

(別添3)



日米 EU 医薬品規制調和国際会議

ICH E2B 専門家作業部会

個別症例安全性報告 (ICSR) の電子的伝送に
係る実装ガイド

付録 I (G)

技術的情報

バージョン 1.01 2014 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 専 門家作 業部会
2014年 11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 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 実装作 業部会

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.4.7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

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 <i>null flavor</i> 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、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']/@codeSystemVersion
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'][@determinerCode='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'][@determinerCode='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='2.16.840.1.113883.3.989.2.1.3.11'][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]/@extension
e	N.2.r.4	メッセージ作成の日付	日付/時間	Point in Time (TS)		値	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[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 (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='2.16.840.1.113883.3.989.2.1.3.1'][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']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/subjectOf2[@typeCode='SUBJ'][@investigationCharacteristic/@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']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/subjectOf2[@typeCode='SUBJ'][@investigationCharacteristic/@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 (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']/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']/subject[@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']/subject[@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']/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']
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']/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'][@document/@classCode='DOC'][@moodCode='EVN']/title/text()

e	C.1.6.1.2	N/A	Encapsulated Data (ED)	値	MCCI_IN200100UV01@TSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01xsd/PORR_IN049016UVI/controlActProcess[classCode=CACT][@moode=EVN/subject][@typeCode=SUBJ][1/investigationEvent][@classCode=INVTG][@moode=EVN/reference][@typeCode=REFR][documentCode=DOC][@moode=EVN/text] 3883.3.989.2.1.1.27][1/document][@classCode=DOC][@moode=EVN/text]	含まれる資料	C.1.6.1.2	e
e	C.1.7	Boolean (BL)	7-1型	値	MCCI_IN200100UV01@TSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01xsd/PORR_IN049016UVI/classCode=CACT][@moode=EVN/subject][@typeCode=SUBJ][1/investigationEvent][@classCode=INVTG][@moode=EVN/component][@typeCode=COMP][1/observationEvent][@code=23][@codeSystem=2.16.840.1.113883.3.989.2.1.1.19][1/observationEvent][@classCode=OBS][@moode=EVN/value][@xsi:type=BL][@value	本症例は当該国の緊急報告の基準を満たすか?	C.1.7	e
e	C.1.8	NullFlavor	NullFlavor	値	MCCI_IN200100UV01@TSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01xsd/PORR_IN049016UVI/controlActProcess[classCode=CACT][@moode=EVN/subject][@typeCode=SUBJ][1/investigationEvent][@classCode=INVTG][@moode=EVN/component][@typeCode=COMP][1/observationEvent][@code=23][@codeSystem=2.16.840.1.113883.3.989.2.1.1.19][1/observationEvent][@classCode=OBS][@moode=EVN/value][@xsi:type=BL][@value	世界的に固有の症例識別子	C.1.8	e
e	C.1.8.1	100AN (II)	Instance Identifier extension=Character String (ST)	値	MCCI_IN200100UV01@TSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01xsd/PORR_IN049016UVI/controlActProcess[classCode=CACT][@moode=EVN/subject][@typeCode=SUBJ][1/investigationEvent][@classCode=INVTG][@moode=EVN/id][@root=2.16.840.1.113883.3.989.2.1.3.2][1/extension	世界的に固有の症例識別子	C.1.8.1	e
e	C.1.8.2	Coded With Equivalents (CE)	code=Character String (ST)	値	MCCI_IN200100UV01@TSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01xsd/PORR_IN049016UVI/controlActProcess[classCode=CACT][@moode=EVN/subject][@typeCode=SUBJ][1/investigationEvent][@classCode=INVTG][@moode=EVN/outboundRelationship][@typeCode=SPRT][1/relatedInvestigation/code][@code=1][@codeSystem=2.16.840.1.113883.3.989.2.1.1.22][1/relatedInvestigation/code][@code=1][@codeSystem=2.16.840.1.113883.3.989.2.1.1.37][@code	本症例の第一送達者	C.1.8.2	e
h	C.1.9				MCCI_IN200100UV01@TSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01xsd/PORR_IN049016UVI/controlActProcess[classCode=CACT][@moode=EVN/subject][@typeCode=SUBJ][1/investigationEvent][@classCode=INVTG][@moode=EVN/outboundRelationship][@typeCode=SPRT][1/relatedInvestigation/code][@code=1][@codeSystem=2.16.840.1.113883.3.989.2.1.1.22][1/relatedInvestigation/code][@code=1][@codeSystem=2.16.840.1.113883.3.989.2.1.1.37][@code	本症例の第一送達者に関する ICH コーピングのバリエーション	C.1.9	h
e	C.1.9.1	Boolean (BL)	7-1型	値	MCCI_IN200100UV01@TSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01xsd/PORR_IN049016UVI/controlActProcess[classCode=CACT][@moode=EVN/subject][@typeCode=SUBJ][1/investigationCharacteristics][@code=2][@codeSystem=2.16.840.1.113883.3.989.2.1.1.23][1/investigationCharacteristics][@classCode=OBS][@moode=EVN/value][@xsi:type=BL][@value	過去の伝送で記載されたその他の症例識別子はあるか?	C.1.9.1	e

