component[@typeCode='COMP']{1}/adverseEventAssessment{1}/adverseEventAssessment [@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ']{1}/primaryRole[@classC ode='INVSBJ']/subjectOf2[@typeCode='SBJ']{1}/organizer/code[@code='4']{1}@codeSystem=2.16.840.1 .113883.3.989.2.1.1.20''{1}/organizer[@classCode='CATEGORY']{1}@moodCode='EVN'/component{ 1}/adverseEventAssessment[@typeCode='COMP']{1}/substanceAdministration[id][k]/substanceAdministration[@classCode='SBADM ']{1}@moodCode='EVN'/outboundRelationship2[@typeCode='COMP']{1}/substanceAdministration[r]/sub stanceAdministration[@classCode='SBADM']{1}@moodCode='EVN'/effectiveTime[@xsi:type='SXPR_ TS']/comp[@xsi:type='IVL_TS']{1}@operator='A'/high/@nullFlavor</pre>

e				<p>3.以下のデータ項目の1つの値のみが表示される場合</p> <p>1) G.k.4.r.2、 G.k.4.r.3</p> <p>2) G.k.4.r.4</p> <p>3) G.k.4.r.5</p> <p>4) G.k.4.r.6a、 G.k.4.r.6b</p> <p>Interval of Point in Time (IVL_TS)</p>	high=Interval Boundary (IVXB)	値	<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='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[@typeCode='COMP'][@substanceAdministration/id][k]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/outboundRelationship2[@typeCode='COMP'][@substanceAdministration][r]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/effectiveTime[@xsi:type='IVL_TS']/high/@value</pre>
e						NullFlavor	<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='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[@typeCode='COMP'][@substanceAdministration/id][k]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/outboundRelationship2[@typeCode='COMP'][@substanceAdministration][r]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/effectiveTime[@xsi:type='IVL_TS']/high/@nullFlavor</pre>
e	G.k.4.r.6a	医薬品投与期間 (数)	5N	<p>1.以下のデータ項目の2つを超える値が表示される場合：</p> <p>1) G.k.4.r.2、 G.k.4.r.3</p> <p>2) G.k.4.r.4</p> <p>3) G.k.4.r.5</p> <p>4) G.k.4.r.6a、 G.k.4.r.6b</p> <p>データ型 SXPR を伴う最初の comp 項目</p> <p>Parenthetic Set Expression of Time (SXPR_TS) [Intervale of Point in Time (IVL_TS)]</p>	width/value=Real Number (REAL)	値	<pre>/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/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[@typeCode='COMP'][@substanceAdministration/id][k]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/outboundRelationship2[@typeCode='COMP'][@substanceAdministration][r]/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> <p>1) G.k.4.r.2、 G.k.4.r.3</p> <p>2) G.k.4.r.4</p> <p>3) G.k.4.r.5</p> <p>4) G.k.4.r.6a、 G.k.4.r.6b</p> <p>データ型 SXPR を伴う2番目のcomp項目</p> <p>Parenthetic Set Expression of Time (SXPR_TS) [Intervale of Point in Time (IVL_TS)]</p>		値	<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='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[@typeCode='COMP']/substanceAdministration/d[k]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/outboundRelationship2[@typeCode='COMP']/substanceAdministration[r]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/effectiveTime[@xsi:type='SXPR_TS']/comp[@xsi:type='IVL_TS'][@operator='A']/width/@value</pre>
e			<p>3.以下のデータ項目の1つの値のみが表示される場合</p> <p>1) G.k.4.r.2、 G.k.4.r.3</p> <p>2) G.k.4.r.4</p> <p>3) G.k.4.r.5</p> <p>4) G.k.4.r.6a、 G.k.4.r.6b</p> <p>Interval of Point in Time (IVL_TS)</p>	width/value=Real Number (REAL)	値	<pre>/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/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[@typeCode='COMP']/substanceAdministration/d[k]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/outboundRelationship2[@typeCode='COMP']/substanceAdministration[r]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/effectiveTime[@xsi:type='IVL_TS']/width/@value</pre>

e	G.k.4.r.6b	医薬品投与期間 (単位)	<p>1.以下のデータ項目の2つを超える値が表示される場合:</p> <p>1) G.k.4.r.2、 G.k.4.r.3 2) G.k.4.r.4 3) G.k.4.r.5 4) G.k.4.r.6a、 G.k.4.r.6b</p> <p>データ型 SXPР を伴う最初の comp 項目</p> <p>Parenthetic Set Expression of Time (SXPР_TS) [[Intervale of Point in Time (IVL_TS)]]</p>	width/unit=Coded Simple Value (CS)	値	<pre>/MCCI_IN200100UV01[@ITSVersion="XML_1.0"][@xsi:schemaLocation="urn:hl7-org:v3 MCCI_IN200100UV01.xsd"/PORR_IN049016UV[r]/controlActProcess[@classCode="CACT"][@moodCode="EVN"]/subject[@typeCode="SUBJ"][1]/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[@typeCode="COMP"]substanceAdministration[id]/k/substanceAdministration[@classCode="SBADM"][@moodCode="EVN"]/outboundRelationship2[@typeCode="COMP"]substanceAdministration[r]/substanceAdministration[@classCode="SBADM"][@moodCode="EVN"]/effectiveTime[@xsi:type="SXPР_TS']/comp[@xsi:type="IVL_TS']/width/@unit</pre>
			<p>2.以下のデータ項目の2つを超える値が表示される場合:</p> <p>1) G.k.4.r.2、 G.k.4.r.3 2) G.k.4.r.4 3) G.k.4.r.5 4) G.k.4.r.6a、 G.k.4.r.6b</p> <p>データ型 SXPР を伴う2番目の comp 項目</p> <p>Parenthetic Set Expression of Time (SXPР_TS)[Interval e of Point in Time (IVL_TS)]</p>		値	<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="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[@typeCode="COMP"]substanceAdministration[id]/k/substanceAdministration[@classCode="SBADM"][@moodCode="EVN"]/outboundRelationship2[@typeCode="COMP"]substanceAdministration[r]/substanceAdministration[@classCode="SBADM"][@moodCode="EVN"]/effectiveTime[@xsi:type="SXPР_TS']/comp[@xsi:type="IVL_TS"][@operator="A']/width/@unit</pre>