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']/subjectOf1[@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']/@nullFlavor
h	C.1.9.1.r	症例識別子の情報源 (必要に応じて繰り返す)				繰り返しノード	/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']controlActEvent/id
e	C.1.9.1.r.1	症例識別子の情報源	100AN	Instance Identifier (II)	assigningAuthorityName=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]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/subjectOf1[@typeCode='SUBJ']controlActEvent/id[r]/controlActEvent/id[@root='2.16.840.1.113883.3.989.2.1.3.3']][1]/@assigningAuthorityName
e	C.1.9.1.r.2	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']/subjectOf1[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/subjectOf1[@typeCode='SUBJ']controlActEvent/id[r]/controlActEvent/id[@root='2.16.840.1.113883.3.989.2.1.3.3']][1]/@extension
e	C.1.10.r	本報告と関連する報告の識別子 (必要に応じて繰り返す)	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']/subjectOf1[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/outboundRelationship[@typeCode='SPRT']relatedInvestigation/code[@nullFlavor='NA']r/relatedInvestigation[@classCode='INVSTG'][@moodCode='EVN']/subjectOf2[@typeCode='SUBJ'][1]/controlActEvent[@classCode='CACT'][@moodCode='EVN']/id[@root='2.16.840.1.113883.3.989.2.1.3.2']][1]/@extension
h	C.1.11	報告破棄/修正					
e	C.1.11.1	報告破棄/修正	1N	Coded With Equivalent (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]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/subjectOf2[@typeCode='SUBJ']investigationCharacteristic/code[@code='3'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.23']][1]/investigationCharacteristic[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='CE'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.5']]/@code
		報告破棄/修正に関する 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']/subjectOf2[@typeCode='SUBJ']investigationCharacteristic/code[@code='3'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.23']][1]/investigationCharacteristic[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='CE'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.5']]/@codeSystemVersion
e	C.1.11.2	報告破棄/修正理由	2000AN	Coded With Equivalent (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']/subjectOf1[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/subjectOf2[@typeCode='SUBJ']investigationCharacteristic/code[@code='4'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.23']][1]/investigationCharacteristic[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='CE']/originalText/text()

h	C2.1	報告者の氏名			MCCI_IN200100UV01@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd/PORR_IN049016UVI/controlAccess[@classCode=CACT][@moode=EVTN/subject[@typeCode=SUBJ][1]/investigationEvent[@classCode=INVTG][@code=2][@codeSystem=2,16,840,1,113883,3,989,2,1,1,22]] de=EVTN/outboundRelationship[@typeCode=SPRT][relatedInvestigation/code@code=2][@code
e	C2.1.1	報告者の職名	Person Name (PN)	prefix=Entry Name Part (ENXP)	MCCI_IN200100UV01@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd/PORR_IN049016UVI/controlAccess[@classCode=CACT][@moode=EVTN/subject[@typeCode=SUBJ][1]/investigationEvent[@classCode=INVTG][@code=2][@codeSystem=2,16,840,1,113883,3,989,2,1,1,22]] de=EVTN/outboundRelationship[@typeCode=SPRT][relatedInvestigation/code@code=2][@code
e				NullFlavor	MCCI_IN200100UV01@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd/PORR_IN049016UVI/controlAccess[@classCode=CACT][@moode=EVTN/subject[@typeCode=SUBJ][1]/investigationEvent[@classCode=INVTG][@code=2][@codeSystem=2,16,840,1,113883,3,989,2,1,1,22]] de=EVTN/outboundRelationship[@typeCode=SPRT][relatedInvestigation/code@code=2][@code
e	C2.1.2	報告者の名前	Person Name (PN)	given=Entry Name Part (ENXP)	MCCI_IN200100UV01@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd/PORR_IN049016UVI/controlAccess[@classCode=CACT][@moode=EVTN/subject[@typeCode=SUBJ][1]/investigationEvent[@classCode=INVTG][@code=2][@codeSystem=2,16,840,1,113883,3,989,2,1,1,22]] de=EVTN/outboundRelationship[@typeCode=SPRT][relatedInvestigation/code@code=2][@code
e				NullFlavor	MCCI_IN200100UV01@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd/PORR_IN049016UVI/controlAccess[@classCode=CACT][@moode=EVTN/subject[@typeCode=SUBJ][1]/investigationEvent[@classCode=INVTG][@code=2][@codeSystem=2,16,840,1,113883,3,989,2,1,1,22]] de=EVTN/outboundRelationship[@typeCode=SPRT][relatedInvestigation/code@code=2][@code
e	C2.1.3	報告者の中間名	Person Name (PN)	given=Entry Name Part (ENXP)	MCCI_IN200100UV01@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd/PORR_IN049016UVI/controlAccess[@classCode=CACT][@moode=EVTN/subject[@typeCode=SUBJ][1]/investigationEvent[@classCode=INVTG][@code=2][@codeSystem=2,16,840,1,113883,3,989,2,1,1,22]] de=EVTN/outboundRelationship[@typeCode=SPRT][relatedInvestigation/code@code=2][@code

(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']]/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']]/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']]/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']]/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']]/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

e	C.2.2.4	報告者の住所 (市町村等)	35AN	Postal Address (AD) city=Address Part (ADXP)	値	<p>MCCI_IN200100UV01@TSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd/PORR_IN049016UV/relatedInvestigation/code=INVESTG][@moode=EVN/subject[@typeCode=SUBJ][1/relatedInvestigation/code=INVESTG][@moode=EVN/outboundRelationship[@typeCode=SPRT][relatedInvestigation/code=2][@codeSystem=2,16,840,1,113883,3,989,2,1,1,22][/relatedInvestigation/code=INVESTG][@moode=EVN/subjectO2[@typeCode=SUBJ]/controlActEvent[@classCode=CACT][@moodeCode=EVN/author[@typeCode=AUT]/assignedEntity[@classCode=ASSIGNED]/addr1/city/addr1/text)</p>
e	C.2.2.3	報告者の住所 (番地)	100AN	Postal Address (AD) streetAddressLine=Address Part (ADXP)	値	<p>MCCI_IN200100UV01@TSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd/PORR_IN049016UV/relatedInvestigation/code=INVESTG][@moode=EVN/subject[@typeCode=SUBJ][1/relatedInvestigation/code=INVESTG][@moode=EVN/outboundRelationship[@typeCode=SPRT][relatedInvestigation/code=2][@codeSystem=2,16,840,1,113883,3,989,2,1,1,22][/relatedInvestigation/code=INVESTG][@moode=EVN/subjectO2[@typeCode=SUBJ]/controlActEvent[@classCode=CACT][@moodeCode=EVN/author[@typeCode=AUT]/assignedEntity[@classCode=ASSIGNED]/addr1/streetAddressLine1/text)</p>
e					NullFlavor	<p>MCCI_IN200100UV01@TSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd/PORR_IN049016UV/relatedInvestigation/code=INVESTG][@moode=EVN/subject[@typeCode=SUBJ][1/relatedInvestigation/code=INVESTG][@moode=EVN/outboundRelationship[@typeCode=SPRT][relatedInvestigation/code=2][@codeSystem=2,16,840,1,113883,3,989,2,1,1,22][/relatedInvestigation/code=INVESTG][@moode=EVN/subjectO2[@typeCode=SUBJ]/controlActEvent[@classCode=CACT][@moodeCode=EVN/author[@typeCode=AUT]/assignedEntity[@classCode=ASSIGNED]/addr1/streetAddressLine1/text)</p>
e					NullFlavor	<p>MCCI_IN200100UV01@TSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd/PORR_IN049016UV/relatedInvestigation/code=INVESTG][@moode=EVN/subjectO2[@typeCode=SUBJ]/controlActEvent[@classCode=CACT][@moodeCode=EVN/author[@typeCode=AUT]/assignedEntity[@classCode=ASSIGNED]/name/text)</p>
e	C.2.2.2	報告者の部署	60AN	Organization Name (ON) name=Entity Name Part (ENXP)	値	<p>MCCI_IN200100UV01@TSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd/PORR_IN049016UV/relatedInvestigation/code=INVESTG][@moode=EVN/subject[@typeCode=SUBJ][1/relatedInvestigation/code=INVESTG][@moode=EVN/outboundRelationship[@typeCode=SPRT][relatedInvestigation/code=2][@codeSystem=2,16,840,1,113883,3,989,2,1,1,22][/relatedInvestigation/code=INVESTG][@moode=EVN/subjectO2[@typeCode=SUBJ]/controlActEvent[@classCode=CACT][@moodeCode=EVN/author[@typeCode=AUT]/assignedEntity[@classCode=ASSIGNED]/representingOrganization/@determinationCode=INSTANCE][name/text)</p>

(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']][r]/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']][r]/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']][r]/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']][r]/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']][r]/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']][r]/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

e					Null Flavor	<p>deSystem=2,16,840,1,113883,3,989,2,1,1,67/@code sCode=PSN][@determineInnerCode=INSTANCE]/asLocation/@code EVN/author/@typeCode=AUT]/assignedEntity/@classCode=L0CE][1/locatIon@ Code=EVA]/subject/@typeCode=SUBJ]/controlActEvent/@classCode=CACT][@mood de=EVA]/outboundRelationship/@typeCode=SPRT][relatedInvestigation/@code=2][@code dCode=EVA]/subject/@typeCode=SUBJ][1/investigationEvent/@classCode=INVESTG][@mood MCCL_IN200100UV01.xsd/PORR_IN049016UV]/controlActProcess/@classCode=CACT][@mood MCCL_IN200100UV01[ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3</p>
e	C.2.r.4	資格	1N	Coded With Equivalents (CE)	code=Character String (ST)	<p>deSystem=2,16,840,1,113883,3,989,2,1,1,67/@code sCode=PSN][@determineInnerCode=INSTANCE]/asQualifier/@code EVN/author/@typeCode=AUT]/assignedEntity/@classCode=QUAL][1/code/@code Code=EVA]/subject/@typeCode=SUBJ]/controlActEvent/@classCode=CACT][@mood de=EVA]/outboundRelationship/@typeCode=SPRT][relatedInvestigation/@code=2][@code dCode=EVA]/subject/@typeCode=SUBJ][1/investigationEvent/@classCode=INVESTG][@mood MCCL_IN200100UV01.xsd/PORR_IN049016UV]/controlActProcess/@classCode=CACT][@mood MCCL_IN200100UV01[ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3</p>
e	C.2.r.4	資格	1N	Coded With Equivalents (CE)	code=Character String (ST)	<p>deSystem=2,16,840,1,113883,3,989,2,1,1,67/@code sCode=PSN][@determineInnerCode=INSTANCE]/asQualifier/@code EVN/author/@typeCode=AUT]/assignedEntity/@classCode=QUAL][1/code/@code Code=EVA]/subject/@typeCode=SUBJ]/controlActEvent/@classCode=CACT][@mood de=EVA]/outboundRelationship/@typeCode=SPRT][relatedInvestigation/@code=2][@code dCode=EVA]/subject/@typeCode=SUBJ][1/investigationEvent/@classCode=INVESTG][@mood MCCL_IN200100UV01.xsd/PORR_IN049016UV]/controlActProcess/@classCode=CACT][@mood MCCL_IN200100UV01[ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3</p>
e					Null Flavor	<p>deSystem=2,16,840,1,113883,3,989,2,1,1,67/@code sCode=PSN][@determineInnerCode=INSTANCE]/asLocation/@code EVN/author/@typeCode=AUT]/assignedEntity/@classCode=L0CE][1/locatIon@ Code=EVA]/subject/@typeCode=SUBJ]/controlActEvent/@classCode=CACT][@mood de=EVA]/outboundRelationship/@typeCode=SPRT][relatedInvestigation/@code=2][@code dCode=EVA]/subject/@typeCode=SUBJ][1/investigationEvent/@classCode=INVESTG][@mood MCCL_IN200100UV01.xsd/PORR_IN049016UV]/controlActProcess/@classCode=CACT][@mood MCCL_IN200100UV01[ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3</p>
e	C.2.r.3	報告者の国コード	2A	Concept Descriptor (CD)	code=Character String (ST)	<p>deSystem=2,16,840,1,113883,3,989,2,1,1,22][relatedInvestigation/@code=2][@code dCode=EVA]/subject/@typeCode=SUBJ][1/investigationEvent/@classCode=INVESTG][@mood MCCL_IN200100UV01.xsd/PORR_IN049016UV]/controlActProcess/@classCode=CACT][@mood MCCL_IN200100UV01[ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3</p>