e				<p>3.以下のデータ項目の1つの値のみが表示される場合</p> <p>1) G.k.4.r.2、 G.k.4.r.3 2) G.k.4.r.4 3) G.k.4.r.5 4) G.k.4.r.6a、 G.k.4.r.6b</p> <p>Interval of Point in Time (IVL_TS)</p>	width/unit=Coded Simple Value (CS)	値	<pre>/MCCI_IN200100UV01[@ITSVersion='XML_1.0']@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd'/PORR_IN049016UV[r/controlActProcess/@classCode='CACT']@moodCode='EVN'/subject/@typeCode='SUBJ'[1]/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/@typeCode='COMP'[substanceAdministration/id][k]/substanceAdministration/@classCode='SBADM']@moodCode='EVN'/outboundRelationship2/@typeCode='COMP'[substanceAdministration][r]/substanceAdministration/@classCode='SBADM']@moodCode='EVN']/effectiveTime[@xsi:type='IVL_TS']/width/@unit</pre>
e	G.k.4.r.7	バッチ/ロット番号	35AN	Character String (ST)		値	<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='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/@typeCode='COMP'[substanceAdministration/id][k]/substanceAdministration/@classCode='SBADM']@moodCode='EVN'/outboundRelationship2/@typeCode='COMP'[substanceAdministration][r]/substanceAdministration/@classCode='SBADM']@moodCode='EVN']/consumable/@typeCode='CSM'[1]/instanceOfKind/@classCode='INST'/productInstanceInstance/@classCode='MMAT']@determinerCode='INSTANCE']/lotNumberText/text()</pre>
e	G.k.4.r.8	投与量を表す記述情報	2000AN	Encapsulated Data (ED)		値	<pre>/MCCI_IN200100UV01[@ITSVersion='XML_1.0']@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd'/PORR_IN049016UV[r/controlActProcess/@classCode='CACT']@moodCode='EVN'/subject/@typeCode='SUBJ'[1]/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/@typeCode='COMP'[substanceAdministration/id][k]/substanceAdministration/@classCode='SBADM']@moodCode='EVN'/outboundRelationship2/@typeCode='COMP'[substanceAdministration][r]/substanceAdministration/@classCode='SBADM']@moodCode='EVN']/text/text()</pre>
h	G.k.4.r.9	医薬品剤形					
e	G.k.4.r.9.1	医薬品剤形 (自由記載)	60AN	Coded With Equivalents (CE)	originalText=Encapsulated Data (ED)	値	<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='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/@typeCode='COMP'[substanceAdministration/id][k]/substanceAdministration/@classCode='SBADM']@moodCode='EVN'/outboundRelationship2/@typeCode='COMP'[substanceAdministration][r]/substanceAdministration/@classCode='SBADM']@moodCode='EVN']/consumable/@typeCode='CSM'[1]/instanceOfKind/@classCode='INST']/kindOfProduct/@classCode='MMAT']@determinerCode='KIND']/formCode/@codeSystem='TBD-DoseForm']/originalText/text()</pre>

e						NullFlavor	/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='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[@typeCode='COMP'] substanceAdministration[id][k]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/outboundRelationship2[@typeCode='COMP'] substanceAdministration[r]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/consumable[@typeCode='CSM'] [1]/instanceOfKind[@classCode='INST']/kindOfProduct[@classCode='MMAT'][@determinerCode='KIND']/formCode[@codeSystem='TBD-DoseForm']/originalText/@nullFlavor
e	G.k.4.r.9.2a	医薬品剤形の ID バージョン 日付/番号	ISO IDMP のとおり	Coded With Equivalents (CE)	codeSystemVersion= Character String (ST)	値	/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='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[@typeCode='COMP'] substanceAdministration[id][k]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/outboundRelationship2[@typeCode='COMP'] substanceAdministration[r]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/consumable[@typeCode='CSM'] [1]/instanceOfKind[@classCode='INST']/kindOfProduct[@classCode='MMAT'][@determinerCode='KIND']/formCode[@codeSystem='TBD-DoseForm']/codeSystemVersion
e	G.k.4.r.9.2b	医薬品剤形の ID	ISO IDMP のとおり	Coded With Equivalents (CE)	code=Character String (ST)	値	/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='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[@typeCode='COMP'] substanceAdministration[id][k]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/outboundRelationship2[@typeCode='COMP'] substanceAdministration[r]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/consumable[@typeCode='CSM'] [1]/instanceOfKind[@classCode='INST']/kindOfProduct[@classCode='MMAT'][@determinerCode='KIND']/formCode[@codeSystem='TBD-DoseForm']/code
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=Encapsu lated Data (ED)	値	/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='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[@typeCode='COMP'] substanceAdministration[id][k]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/outboundRelationship2[@typeCode='COMP'] substanceAdministration[r]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/routeCode[@codeSystem='2.16.840.1.113883.3.989.2.1.1.14']/originalText/text()

e						NullFlavor	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVTG'][@moodCode='EVN']/component[@typeCode='COMP'] adverseEventAssessment[1] adverseEventAssessment[@classCode='INVTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ']/organizer/code[@code='4'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20'] [1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'] [substanceAdministration/d][k]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/outboundRelationship2[@typeCode='COMP'] [substanceAdministration/r]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/routeCode[@codeSystem='2.16.840.1.113883.3.989.2.1.1.14']/originalText/@nullFlavor
e	G.k.4.r.10.2a	投与経路の ID バージョン日付／番号	ISO IDMP のとおり	Coded With Equivalents (CE)	codeSystemVersion=Character String (ST)	値	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVTG'][@moodCode='EVN']/component[@typeCode='COMP'] adverseEventAssessment[1] adverseEventAssessment[@classCode='INVTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ']/organizer/code[@code='4'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20'] [1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'] [substanceAdministration/d][k]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/outboundRelationship2[@typeCode='COMP'] [substanceAdministration/r]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/routeCode[@codeSystem='2.16.840.1.113883.3.989.2.1.1.14']/@codeSystemVersion
e	G.k.4.r.10.2b	投与経路の ID	ISO IDMP のとおり (3N)	Coded With Equivalents (CE)	code=Character String (ST)	値	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVTG'][@moodCode='EVN']/component[@typeCode='COMP'] adverseEventAssessment[1] adverseEventAssessment[@classCode='INVTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ']/organizer/code[@code='4'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20'] [1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'] [substanceAdministration/d][k]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/outboundRelationship2[@typeCode='COMP'] [substanceAdministration/r]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/routeCode[@codeSystem='2.16.840.1.113883.3.989.2.1.1.14']/@code
h	G.k.4.r.11	親への投与経路 (親一子/胎児報告の場合)					
e	G.k.4.r.11.1	親への投与経路 (自由記載)	60AN	Coded With Equivalents (CE)	originalText=Encapsulated Data (ED)	値	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVTG'][@moodCode='EVN']/component[@typeCode='COMP'] adverseEventAssessment[1] adverseEventAssessment[@classCode='INVTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ']/organizer/code[@code='4'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20'] [1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'] [substanceAdministration/d][k]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/outboundRelationship2[@typeCode='COMP'] [substanceAdministration/r]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/inboundRelationship[@typeCode='REFR'] [observation/code[@code='2B'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19'] [1]/observation[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='CE'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.14'] [1]/originalText/text()

e						NullFlavor	/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='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[@typeCode='COMP'] substanceAdministration/d[k]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/outboundRelationship2[@typeCode='COMP'] substanceAdministration[r]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/inboundRelationship[@typeCode='REFR'] observation/code[@code='28'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']][1] observation[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='CE'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.14']][1]/originalText/@nullFlavor
e	G.k.4.r.11.2a	親への投与経路の ID バージョン日付/番号	ISO IDMP のとおり	Coded With Equivalents (CE)	codeSystemVersion= Character String (ST)	値	/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='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[@typeCode='COMP'] substanceAdministration/d[k]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/outboundRelationship2[@typeCode='COMP'] substanceAdministration[r]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/inboundRelationship[@typeCode='REFR'] observation/code[@code='28'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']][1] observation[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='CE'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.14']][1]/@codeSystemVersion
e	G.k.4.r.11.2b	親への投与経路の ID	ISO IDMP のとおり (3N)	Coded With Equivalents (CE)	code=Character String (ST)	値	/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='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[@typeCode='COMP'] substanceAdministration/d[k]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/outboundRelationship2[@typeCode='COMP'] substanceAdministration[r]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/inboundRelationship[@typeCode='REFR'] observation/code[@code='28'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']][1] observation[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='CE'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.14']][1]/@code
e	G.k.5a	副作用/有害事象発現までの累積総投与量 (数)	10N	Physical Quantity (PQ)	value=Real Number (REAL)	値	/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='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[@typeCode='COMP'] substanceAdministration/d[k]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/outboundRelationship2[@typeCode='SUMM'] observation/code[@code='14'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']][1] observation[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='PQ']][1]/@value