(別添 3)

(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']/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']/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']/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']/code[@codeSystem='2.16.840.1.113883.3.989.2.1.1.7']]/@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']/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']/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']/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']/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']/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/prefix[1]/text()

e	C.3.3.3	送信者の名前	Person Name (PN)	60AN	送信者の住所 (郵便番号等)	40AN	Postal Address (AD)	state=Address Part (ADXP)	権	M/CCL_IN200100UV01[0]@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd/P/ORA_IN049016UV1/controlActProcess[classCode=CACT][@modeCode=EVN]/subjectOr[1]/typeCode=SUBJ][1]/investigationEvent[1]/classCode=INVESTG][@modeCode=EVN]/subjectOr[1]/typeCode=SUBJ][1]/controlActEvent[1]/classCode=CACT][@modeCode=EVN] m=2,16,840,1,113883,3,989,2,1,1,7][1]/controlActEvent[1]/classCode=CACT][@modeCode=EVN] /author[typeCode=AUT]/assignedEntity[1]/classCode=ASSIGNED/addr[1]/state[1]/text()
e	C.3.3.4	送信者の中間名	Person Name (PN)	60AN	送信者の住所 (郵便番号等)	35AN	Postal Address (AD)	city=Address Part (ADXP)	権	M/CCL_IN200100UV01[0]@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd/P/ORA_IN049016UV1/controlActProcess[classCode=CACT][@modeCode=EVN]/subjectOr[1]/typeCode=SUBJ][1]/investigationEvent[1]/classCode=INVESTG][@modeCode=EVN]/subjectOr[1]/typeCode=SUBJ][1]/controlActEvent[1]/classCode=CACT][@modeCode=EVN] m=2,16,840,1,113883,3,989,2,1,1,7][1]/controlActEvent[1]/classCode=CACT][@modeCode=EVN] /author[typeCode=AUT]/assignedEntity[1]/classCode=ASSIGNED/addr[1]/city[1]/text()
e	C.3.3.5	送信者の姓	Person Name (PN)	60AN	送信者の住所 (郵便番号等)	100AN	Postal Address (AD)	streetAddressLine=Address Part (ADXP)	権	M/CCL_IN200100UV01[0]@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd/P/ORA_IN049016UV1/controlActProcess[classCode=CACT][@modeCode=EVN]/subjectOr[1]/typeCode=SUBJ][1]/investigationEvent[1]/classCode=INVESTG][@modeCode=EVN]/subjectOr[1]/typeCode=SUBJ][1]/controlActEvent[1]/classCode=CACT][@modeCode=EVN] m=2,16,840,1,113883,3,989,2,1,1,7][1]/controlActEvent[1]/classCode=CACT][@modeCode=EVN] /author[typeCode=AUT]/assignedEntity[1]/classCode=ASSIGNED/addr[1]/streetAddressLine[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)	Person Name (PN)	60AN	送信者の住所 (郵便番号等)	100AN	Postal Address (AD)	streetAddressLine=Address Part (ADXP)	権	M/CCL_IN200100UV01[0]@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd/P/ORA_IN049016UV1/controlActProcess[classCode=CACT][@modeCode=EVN]/subjectOr[1]/typeCode=SUBJ][1]/investigationEvent[1]/classCode=INVESTG][@modeCode=EVN]/subjectOr[1]/typeCode=SUBJ][1]/controlActEvent[1]/classCode=CACT][@modeCode=EVN] m=2,16,840,1,113883,3,989,2,1,1,7][1]/controlActEvent[1]/classCode=CACT][@modeCode=EVN] /author[typeCode=AUT]/assignedEntity[1]/classCode=ASSIGNED/addr[1]/streetAddressLine[1]/text()
e	C.3.4.2	送信者の住所 (市町村等)	Person Name (PN)	60AN	送信者の住所 (郵便番号等)	35AN	Postal Address (AD)	city=Address Part (ADXP)	権	M/CCL_IN200100UV01[0]@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd/P/ORA_IN049016UV1/controlActProcess[classCode=CACT][@modeCode=EVN]/subjectOr[1]/typeCode=SUBJ][1]/investigationEvent[1]/classCode=INVESTG][@modeCode=EVN]/subjectOr[1]/typeCode=SUBJ][1]/controlActEvent[1]/classCode=CACT][@modeCode=EVN] m=2,16,840,1,113883,3,989,2,1,1,7][1]/controlActEvent[1]/classCode=CACT][@modeCode=EVN] /author[typeCode=AUT]/assignedEntity[1]/classCode=ASSIGNED/addr[1]/city[1]/text()
e	C.3.4.3	送信者の住所 (都道府県等)	Person Name (PN)	60AN	送信者の住所 (郵便番号等)	40AN	Postal Address (AD)	state=Address Part (ADXP)	権	M/CCL_IN200100UV01[0]@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd/P/ORA_IN049016UV1/controlActProcess[classCode=CACT][@modeCode=EVN]/subjectOr[1]/typeCode=SUBJ][1]/investigationEvent[1]/classCode=INVESTG][@modeCode=EVN]/subjectOr[1]/typeCode=SUBJ][1]/controlActEvent[1]/classCode=CACT][@modeCode=EVN] m=2,16,840,1,113883,3,989,2,1,1,7][1]/controlActEvent[1]/classCode=CACT][@modeCode=EVN] /author[typeCode=AUT]/assignedEntity[1]/classCode=ASSIGNED/addr[1]/state[1]/text()