(別添3)

e	G.k.5b	副作用／有害事象発現までの累積総投与量（単位）	50AN	Physical Quantity (PQ)	unit=Coded Simple Value (CS)	値	/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="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[@typeCode="COMP"][substanceAdministration/d][k]/substanceAdministration[@classCode="SBADM"][@moodCode="EVN"]/outboundRelationship2[@typeCode="SUMM"][observation/code[@code="14"][@codeSystem="2.16.840.1.113883.3.989.2.1.1.19"]][1]/observation[@classCode="OBS"][@moodCode="EVN"]/value[@xsi:type="PQ"][1]/@unit
e	G.k.6a	曝露時の妊娠期間（数）	3N	Physical Quantity (PQ)	value=Real Number (REAL)	値	/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="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[@typeCode="COMP"][substanceAdministration/d][k]/substanceAdministration[@classCode="SBADM"][@moodCode="EVN"]/outboundRelationship2[@typeCode="PERT"][observation/code[@code="16"][@codeSystem="2.16.840.1.113883.3.989.2.1.1.19"]][1]/observation[@classCode="OBS"][@moodCode="EVN"]/value[@xsi:type="PQ"][1]/@value
e	G.k.6b	曝露時の妊娠期間（単位）	50AN	Physical Quantity (PQ)	unit=Coded Simple Value (CS)	値	/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="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[@typeCode="COMP"][substanceAdministration/d][k]/substanceAdministration[@classCode="SBADM"][@moodCode="EVN"]/outboundRelationship2[@typeCode="PERT"][observation/code[@code="16"][@codeSystem="2.16.840.1.113883.3.989.2.1.1.19"]][1]/observation[@classCode="OBS"][@moodCode="EVN"]/value[@xsi:type="PQ"][1]/@unit
h	G.k.7.r	医薬品使用理由（必要に応じ繰り返す）				繰り返しノード	/MCCI_IN200100UV01[@ITSVersion="XML_1.0"][@xsi:schemaLocation="urn:hl7-org:v3 MCCI_IN200100UV01.xsd"/]PORR_IN049016UV[r]/controlActProcess[@classCode="CACT"][@moodCode="EVN"]/subject[@typeCode="SUBJ"][1]/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[@typeCode="COMP"][substanceAdministration/d][k]/substanceAdministration[@classCode="SBADM"][@moodCode="EVN"]/inboundRelationship[@typeCode="RSON"][observation/code[@code="19"][@codeSystem="2.16.840.1.113883.3.989.2.1.1.19"]]

e	G.k.7.r.1	第一次情報源により報告された使用理由	250AN	Coded With Equivalents (CE)	originalText=Encapsulated Data (ED)	値	/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='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[@typeCode='COMP'] substanceAdministration/d[k]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/inboundRelationship[@typeCode='RSON'] observation/code[@code='19'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19'] [r] observation[@classCode='OBS'][@moodCode='EVN'] performer[@typeCode='PRF'] assignedEntity[@classCode='ASSIGNED']/code[@code='3'][@codeSystem='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] originalText/text()
e						NullFlavor	/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='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[@typeCode='COMP'] substanceAdministration/d[k]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/inboundRelationship[@typeCode='RSON'] observation/code[@code='19'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19'] [r] observation[@classCode='OBS'][@moodCode='EVN'] performer[@typeCode='PRF'] assignedEntity[@classCode='ASSIGNED']/code[@code='3'][@codeSystem='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] originalText/@nullFlavor
e	G.k.7.r.2a	使用理由の MedDRA パージョン	4AN	Coded With Equivalents (CE)	codeSystemVersion=Character String (ST)	値	/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='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[@typeCode='COMP'] substanceAdministration/d[k]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/inboundRelationship[@typeCode='RSON'] observation/code[@code='19'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19'] [r] observation[@classCode='OBS'][@moodCode='EVN'] performer[@typeCode='PRF'] assignedEntity[@classCode='ASSIGNED']/code[@code='3'][@codeSystem='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

e	G.k.7.r.2b	使用理由 (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']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/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[@typeCode='COMP']/substanceAdministration[id]/k/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/inboundRelationship[@typeCode='RSON']/observation/code[@code='19'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19'] [r]/observation[@classCode='OBS'][@moodCode='EVN']/performer[@typeCode='PRF']/assignedEntity[@classCode='ASSIGNED']/code[@code='3'][@codeSystem='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
e	G.k.8	医薬品に対して取られた処置	1N	Concept Descriptor (CD)	code=Character String (ST)	値	/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='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[@typeCode='COMP']/substanceAdministration[id]/k/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/inboundRelationship[@typeCode='CAUS']/act/code[@codeSystem='2.16.840.1.113883.3.989.2.1.1.15'] [1] act[@classCode='ACT'][@moodCode='EVN']/code[@codeSystem='2.16.840.1.113883.3.989.2.1.1.15']/@code
		医薬品に対して取られた処置に関する ICH コードリストのバージョン					/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='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[@typeCode='COMP']/substanceAdministration[id]/k/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/inboundRelationship[@typeCode='CAUS']/act/code[@codeSystem='2.16.840.1.113883.3.989.2.1.1.15'] [1] act[@classCode='ACT'][@moodCode='EVN']/code[@codeSystem='2.16.840.1.113883.3.989.2.1.1.15']/@codeSystemVersion
h	G.k.9.i	医薬品と副作用/有害事象のマトリックス (必要に応じ繰り返す)					
e	G.k.9.i.1	評価対象の副作用/有害事象	N/A			値	
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_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'] adverseEventAssessment[1] adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'] causalityAssessment[code='39'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19'] [subject1[@typeCode='SUBJ'] adverseEffectReference[@classCode='OBS'][@moodCode='EVN']/id[@root='UUID of i-th reaction']] [subject2[@typeCode='SUBJ']/productUseReference[@classCode='SBADM'][@moodCode='EVN']/id[@root='UUID of k-th drug']]]

(別添3)

e	G.k.9.i.2.r.1	評価の情報源	60AN	Coded With Equivalents (CE)	originalText=Encapsulated Data (ED)	値	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ']{1}/investigationEvent[@classCode='INVTG'][@moodCode='EVN']/component[@typeCode='COMP']{1}/adverseEventAssessment{1}/adverseEventAssessment[@classCode='INVTG'][@moodCode='EVN']/component[@typeCode='COMP']{1}/causalityAssessment/code[@code='39'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']{1}/causalityAssessment[@classCode='OBS'][@moodCode='EVN']{1}/subject1[@typeCode='SUBJ']/adverseEffectReference[@classCode='OBS']{1}/subject2[@typeCode='SUBJ']/productUseReference[@classCode='SBADM']{1}/subject2[@typeCode='SUBJ']/productUseReference[@classCode='SBADM']{1}/methodCode{1}/originalText/text()
e	G.k.9.i.2.r.2	評価方法	60AN	Coded With Equivalents (CE)	originalText=Encapsulated Data (ED)	値	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ']{1}/investigationEvent[@classCode='INVTG'][@moodCode='EVN']/component[@typeCode='COMP']{1}/adverseEventAssessment{1}/adverseEventAssessment[@classCode='INVTG'][@moodCode='EVN']/component[@typeCode='COMP']{1}/causalityAssessment/code[@code='39'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']{1}/causalityAssessment[@classCode='OBS'][@moodCode='EVN']{1}/subject1[@typeCode='SUBJ']/adverseEffectReference[@classCode='OBS']{1}/subject2[@typeCode='SUBJ']/productUseReference[@classCode='SBADM']{1}/subject2[@typeCode='SUBJ']/productUseReference[@classCode='SBADM']{1}/methodCode{1}/originalText/text()
e	G.k.9.i.2.r.3	評価結果	60AN	Character String (ST)		値	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ']{1}/investigationEvent[@classCode='INVTG'][@moodCode='EVN']/component[@typeCode='COMP']{1}/adverseEventAssessment{1}/adverseEventAssessment[@classCode='INVTG'][@moodCode='EVN']/component[@typeCode='COMP']{1}/causalityAssessment/code[@code='39'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']{1}/causalityAssessment[@classCode='OBS'][@moodCode='EVN']{1}/subject1[@typeCode='SUBJ']/adverseEffectReference[@classCode='OBS']{1}/subject2[@typeCode='SUBJ']/productUseReference[@classCode='SBADM']{1}/subject2[@typeCode='SUBJ']/productUseReference[@classCode='SBADM']{1}/value[@xsi:type='ST']/text()
e	G.k.9.i.3.1a	医薬品の投与開始から副作用／有害事象発現までの時間間隔 (数)	5N	Physical Quantity (PQ)	value=Real Number (REAL)	値	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ']{1}/investigationEvent[@classCode='INVTG'][@moodCode='EVN']/component[@typeCode='COMP']{1}/adverseEventAssessment{1}/adverseEventAssessment[@classCode='INVTG'][@moodCode='EVN']/subject1[@typeCode='SUBJ']{1}/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ']/organizer[@classCode='CATEGORY']{1}/component[@typeCode='COMP']{1}/substanceAdministration[id][k]/substanceAdministration[@classCode='SBADM']{1}/outboundRelationship1[@typeCode='SAS']{1}/actReference[@classCode='OBS']{1}/actReference[@classCode='OBS']{1}/pauseQuantity/@value