(別添 3)

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']/subjectOf1[@typeCode='SUBJ']{1}/investigationEvent[@classCode='INVSTG']{1}[@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']{1}[@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']{1}[@moodCode='EVN']/subjectOf1[@typeCode='SUBJ']{1}/investigationEvent[@classCode='INVSTG']{1}[@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']{1}[@moodCode='EVN']/author[@typeCode='AUT']/assignedEntity[@classCode='ASSIGNED']/assignedPerson[@classCode='PSN']{1}[@determinerCode='INSTANCE']/asLocatedEntity[@classCode='LOCE']{1}/location[@classCode='COUNTRY']{1}[@determinerCode='INSTANCE']/code[@codeSystem='1.0.3166.1.2.2']{1}/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']{1}[@moodCode='EVN']/subjectOf1[@typeCode='SUBJ']{1}/investigationEvent[@classCode='INVSTG']{1}[@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']{1}[@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']{1}[@moodCode='EVN']/subjectOf1[@typeCode='SUBJ']{1}/investigationEvent[@classCode='INVSTG']{1}[@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']{1}[@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']{1}[@moodCode='EVN']/subjectOf1[@typeCode='SUBJ']{1}/investigationEvent[@classCode='INVSTG']{1}[@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']{1}[@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']{1}[@moodCode='EVN']/subjectOf1[@typeCode='SUBJ']{1}/investigationEvent[@classCode='INVSTG']{1}[@moodCode='EVN']/reference[@typeCode='REFR']{1}/document/code[@code='2']{1}[@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']{1}[@moodCode='EVN']/subjectOf1[@typeCode='SUBJ']{1}/investigationEvent[@classCode='INVSTG']{1}[@moodCode='EVN']/reference[@typeCode='REFR']{1}/document/code[@code='2']{1}[@codeSystem='2.16.840.1.113883.3.989.2.1.1.27']{1}/document[@classCode='DOC']{1}[@moodCode='EVN']/bibliographicDesignationText/text()

e	C.4.1.2	試験の登録番号	2A	Concept Descriptor (CD)	値	<pre> MCCI_IN200100UV01.xsd/PORR_IN049016UVI/controlActPprocess[classCode=CACTI]@moode=EVTN/subjct[@typeCode=SUBJ][1]/investigationEvent[classCode=INVESTG][@moode=EVTN/component[@typeCode=COMP][1]/adverseEventAssessment[classCode=INVESTG][@typeCode=SBJ][1]/primaryRole[classCode=INVESTG][@typeCode=SBJ][1]/researchStudy[classCode=CLNTRL][@moode=EVTN/authorization[@typeCode=AUTH][1]/studyRegistration[classCode=ACTI]@moode=EVTN/authority[@typeCode=AUT]/emotionalAuthority[classCode=TERR][governingPlace[classCode=COUNTRY][determineInerCode=INSTANACE]/code[System=1.0.3166.1.2.2]/@code </pre>
e	C.5.1.1.1	試験の登録番号	50AN	Instance Identifier (II)	値	<pre> MCCI_IN200100UV01.xsd/PORR_IN049016UVI/controlActPprocess[classCode=CACTI]@moode=EVTN/subjct[@typeCode=SUBJ][1]/investigationEvent[classCode=INVESTG][@moode=EVTN/component[@typeCode=COMP][1]/adverseEventAssessment[classCode=INVESTG][@typeCode=SBJ][1]/primaryRole[classCode=INVESTG][@typeCode=SBJ][1]/researchStudy[classCode=CLNTRL][@moode=EVTN/authorization[@typeCode=AUTH][1]/studyRegistration[classCode=ACTI]@moode=EVTN/authority[@typeCode=AUT]/emotionalAuthority[classCode=TERR][governingPlace[classCode=COUNTRY][determineInerCode=INSTANACE]/code[System=1.0.3166.1.2.2]/@code </pre>
h	C.5.1.1	試験の登録情報 (必要に応じて繰り返す)			繰り返す	<pre> MCCI_IN200100UV01.xsd/PORR_IN049016UVI/controlActPprocess[classCode=CACTI]@moode=EVTN/subjct[@typeCode=SUBJ][1]/investigationEvent[classCode=INVESTG][@moode=EVTN/component[@typeCode=COMP][1]/adverseEventAssessment[classCode=INVESTG][@typeCode=SBJ][1]/primaryRole[classCode=INVESTG][@typeCode=SBJ][1]/researchStudy[classCode=CLNTRL][@moode=EVTN/authorization[@typeCode=AUTH][1]/studyRegistration[classCode=ACTI]@moode=EVTN/authority[@typeCode=AUT]/emotionalAuthority[classCode=TERR][governingPlace[classCode=COUNTRY][determineInerCode=INSTANACE]/code[System=1.0.3166.1.2.2]/@code </pre>
h	C.5	試験の識別				
e	C.4.1.2	含まれる資料	N/A	Encapsulated Data (ED)	値	<pre> MCCI_IN200100UV01.xsd/PORR_IN049016UVI/controlActPprocess[classCode=CACTI]@moode=EVTN/reference[@typeCode=REFR][document/code=2][@codeSystem=2.16.840.1.113883.3.989.2.1.1.27][[t]/document[@classCode=DCC][@moode=EVTN/text)(</pre>
e					Null Flavor	<pre> MCCI_IN200100UV01.xsd/PORR_IN049016UVI/controlActPprocess[classCode=CACTI]@moode=EVTN/reference[@typeCode=REFR][document/code=2][@codeSystem=2.16.840.1.113883.3.989.2.1.1.27][[t]/document[@classCode=DCC][@moode=EVTN/text)(</pre>