e	G.k.9.i.3.1b	医薬品の投与開始から副作用／有害事象発現までの時間間隔 (単位)	50AN	Physical Quantity (PQ)	unit=Coded Simple Value (CS)	値	/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='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'] adverseEventAssessment[1] adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ']/organizer[@classCode='CATEGORY'][@moodCode='EVN'] code[@code='4'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20'] component[@typeCode='COMP'] substanceAdministration[id][k]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/outboundRelationship1[@typeCode='SAS'] actReference[@classCode='OBS'][@moodCode='EVN']/id[@root='UUID of i-th reaction']/pauseQuantity/@unit
e	G.k.9.i.3.2a	医薬品の最終投与から副作用／有害事象発現までの時間間隔 (数)	5N	Physical Quantity (PQ)	value=Real Number (REAL)	値	/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='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'] adverseEventAssessment[1] adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ']/organizer[@classCode='CATEGORY'][@moodCode='EVN'] code[@code='4'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20'] component[@typeCode='COMP'] substanceAdministration[id][k]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/outboundRelationship1[@typeCode='SAE'] actReference[@classCode='OBS'][@moodCode='EVN']/id[@root='UUID of i-th reaction']/pauseQuantity/@value
e	G.k.9.i.3.2b	医薬品の最終投与から副作用／有害事象発現までの時間間隔 (単位)	50AN	Physical Quantity (PQ)	unit=Coded Simple Value (CS)	値	/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='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'] adverseEventAssessment[1] adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ']/organizer[@classCode='CATEGORY'][@moodCode='EVN'] code[@code='4'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20'] component[@typeCode='COMP'] substanceAdministration[id][k]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/outboundRelationship1[@typeCode='SAE'] actReference[@classCode='OBS'][@moodCode='EVN']/id[@root='UUID of i-th reaction']/pauseQuantity/@unit
e	G.k.9.i.4	再投与で副作用は再発したか?	1N	Coded With Equivalents (CE)	code=Character String (ST)	値	/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='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'] adverseEventAssessment[1] adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ']/organizer[@classCode='CATEGORY'][@moodCode='EVN'] code[@code='4'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20'] component[@typeCode='COMP'] substanceAdministration[id][k]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/outboundRelationship2[@typeCode='PERT'] observation/code[@code='31'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19'] observation[@classCode='OBS'][@moodCode='EVN']/outboundRelationship1[@typeCode='REFR'] actReference[@classCode='OBS'][@moodCode='EVN']/id[@root='UUID of i-th reaction']/value[@xsi:type='CE'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.16'] [1]/@code

		再投与で副作用は再発したか？に関する ICH コードリストのバージョン					<pre> /MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moo dCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCo de='EVN']/component[@typeCode='COMP'] adverseEventAssessment[1] adverseEventAssessment [@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classC ode='INVSBJ']/subjectOf2[@typeCode='SBJ']/organizer[@classCode='CATEGORY'][@moodCode=' EVN'] [code=@code='4'] [codeSystem='2.16.840.1.113883.3.989.2.1.1.20'] [1] component[@typeCo de='COMP'] [substanceAdministration/d][k]/substanceAdministration[@classCode='SBADM'] [moo dCode='EVN']/outboundRelationship2[@typeCode='PERT'] [observation/code[@code='31']] [codeSy stem='2.16.840.1.113883.3.989.2.1.1.19'] [r]/observation[@classCode='OBS'] [moodCode='EVN'] [ou tboundRelationship1[@typeCode='REFR'] actReference[@classCode='OBS'] [moodCode='EVN'] [i- d[@root='UUID of reaction']/value[@xsi:type='CE']] [codeSystem='2.16.840.1.113883.3.989.2.1.1.16'] [1] [1] @codeSyste mVerison </pre>
e	G.k.10.r	医薬品に関するその他の情報 (コード化) (必要に応じ繰り返す)	2N	Coded With Equivalents (CE)	code=Character String (ST)	値	<pre> /MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moo dCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCo de='EVN']/component[@typeCode='COMP'] adverseEventAssessment[1] adverseEventAssessment [@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classC ode='INVSBJ']/subjectOf2[@typeCode='SBJ']/organizer/code[@code='4'] [codeSystem='2.16.840.1 .113883.3.989.2.1.1.20'] [1] organizer[@classCode='CATEGORY'] [moodCode='EVN']/component[@typeCode='COMP'] [substanceAdministration/d][k]/substanceAdministration[@classCode='SBADM '] [moodCode='EVN']/outboundRelationship2[@typeCode='REFR'] [observation/code[@code='9']] [c odeSystem='2.16.840.1.113883.3.989.2.1.1.19'] [r]/observation[@classCode='OBS'] [moodCode= 'EVN']/value[@xsi:type='CE']] [codeSystem='2.16.840.1.113883.3.989.2.1.1.17'] [1] [1] @code </pre>
		医薬品に関するその他の情報 (コード化) (必要に応じ繰り返す)に関する ICH コードリストのバージョン					<pre> /MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moo dCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCo de='EVN']/component[@typeCode='COMP'] adverseEventAssessment[1] adverseEventAssessment [@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classC ode='INVSBJ']/subjectOf2[@typeCode='SBJ']/organizer/code[@code='4'] [codeSystem='2.16.840.1 .113883.3.989.2.1.1.20'] [1] organizer[@classCode='CATEGORY'] [moodCode='EVN']/component[@typeCode='COMP'] [substanceAdministration/d][k]/substanceAdministration[@classCode='SBADM '] [moodCode='EVN']/outboundRelationship2[@typeCode='REFR'] [observation/code[@code='9']] [c odeSystem='2.16.840.1.113883.3.989.2.1.1.19'] [r]/observation[@classCode='OBS'] [moodCode= 'EVN']/value[@xsi:type='CE']] [codeSystem='2.16.840.1.113883.3.989.2.1.1.17'] [1] [1] @codeSystemV ersion </pre>
e						繰り返しノード	<pre> /MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moo dCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCo de='EVN']/component[@typeCode='COMP'] adverseEventAssessment[1] adverseEventAssessment [@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classC ode='INVSBJ']/subjectOf2[@typeCode='SBJ']/organizer/code[@code='4'] [codeSystem='2.16.840.1 .113883.3.989.2.1.1.20'] [1] organizer[@classCode='CATEGORY'] [moodCode='EVN']/component[@typeCode='COMP'] [substanceAdministration/d][k]/substanceAdministration[@classCode='SBADM '] [moodCode='EVN']/outboundRelationship2[@typeCode='REFR'] [observation/code[@code='9']] [c odeSystem='2.16.840.1.113883.3.989.2.1.1.19'] </pre>

(別添3)

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	/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='INVSTG']{1}[@moodCode='EVN']/component[@typeCode='COMP']{1}/adverseEventAssessment[@classCode='INVSTG']{1}[@moodCode='EVN']/subject1[@typeCode='SBJ']{1}/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ']{1}/organizer/code[@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']/outboundRelationship2[@typeCode='REFR']{1}/observation/code[@code='2']{1}[@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']{1}/observation[@classCode='OBS']{1}[@moodCode='EVN']/value[@xsi:type='ST']{1}/text()
h	H	症例概要及びその他の情報の記述					
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	10000AN	Encapsulated Data (ED)		値	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT']{1}[@moodCode='EVN']/subject[@typeCode='SUBJ']{1}/investigationEvent[@classCode='INVSTG']{1}[@moodCode='EVN']/text/text()
e	H.2	報告者の意見	2000AN	Encapsulated Data (ED)		値	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT']{1}[@moodCode='EVN']/subject[@typeCode='SUBJ']{1}/investigationEvent[@classCode='INVSTG']{1}[@moodCode='EVN']/component[@typeCode='COMP']{1}/adverseEventAssessment{1}[@classCode='INVSTG']{1}[@moodCode='EVN']/component1[@typeCode='COMP']{1}/observationEvent[code[@code='10']]{1}[@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']{1}[author[@typeCode='AUT']/assignedEntity[@classCode='ASSIGNED']/code[@code='3']]{1}[@codeSystem='2.16.840.1.113883.3.989.2.1.1.21']{1}/observationEvent[@classCode='OBS']{1}[@moodCode='EVN']/value[@xsi:type='ED']/text()
h	H.3.r	送信者による診断名 (必要に応じて繰り返す)				繰り返しノード	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT']{1}[@moodCode='EVN']/subject[@typeCode='SUBJ']{1}/investigationEvent[@classCode='INVSTG']{1}[@moodCode='EVN']/component[@typeCode='COMP']{1}/adverseEventAssessment{1}[@classCode='INVSTG']{1}[@moodCode='EVN']/component1[@typeCode='COMP']{1}/observationEvent[code[@code='15']]{1}[@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']{1}[author[@typeCode='AUT']/assignedEntity[@classCode='ASSIGNED']/code[@code='1']]{1}[@codeSystem='2.16.840.1.113883.3.989.2.1.1.21']{1}]
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 バージョン	4AN	Coded With Equivalents (CE)	codeSystemVersion= Character String (ST)	値	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT']{1}[@moodCode='EVN']/subject[@typeCode='SUBJ']{1}/investigationEvent[@classCode='INVSTG']{1}[@moodCode='EVN']/component[@typeCode='COMP']{1}/adverseEventAssessment{1}[@classCode='INVSTG']{1}[@moodCode='EVN']/component1[@typeCode='COMP']{1}/observationEvent[code[@code='15']]{1}[@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']{1}[author[@typeCode='AUT']/assignedEntity[@classCode='ASSIGNED']/code[@code='1']]{1}[@codeSystem='2.16.840.1.113883.3.989.2.1.1.21']{1}]/observationEvent[@classCode='OBS']{1}[@moodCode='EVN']/value[@xsi:type='CE']{1}[@codeSystem='2.16.840.1.113883.6.163']{1}/codeSystemVersion

(別添3)

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)	code=Character String (ST)	値	/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='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP']{1}/adverseEventAssessment{1}/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/component1[@typeCode='COMP']{1}/observationEvent[code[@code='15']][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']{1}[author[@typeCode='AUT']/assignedEntity[@classCode='ASSIGNED']/code[@code='1']][@codeSystem='2.16.840.1.113883.3.989.2.1.1.21']}{1}/observationEvent[@classCode='OBS']{1}/value[@xsi:type='CE']{1}/@code
e	H.4	送信者の意見	20000AN	Encapsulated Data (ED)		値	/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='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP']{1}/adverseEventAssessment{1}/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/component1[@typeCode='COMP']{1}/observationEvent[code[@code='10']][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']{1}[author[@typeCode='AUT']/assignedEntity[@classCode='ASSIGNED']/code[@code='1']][@codeSystem='2.16.840.1.113883.3.989.2.1.1.21']}{1}/observationEvent[@classCode='OBS']{1}/value[@xsi:type='ED']{1}/text()
h	H.5.r	母国語で記載された症例概要及び報告者の意見(必要に応じて繰り返す)				繰り返しノード	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ']{1}/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP']{1}/observationEvent[code[@code='36']][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']{1}[author[@typeCode='AUT']/assignedEntity[@classCode='ASSIGNED']/code[@code='2']][@codeSystem='2.16.840.1.113883.3.989.2.1.1.21']}{1}
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	/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='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP']{1}/observationEvent[code[@code='36']][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']{1}[author[@typeCode='AUT']/assignedEntity[@classCode='ASSIGNED']/code[@code='2']][@codeSystem='2.16.840.1.113883.3.989.2.1.1.21']}{1}/observationEvent[@classCode='OBS']{1}/value[@xsi:type='ED']{1}/text()
e	H.5.r.1b	症例概要及び報告者の意見の記載言語	3A	Encapsulated Data (ED)	language=Coded Simple Value (CS)	値	/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='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP']{1}/observationEvent[code[@code='36']][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']{1}[author[@typeCode='AUT']/assignedEntity[@classCode='ASSIGNED']/code[@code='2']][@codeSystem='2.16.840.1.113883.3.989.2.1.1.21']}{1}/observationEvent[@classCode='OBS']{1}/value[@xsi:type='ED']{1}/@language

h: ヘッダ e: エン ティティ	フィールド 番号	フィールド名	ICSR メッ セージにおけ るフィールド 番号	ICH デー タ型	HL7 データ型	HL7 データ型 (下位構成要素)	分類	Xpath
h	ACK.M/A	ICH ICSR バッチ確認 応答						
e	ACK.M.1	確認応答バッチ番号		100AN	Instance Identifier (II)	extension=Character String (ST)	値	/MCCI_IN200101UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200101UV01.xsd']/id[@root='2.16.840.1.113883.3.989.2.1.3.20']/@extension
e	ACK.M.2	確認応答バッチ送信 者識別子	N.1.4	60AN	Instance Identifier (II)	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='2.16.840.1.113883.3.989.2.1.3.17'][1]/@extension
e	ACK.M.3	確認応答バッチ受信 者識別子	N.1.3	60AN	Instance Identifier (II)	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='2.16.840.1.113883.3.989.2.1.3.18'][1]/@extension
e	ACK.M.4	バッチ伝送の確認応 答日		日付/時 間	Point in Time (TS)		値	/MCCI_IN200101UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200101UV01.xsd']/creationTime/@value
e	ACK.A.1	ICSR バッチ番号	N.1.2	100AN	Instance Identifier (II)	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='2.16.840.1.113 883.3.989.2.1.3.22']/@extension
e	ACK.A.2	確認応答地域メッ セージ番号		100AN	Instance Identifier (II)	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 3883.3.989.2.1.1.24']][1]/value[@xsi:type='II'][@root='2.16.840.1.113883.3.989.2.1.3.21']/@extens ion
e	ACK.A.3	ICSR バッチ伝送日	N.1.5	日付/時 間	Point in Time (TS)		値	/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 3883.3.989.2.1.1.24']][1]/value[@xsi:type='TS']/@value