(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']/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

h	D	患者特性				<p>M/CCL_IN200100UV01@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 M/CCL_IN200100UV01.xsd/P/ORA_IN049016UVI/controlActProcess@classCode=CACT][@moode=EVN/subject[@typeCode=SUBJ][1/investigationEvent@classCode=INVTG][@moode=EVN/component[@typeCode=COMP][1/adverseEventAssessment][1/adverseEventAssessment@classCode=INVTG][@typeCode=SBJ][1/primaryRole@classCode=INVTG][@typeCode=SBJ][1/researchStudy@classCode=CLNTR][@moode=EVN/code@codeSystem=2.16.840.1.113883.3.989.2.1.1.8]/@codeSystemVersion</p>
e	D.1	患者 (名前又はイニシャル)	60AN	Entry Name (EN)	name=Entry Name Part (ENXP)	<p>M/CCL_IN200100UV01@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 M/CCL_IN200100UV01.xsd/P/ORA_IN049016UVI/controlActProcess@classCode=CACT][@moode=EVN/subject[@typeCode=SUBJ][1/investigationEvent@classCode=INVTG][@moode=EVN/component[@typeCode=COMP][1/adverseEventAssessment][1/adverseEventAssessment@classCode=INVTG][@typeCode=SBJ][1/primaryRole@classCode=INVTG][@typeCode=SBJ][1/player1[@classCode=PSN][@determineInCode=INSTANACEY/name1]/@nullFlavor</p>
e	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)				<p>M/CCL_IN200100UV01@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 M/CCL_IN200100UV01.xsd/P/ORA_IN049016UVI/controlActProcess@classCode=CACT][@moode=EVN/subject[@typeCode=SUBJ][1/investigationEvent@classCode=INVTG][@moode=EVN/component[@typeCode=COMP][1/adverseEventAssessment][1/adverseEventAssessment@classCode=INVTG][@typeCode=SBJ][1/primaryRole@classCode=INVTG][@typeCode=SBJ][1/player1[@classCode=PSN][@determineInCode=INSTANACEY/name1]/@nullFlavor</p>
h	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	extension=Character String (ST)	<p>M/CCL_IN200100UV01@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 M/CCL_IN200100UV01.xsd/P/ORA_IN049016UVI/controlActProcess@classCode=CACT][@moode=EVN/subject[@typeCode=SUBJ][1/investigationEvent@classCode=INVTG][@moode=EVN/component[@typeCode=COMP][1/adverseEventAssessment][1/adverseEventAssessment@classCode=INVTG][@typeCode=SBJ][1/primaryRole@classCode=INVTG][@typeCode=SBJ][1/player1[@classCode=PSN][@determineInCode=INSTANACEY/aspectIdentifiedEntity@classCode=IDENT][@codeSystem=2.16.840.1.113883.3.989.2.1.3.7]/@nullFlavor</p>
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	extension=Character String (ST)	<p>M/CCL_IN200100UV01@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 M/CCL_IN200100UV01.xsd/P/ORA_IN049016UVI/controlActProcess@classCode=CACT][@moode=EVN/subject[@typeCode=SUBJ][1/investigationEvent@classCode=INVTG][@moode=EVN/component[@typeCode=COMP][1/adverseEventAssessment][1/adverseEventAssessment@classCode=INVTG][@typeCode=SBJ][1/primaryRole@classCode=INVTG][@typeCode=SBJ][1/player1[@classCode=PSN][@determineInCode=INSTANACEY/aspectIdentifiedEntity@classCode=IDENT][@codeSystem=2.16.840.1.113883.3.989.2.1.3.8]/@extension</p>

(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']/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[@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[@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[@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[@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[@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[@classCode='INVSTG']@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/player1[@classCode='PSN'][@determinerCode='INSTANCE']/birthTime/@value