(別添3)

e	ACK.A.4	伝送確認応答コード		2A	Coded Simple Value (CS)		値	/MCCI_IN200101UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='um:hl7-org:v3 MCCI_IN200101UV01.xsd']/acknowledgement/@typeCode
e	ACK.A.5	バッチバリデーションエラー		250AN	Encapsulated Data (ED)		値	/MCCI_IN200101UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='um:hl7-org:v3 MCCI_IN200101UV01.xsd']/acknowledgement/@typeCode/acknowledgementDetail[1]/text/text()
h	ACK.B.r	ICH ICSR メッセージ確認応答					繰り返しノード	/MCCI_IN200101UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='um:hl7-org:v3 MCCI_IN200101UV01.xsd']/MCCI_IN000002UV01
e	ACK.B.r.1	ICSR メッセージ番号	N.2.r.1 C.1.1	100AN	Instance Identifier (II)	extension=Character String (ST)	値	/MCCI_IN200101UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='um:hl7-org:v3 MCCI_IN200101UV01.xsd']/MCCI_IN000002UV01[r]/acknowledgement[@typeCode][1]/targetMessage/id[@root='2.16.840.1.113883.3.989.2.1.3.1']/@extension
e	ACK.B.r.2	地域報告番号		100AN	Instance Identifier (II)	extension=Character String (ST)	値	/MCCI_IN200101UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='um:hl7-org:v3 MCCI_IN200101UV01.xsd']/MCCI_IN000002UV01[r]/id[@root='2.16.840.1.113883.3.989.2.1.3.19']/@extension
e	ACK.B.r.3	ICSR メッセージ確認応答受信者	N.2.r.2	60AN	Instance Identifier (II)	extension=Character String (ST)	値	/MCCI_IN200101UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='um:hl7-org:v3 MCCI_IN200101UV01.xsd']/MCCI_IN000002UV01[r]/receiver[@typeCode='RCV']/device[@classCode='DEV'][@determinerCode='INSTANCE']/id[@root='2.16.840.1.113883.3.989.2.1.3.16']/@extension
e	ACK.B.r.4	ICSR メッセージ確認応答送信者	N.2.r.3	60AN	Instance Identifier (II)	extension=Character String (ST)	値	/MCCI_IN200101UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='um:hl7-org:v3 MCCI_IN200101UV01.xsd']/MCCI_IN000002UV01[r]/sender[@typeCode='SND']/device[@classCode='DEV'][@determinerCode='INSTANCE']/id[@root='2.16.840.1.113883.3.989.2.1.3.15']/@extension
e	ACK.B.r.5	ICSR メッセージ作成日	N.2.r.4 C.1.2	日付 / 時間	Point in Time (TS)		値	/MCCI_IN200101UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='um:hl7-org:v3 MCCI_IN200101UV01.xsd']/MCCI_IN000002UV01[r]/attentionLine[keyWordText[@code='1']]@codeSystem='2.16.840.1.113883.3.989.2.1.1.24'[1]/value[@xsi:type='TS']/@value
e	ACK.B.r.6	ICSR メッセージの確認応答コード		2A	Coded Simple Value (CS)		値	/MCCI_IN200101UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='um:hl7-org:v3 MCCI_IN200101UV01.xsd']/MCCI_IN000002UV01[r]/acknowledgement[1]/@typeCode

(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[r]/acknowledgement[@typeCode][1]/acknowledgementDetail[1]/text/text()
---	-----------	-----------------	-------	------------------------	---	---

2. 複数の XML 表現に関する XML 断片

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。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 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 (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に対する XML 断片を示す。

2.1 開始日、終了日及び持続期間

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 つに入力する方がよい。

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

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

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

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

```

displayName="reaction"/>
  <effectiveTime xsi:type="IVL_TS">
    <low value="20090101"/>
    <!-- E.i.4 Date of Start of Reaction / Event -->
    <width value="24" unit="E.i.6b"/>
    <!-- E.i.6a: Duration of Reaction / Event -->
    <!-- E.i.6b: Duration of Reaction / Event (Duration Unit) -->
  </effectiveTime>
  <value xsi:type="CE" code="E.i.2.1b" codeSystem="2.16.840.1.113883.6.163"
codeSystemVersion="E.i.2.1a">
    <!-- E.i.2.1a: MedDRA Version for Reaction / Event -->
    <!-- E.i.2.1b: Reaction / Event in MedDRA Terminology-->
    <originalText>E.i.0.a</originalText>
    <originalText language="E.i.1.1b">E.i.1.1a</originalText>
    <!-- E.i.1a: Reaction / Event as Reported by the Primary Source in Native Language
-->

  </value>

```

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

```

<observation classCode="OBS" moodCode="EVN">
  <id root="154eb889-958b-45f2-a02f-42d4d6f4657f"/>
  <code code="29" codeSystem="2.16.840.1.113883.3.989.2.1.1.19"
displayName="reaction"/>
  <effectiveTime xsi:type="SXPR_TS">
    <comp xsi:type="IVL_TS">
      <low value="20090101"/>
      <!-- E.i.4 Date of Start of Reaction / Event -->
      <high value="20090102"/>
      <!-- E.i.5: Date of End of Reaction / Event -->
    </comp>
    <comp xsi:type="IVL_TS" operator="A">
      <width value="24" unit="h"/>
      <!-- E.i.6a: Duration of Reaction / Event -->
      <!-- E.i.6b: Duration of Reaction / Event (Duration Unit) -->
    </comp>
  </effectiveTime>
  <value xsi:type="CE" code="E.i.2.1b" codeSystem="2.16.840.1.113883.6.163"
codeSystemVersion="E.i.2.1a">
    <!-- E.i.2.1a: MedDRA Version for Reaction / Event -->

```



```

      <!-- E.i.2.1b: Reaction / Event in MedDRA Terminology-->
      <originalText language="E.i.1.1b">E.i.1.1a</originalText>
      <!-- E.i.1.1a: Reaction / Event as Reported by the Primary Source in Native
Language -->
      <!-- E.i.1.1b: Reaction / Event as Reported by the Primary Source Language
-->
      </value>

```

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

```

<substanceAdministration classCode="SBADM" moodCode="EVN">
  <text>G.k.4.r.8</text>
  <!-- G.k.4.r.8: Dosage Text -->
  <effectiveTime xsi:type="SXPR_TS">
    <comp xsi:type="PIVL_TS">
      <period value="10" unit="G.k.4.r.3"/>
      <!-- G.k.4.r.2: Number of Units in the Interval -->
      <!-- G.k.4.r.3: Definition of the Time Interval Unit -->
    </comp>
    <comp xsi:type="IVL_TS" operator="A">
      <low value="20090101"/>
      <!-- G.k.4.r.4: Date and Time of Start of Drug-->
      <high value="20090101"/>
      <!-- G.k.4.r.5: Date and Time of Last Administration-->
    </comp>
  </effectiveTime>

```

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

```

<substanceAdministration classCode="SBADM" moodCode="EVN">
  <text>G.k.4.r.8</text>
  <!-- G.k.4.r.8: Dosage Text -->
  <effectiveTime xsi:type="SXPR_TS">
    <comp xsi:type="PIVL_TS">
      <period value="10" unit="G.k.4.r.3"/>
      <!-- G.k.4.r.2: Number of Units in the Interval -->
      <!-- G.k.4.r.3: Definition of the Time Interval Unit -->
    </comp>
    <comp xsi:type="IVL_TS" operator="A">