(別添 3)

e	NullFlavor					<code>M/CCL_IN200100UV01@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3</code> <code>M/CCL_IN200100UV01.xsd/P/ORA_IN049016UVI/controlAct/process/@classCode=CACT][@mo</code> <code>oode=EVN/subjct[@typeCode=SUBJ][1/investigationEvent/@classCode=INVESTG][@modco</code> <code>de=EVN/component/@typeCode=COMP][adverseEventAssessment[1/adverseEventAssessm</code> <code>ent[1/primaryRole/@classCode=INVESTG][@typeCode=EVN/subjct1[@typeCode=SBJ][1/primaryRole/@class</code> <code>@classCode=INVESTG][@typeCode=EVN/subjct1[@typeCode=SBJ][1/primaryRole/@class</code>
h	副作用 / 有害事象発現時の年齢					
e	副作用 / 有害事象発現時の年齢(数)	5N	Physical Quantity (PQ)	value=Real Number (REAL)	量	<code>M/CCL_IN200100UV01@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3</code> <code>M/CCL_IN200100UV01.xsd/P/ORA_IN049016UVI/controlAct/process/@classCode=CACT][@mo</code> <code>oode=EVN/subjct[@typeCode=SUBJ][1/investigationEvent/@classCode=INVESTG][@modco</code> <code>de=EVN/component/@typeCode=COMP][adverseEventAssessment[1/adverseEventAssessm</code> <code>ent[1/primaryRole/@classCode=INVESTG][@typeCode=EVN/subjct1[@typeCode=SBJ][1/primaryRole/@class</code> <code>@classCode=INVESTG][@typeCode=EVN/subjct1[@typeCode=SBJ][1/primaryRole/@class</code>
e	副作用 / 有害事象発現時の年齢(単位)	50AN	Physical Quantity (PQ)	unit=Coded Simple Value (CS)	量	<code>M/CCL_IN200100UV01@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3</code> <code>M/CCL_IN200100UV01.xsd/P/ORA_IN049016UVI/controlAct/process/@classCode=CACT][@mo</code> <code>oode=EVN/subjct[@typeCode=SUBJ][1/investigationEvent/@classCode=INVESTG][@modco</code> <code>de=EVN/component/@typeCode=COMP][adverseEventAssessment[1/adverseEventAssessm</code> <code>ent[1/primaryRole/@classCode=INVESTG][@typeCode=EVN/subjct1[@typeCode=SBJ][1/primaryRole/@class</code> <code>@classCode=INVESTG][@typeCode=EVN/subjct1[@typeCode=SBJ][1/primaryRole/@class</code>
e	副作用 / 有害事象発現時の発現時の妊娠期間(単位)	50AN	Physical Quantity (PQ)	unit=Coded Simple Value (CS)	量	<code>M/CCL_IN200100UV01@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3</code> <code>M/CCL_IN200100UV01.xsd/P/ORA_IN049016UVI/controlAct/process/@classCode=CACT][@mo</code> <code>oode=EVN/subjct[@typeCode=SUBJ][1/investigationEvent/@classCode=INVESTG][@modco</code> <code>de=EVN/component/@typeCode=COMP][adverseEventAssessment[1/adverseEventAssessm</code> <code>ent[1/primaryRole/@classCode=INVESTG][@typeCode=EVN/subjct1[@typeCode=SBJ][1/primaryRole/@class</code> <code>@classCode=INVESTG][@typeCode=EVN/subjct1[@typeCode=SBJ][1/primaryRole/@class</code>
e	副作用 / 有害事象発現時の発現時の妊娠期間(数)	3N	Physical Quantity (PQ)	value=Real Number (REAL)	量	<code>M/CCL_IN200100UV01@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3</code> <code>M/CCL_IN200100UV01.xsd/P/ORA_IN049016UVI/controlAct/process/@classCode=CACT][@mo</code> <code>oode=EVN/subjct[@typeCode=SUBJ][1/investigationEvent/@classCode=INVESTG][@modco</code> <code>de=EVN/component/@typeCode=COMP][adverseEventAssessment[1/adverseEventAssessm</code> <code>ent[1/primaryRole/@classCode=INVESTG][@typeCode=EVN/subjct1[@typeCode=SBJ][1/primaryRole/@class</code> <code>@classCode=INVESTG][@typeCode=EVN/subjct1[@typeCode=SBJ][1/primaryRole/@class</code>
e	胎児での副作用 / 有害事象発現時の発現時の妊娠期間(単位)	50AN	Physical Quantity (PQ)	unit=Coded Simple Value (CS)	量	<code>M/CCL_IN200100UV01@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3</code> <code>M/CCL_IN200100UV01.xsd/P/ORA_IN049016UVI/controlAct/process/@classCode=CACT][@mo</code> <code>oode=EVN/subjct[@typeCode=SUBJ][1/investigationEvent/@classCode=INVESTG][@modco</code> <code>de=EVN/component/@typeCode=COMP][adverseEventAssessment[1/adverseEventAssessm</code> <code>ent[1/primaryRole/@classCode=INVESTG][@typeCode=EVN/subjct1[@typeCode=SBJ][1/primaryRole/@class</code> <code>@classCode=INVESTG][@typeCode=EVN/subjct1[@typeCode=SBJ][1/primaryRole/@class</code>
e	胎児での副作用 / 有害事象発現時の発現時の妊娠期間(数)	3N	Physical Quantity (PQ)	value=Real Number (REAL)	量	<code>M/CCL_IN200100UV01@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3</code> <code>M/CCL_IN200100UV01.xsd/P/ORA_IN049016UVI/controlAct/process/@classCode=CACT][@mo</code> <code>oode=EVN/subjct[@typeCode=SUBJ][1/investigationEvent/@classCode=INVESTG][@modco</code> <code>de=EVN/component/@typeCode=COMP][adverseEventAssessment[1/adverseEventAssessm</code> <code>ent[1/primaryRole/@classCode=INVESTG][@typeCode=EVN/subjct1[@typeCode=SBJ][1/primaryRole/@class</code> <code>@classCode=INVESTG][@typeCode=EVN/subjct1[@typeCode=SBJ][1/primaryRole/@class</code>
e	患者の年齢群 (報告者の表現による)	1N	Coded With Equivalents (CE)	code=Character String (ST)	値	<code>M/CCL_IN200100UV01@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3</code> <code>M/CCL_IN200100UV01.xsd/P/ORA_IN049016UVI/controlAct/process/@classCode=CACT][@mo</code> <code>oode=EVN/subjct[@typeCode=SUBJ][1/investigationEvent/@classCode=INVESTG][@modco</code> <code>de=EVN/component/@typeCode=COMP][adverseEventAssessment[1/adverseEventAssessm</code> <code>ent[1/primaryRole/@classCode=INVESTG][@typeCode=EVN/subjct1[@typeCode=SBJ][1/primaryRole/@class</code> <code>@classCode=INVESTG][@typeCode=EVN/subjct1[@typeCode=SBJ][1/primaryRole/@class</code>