```

```

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

```

- 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 のいずれかに入力する

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。SXPR_TSは許可されない。

IVL_TSの例：

```

<substanceAdministration classCode="SBADM" moodCode="EVN">
  <text>G.k.4.r.8</text>
  <!-- G.k.4.r.8: Dosage Text -->
  <effectiveTime xsi:type="IVL_TS">
    <low value="20090101"/>
    <!-- G.k.4.r.4: Date and Time of Start of Drug -->
    <width value="4" unit="G.k.4.6b"/>
    <!-- G.k.4.r.6a: Duration of Drug Administration (number) -->
    <!-- G.k.4.r.6b: Duration of Drug Administration (unit) -->
  </effectiveTime>

```

PIVL_TSのもう1つの例：

```

<substanceAdministration classCode="SBADM" moodCode="EVN">
  <text>G.k.4.r.9</text>
  <!-- G.k.4.r.9: Dosage Text -->
  <effectiveTime xsi:type="PIVL_TS">
    <period value="10" unit="G.k.4.r.4"/>
    <!-- G.k.4.r.3: Number of Units in the Interval -->
    <!-- G.k.4.r.4: Definition of the Time Interval Unit -->
  </effectiveTime>

```

- 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

```

<substanceAdministration classCode="SBADM" moodCode="EVN">
  <text>G.k.4.r.8</text>
  <!-- G.k.4.r.8: Dosage Text -->

```

```

<effectiveTime xsi:type="SXPRTS">
  <comp xsi:type="PIVLTST">
    <period value="10" unit="G.k.4.r.3"/>
    <!-- G.k.4.r.2: Number of Units in the Interval -->
    <!-- G.k.4.r.3: Definition of the Time Interval Unit -->
  </comp>
  <comp xsi:type="IVLTST" operator="A">
    <low value="20090101"/>
    <!-- G.k.4.r.4: Date and Time of Start of Drug-->
    <high value="20090101"/>
    <!-- G.k.4.r.5: Date and Time of Last Administration -->
  </comp>
  <comp xsi:type="IVLTST" operator="A">
    <width value="24" unit="h"/>
    <!-- G.k.4.r.6a: Duration of Drug Administration (number) -->
    <!-- G.k.4.r.6b: Duration of Drug Administration (unit) -->
  </comp>
</effectiveTime>

```

2.2. F 検査結果

2.2.1. F.r.3.2 値及び限定子

2.2.1.1. 値 (例 : "10 mg/dL")

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

```

<value xsi:type="IVLPQ" >
  <center value="10" unit="mg/dl" />
</value>

```

2.2.1.2. 値より大きい (例 : "> 10 mg/dL")

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)。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"に設定される。

```

<value xsi:type="IVLPQ" >
  <low value="10" unit="mg/dl" inclusive="false"/>
  <high nullFlavor="PINF"/>
</value>

```

2.2.1.3. 値より小さい (例: "< 10 mg/dL")

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)。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"に設定される。

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

2.2.1.4. 値以上 (例: ">= 10 mg/dL")

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」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)。属性"inclusive"は、同等であることを示すため"true"に設定される。

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

2.2.1.5. 値以下 (例: "<= 10 mg/dL")

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)。属性"inclusive"は、同等であることを示すため"true"に設定される。

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

2.2.2 F.r.3.2 及び F.r.3.3

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

```

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

```

2.2.3. F.r.3.1

```

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

```

2.2.4. F.r.3.4

```

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

```

2.3. G.k.4 投与量の例

2.3.1. 1日当たり 1/回

```

<outboundRelationship2 typeCode="COMP">
<substanceAdministration classCode="SBADM" moodCode="EVN">
<text>1 per day</text>
<effectiveTime xsi:type="SXPR_TS">
<comp xsi:type="PIVL_TS">
<period value="1" unit="d"/>
</comp>
</effectiveTime>
</substanceAdministration>

```

```
</outboundRelationship2>
```

2.3.2. 1日当たり1錠/回

```
<outboundRelationship2 typeCode="COMP">
  <substanceAdministration classCode="SBADM" moodCode="EVN">
    <text>1 tablet per day </text>
    <effectiveTime xsi:type="SXPR_TS">
      <comp xsi:type="PIVL_TS">
        <period value="1" unit="d"/>
      </comp>
    </effectiveTime>
    <doseQuantity value="1" unit="{DF}"/>
    <consumable typeCode="CSM">
      <instanceOfKind classCode="INST">
        <kindOfProduct classCode="MMAT" determinerCode="KIND">
          <formCode>
            <originalText>Tablet</originalText>
          </formCode>
        </kindOfProduct>
      </instanceOfKind>
    </consumable>
  </substanceAdministration>
</outboundRelationship2>
```

2.3.3. 1日1回、1/4錠/回

```
<outboundRelationship2 typeCode="COMP">
  <substanceAdministration classCode="SBADM" moodCode="EVN">
    <effectiveTime xsi:type="SXPR_TS">
      <comp xsi:type="PIVL_TS">
        <period value="1" unit="d"/>
      </comp>
    </effectiveTime>
    <doseQuantity value="0.25" unit="{DF}"/>
    <consumable typeCode="CSM">
      <instanceOfKind classCode="INST">
        <kindOfProduct classCode="MMAT" determinerCode="KIND">
          <formCode>
            <originalText>Tablet</originalText>
          </formCode>
        </kindOfProduct>
      </instanceOfKind>
    </consumable>
  </substanceAdministration>
</outboundRelationship2>
```

```

        </formCode>
      </kindOfProduct>
    </instanceOfKind>
  </consumable>
</substanceAdministration>
</outboundRelationship2>

```

2.3.4. 週 1 回、6 錠／回

```

<outboundRelationship2 typeCode="COMP">
  <substanceAdministration classCode="SBADM" moodCode="EVN">
    <effectiveTime xsi:type="SXPRTS">
      <comp xsi:type="PIVLTST">
        <period value="1" unit="w"/>
      </comp>
    </effectiveTime>
    <doseQuantity value="6" unit="{DF}"/>
    <consumable typeCode="CSM">
      <instanceOfKind classCode="INST">
        <kindOfProduct classCode="MMAT" determinerCode="KIND">
          <formCode>
            <originalText>Tablet</originalText>
          </formCode>
        </kindOfProduct>
      </instanceOfKind>
    </consumable>
  </substanceAdministration>
</outboundRelationship2>

```

2.3.5. 1 日 2 回、1 錠／回

例 1

```

<outboundRelationship2 typeCode="COMP">
  <substanceAdministration classCode="SBADM" moodCode="EVN">
    <effectiveTime xsi:type="SXPRTS">
      <comp xsi:type="PIVLTST">
        <period value="12" unit="h"/>
      </comp>
    </effectiveTime>

```

```

<doseQuantity value="1" unit="{DF}"/>
<consumable typeCode="CSM">
  <instanceOfKind classCode="INST">
    <kindOfProduct classCode="MMAT" determinerCode="KIND">
      <formCode>
        <originalText>Tablet</originalText>
      </formCode>
    </kindOfProduct>
  </instanceOfKind>
</consumable>
</substanceAdministration>
</outboundRelationship2>

```

例2

```

<outboundRelationship2 typeCode="COMP">
  <substanceAdministration classCode="SBADM" moodCode="EVN">
    <effectiveTime xsi:type="SXPR_TS">
      <comp xsi:type="PIVL_TS">
        <period value="1" unit="d"/>
      </comp>
    </effectiveTime>
    <doseQuantity value="2" unit="{DF}"/>
    <consumable typeCode="CSM">
      <instanceOfKind classCode="INST">
        <kindOfProduct classCode="MMAT" determinerCode="KIND">
          <formCode>
            <originalText>Tablet</originalText>
          </formCode>
        </kindOfProduct>
      </instanceOfKind>
    </consumable>
  </substanceAdministration>
</outboundRelationship2>

```

2.3.6. 1日4回、7.5 mg/回

例1

```

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

```



```

    <effectiveTime xsi:type="SXPR_TS">
      <comp xsi:type="PIVL_TS">
        <period value="6" unit="h"/>
      </comp>
    </effectiveTime>
    <doseQuantity value="7.5" unit="mg"/>
  </substanceAdministration>
</outboundRelationship2>

```

例2

```

<outboundRelationship2 typeCode="COMP">
  <substanceAdministration classCode="SBADM" moodCode="EVN">
    <effectiveTime xsi:type="SXPR_TS">
      <comp xsi:type="PIVL_TS">
        <period value="1" unit="d"/>
      </comp>
    </effectiveTime>
    <doseQuantity value="30" unit="mg"/>
  </substanceAdministration>
</outboundRelationship2>

```

2.3.7. 1日1回、15 mL/回

```

<outboundRelationship2 typeCode="COMP">
  <substanceAdministration classCode="SBADM" moodCode="EVN">
    <effectiveTime xsi:type="SXPR_TS">
      <comp xsi:type="PIVL_TS">
        <period value="1" unit="d"/>
      </comp>
    </effectiveTime>
    <doseQuantity value="15" unit="mL"/>
  </substanceAdministration>
</outboundRelationship2>

```

2.3.8. 2日に1回、1錠/回

```

<outboundRelationship2 typeCode="COMP">
  <substanceAdministration classCode="SBADM" moodCode="EVN">
    <effectiveTime xsi:type="SXPR_TS">
      <comp xsi:type="PIVL_TS">
        <period value="2" unit="d"/>
      </comp>
    </effectiveTime>

```

```

<doseQuantity value="1" unit="{DF}"/>
<consumable typeCode="CSM">
  <instanceOfKind classCode="INST">
    <kindOfProduct classCode="MMAT" determinerCode="KIND">
      <formCode>
        <originalText>Tablet</originalText>
      </formCode>
    </kindOfProduct>
  </instanceOfKind>
</consumable>
</substanceAdministration>
</outboundRelationship2>

```

2.3.9. 頓用、1錠/回、開始日、終了日

```

<outboundRelationship2 typeCode="COMP">
<substanceAdministration classCode="SBADM" moodCode="EVN">
  <effectiveTime xsi:type="SXPR_TS">
    <comp xsi:type="PIVL_TS">
      <periodunit="{as necessary}"/>
    </comp>
    <comp xsi:type="IVL_TS" operator="A">
      <low value="200906"/>
      <high value="200908"/>
    </comp>
  </effectiveTime>
  <doseQuantity value="1" unit="{DF}"/>

```

2.3.10. 頓用、20 mg/回

```

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

```

2.3.11. 周期的、500 mg/回、開始日、終了日

```

<outboundRelationship2 typeCode="COMP">
  <substanceAdministration classCode="SBADM" moodCode="EVN">
    <effectiveTime xsi:type="SXPR_TS">
      <comp xsi:type="PIVL_TS">
        <periodunit="{cyclical}"/>
      </comp>
      <comp xsi:type="IVL_TS" operator="A">
        <low value="200906"/>
        <high value="200908"/>
      </comp>
    </effectiveTime>
    <doseQuantity value="500" unit="mg"/>
  </substanceAdministration>
</outboundRelationship2>

```

2.3.12. 周期的、500 mg/回

```

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

```

2.3.13. 総投与量 20,000 mg、開始日、終了日

```

<substanceAdministration classCode="SBADM" moodCode="EVN">
  <effectiveTime xsi:type="SXPR_TS">
    <comp xsi:type="PIVL_TS">
      <periodunit="{total}"/>
    </comp>
    <comp xsi:type="IVL_TS" operator="A">
      <low value="200906"/>
      <high value="201005"/>
    </comp>
  </effectiveTime>
  <doseCheckQuantity>
    <numerator xsi:type="PQ" value="20000" unit="mg"/>
    <denominator xsi:type="PQ" nullFlavor="UNK"/>
  </doseCheckQuantity>
</substanceAdministration>

```

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

HL7 telecom データ型の構文 -

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

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

"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 flavor=MSK の使用を推奨している。

例 -

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

これは標準のHL7のnull flavorではないことに留意する。

2.6. トライメスターを使用した妊娠期間 (D.2.2.1b)

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

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 (G.k.2.3.r.1)

```
<ingredient classCode="ACTI">
  <quantity>
    <numerator value="10" unit="mg"/>
    <denominator value="1"/>
  </quantity>
  <ingredientSubstance classCode="MMA1" determinerCode="KIND">
    <name nullFlavor="UNK"/>
  </ingredientSubstance>
```

```
</ingredient>
```

2.8. 各副作用に関する因果関係情報の例

```
<component typeCode="COMP">
  <causalityAssessment classCode="OBS" moodCode="EVN">
    <code code="39" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" displayName="causality"/>
    <value xsi:type="ST">G.k.9.i.2.r.3</value>
    <methodCode>
      <originalText>G.k.9.i.2.r.2</originalText>
    </methodCode>
    <author typeCode="AUT">
      <assignedEntity classCode="ASSIGNED">
        <code>
          <originalText>G.k.9.i.2.r.1</originalText>
        </code>
      </assignedEntity>
    </author>
    <subject1 typeCode="SUBJ">
      <adverseEffectReference classCode="OBS" moodCode="EVN">
        <id root="154eb889-958b-45f2-a02f-42d4d6f4657f"/>
      </adverseEffectReference>
    </subject1>
    <subject2 typeCode="SUBJ">
      <productUseReference classCode="SBADM" moodCode="EVN">
        <id root="3c91b4d5-e039-4a7a-9c30-67671b0ef9e4"/>
      </productUseReference>
    </subject2>
  </causalityAssessment>
</component>
```

III. 参照インスタンスについての注意事項

- 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はXML中にコメントとして示されている。
- 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 *display name* に示す。
- 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。
- 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25及び26を参照のこと。
- 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ゼクション内の繰り返しの子構造 (インバウンド及びアウトバウンドの関係) を用いて入力する。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ド化された情報と自由記述の両方をサポートするオブザーベーションコードと値の組合せを用いて表す。

例:

```
<outboundRelationship2typeCode="COMP">
  <substanceAdministrationclassCode="SBADM"moodCode="EVN">
    <inboundRelationshiptypeCode="REFR">
      <observationclassCode="OBS"moodCode="EVN">
        <code code="parentRouteOfAdministration"
          codeSystem="2.16.840.1.113883.3.989.2.1.1.19"/>
        <valuexsi:type="CE" code="G.k.4.r.11.2b"
          codeSystem="2.16.840.1.113883.3.989.2.1.1.14"
          codeSystemVersion="G.k.4.r.11.2a">
          <!-- G.k.4.r.11.2a: Parent Route of Administration TermID Version Date / Number
            #1-1 -->
          <!-- G.k.4.r.11.2b: Parent Route of Administration TermID #1-1 -->
          <originalText>G.k.4.r.11.1</originalText>
          <!-- G.k.4.r.11.1: Parent Route of Administration (free text) #1-1 -->
        </value>
      </observation>
    </inboundRelationship>
  </substanceAdministration>
</outboundRelationship2>
```

IV. 参考

ICSR メッセージにおける E2B (R3) データ項目構造

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は更新されない可能性があることに留意する。