		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

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[@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[@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[@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[@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[@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

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='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='2'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20'] organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'] substanceAdministration
e	D.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='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='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'] instanceOfKind[@classCode='INST']/kindOfProduct[@classCode='MMAT'][@determinerCode='KIND']/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='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='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'] instanceOfKind[@classCode='INST']/kindOfProduct[@classCode='MMAT'][@determinerCode='KIND']/name[1]/nullFlavor
e	D.8.r.2a	MPID バージョン日付/番号	M5 ガイドを参照	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='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'] instanceOfKind[@classCode='INST']/kindOfProduct[@classCode='MMAT'][@determinerCode='KIND']/code[@codeSystem='TBD-MPID']/@codeSystemVersion
e	D.8.r.2b	医薬品製品識別子 (MPID)	M5 ガイドを参照	Coded With Equivalents (CE)	code=Character String (ST)	値	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@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='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'] instanceOfKind[@classCode='INST']/kindOfProduct[@classCode='MMAT'][@determinerCode='KIND']/code[@codeSystem='TBD-MPID']/@code

e	D.8.r.5	終了日	日付/時間	Interval of Point in Time (VL<TS>)	high=Interval Boundary (VXB)	<pre> MCL_IN200100UV01@TSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCL_IN200100UV01.xsd/PORR_IN049016UVI/controlAccess@classCode=CACTI][@mo dCode=EVN/subject][@typeCode=SUBJ][1/investigationEvent][@classCode=INVTG][@mo de=EVN/component][@typeCode=COMP][adverseEventAssessment][1/adverseEventAssessment @classCode=INVTG][@typeCode=EVN/subject][@typeCode=SBJ][1/primaryRole][@class ode=INVSBJ/subject][@typeCode=SBJ][organizer/code][@code=2][@codeSystem=2.16.840.1 13883.3.989.2.1.1.20][1/organizer][@classCode=CATEGORY][@component @typeCode=COMP][substanceAdministration][1/substanceAdministration][@classCode=SBADM][@mo dCode=EVN/reflectiveTime][@xsi:type=VL_TSI/low/@value </pre>
e	D.8.r.4	開始日	日付/時間	Interval of Point in Time (VL<TS>)	low=Interval Boundary (VXB)	<pre> MCL_IN200100UV01@TSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCL_IN200100UV01.xsd/PORR_IN049016UVI/controlAccess@classCode=CACTI][@mo dCode=EVN/subject][@typeCode=SUBJ][1/investigationEvent][@classCode=INVTG][@mo de=EVN/component][@typeCode=COMP][adverseEventAssessment][1/adverseEventAssessment @classCode=INVTG][@typeCode=EVN/subject][@typeCode=SBJ][1/primaryRole][@class ode=INVSBJ/subject][@typeCode=SBJ][organizer/code][@code=2][@codeSystem=2.16.840.1 13883.3.989.2.1.1.20][1/organizer][@classCode=CATEGORY][@component @typeCode=COMP][substanceAdministration][1/substanceAdministration][@classCode=SBADM][@mo dCode=EVN/reflectiveTime][@xsi:type=VL_TSI/low/@value </pre>
e	D.8.r.3b	製剤識別子 (PPIID)	M5 カイフ を参照	Coded With Equivalents (CE)	code=Character String (ST)	<pre> MCL_IN200100UV01@TSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCL_IN200100UV01.xsd/PORR_IN049016UVI/controlAccess@classCode=CACTI][@mo dCode=EVN/subject][@typeCode=SUBJ][1/investigationEvent][@classCode=INVTG][@mo de=EVN/component][@typeCode=COMP][adverseEventAssessment][1/adverseEventAssessment @classCode=INVTG][@typeCode=EVN/subject][@typeCode=SBJ][1/primaryRole][@class ode=INVSBJ/subject][@typeCode=SBJ][organizer/code][@code=2][@codeSystem=2.16.840.1 13883.3.989.2.1.1.20][1/organizer][@classCode=CATEGORY][@component @typeCode=COMP][substanceAdministration][1/substanceAdministration][@classCode=SBADM][@mo dCode=EVN/consumable][@typeCode=CSM][1/instanceOfKIND][@classCode=INSTI/KIND @typeCode=INSTI/KIND][@codeSystem=TBDF-PPIID]/@cod eSystemVersion </pre>
e	D.8.r.3a	PPIID パーセント日付/番号	M5 カイフ を参照	Coded With Equivalents (CE)	Character String (ST)	<pre> MCL_IN200100UV01@TSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCL_IN200100UV01.xsd/PORR_IN049016UVI/controlAccess@classCode=CACTI][@mo dCode=EVN/subject][@typeCode=SUBJ][1/investigationEvent][@classCode=INVTG][@mo de=EVN/component][@typeCode=COMP][adverseEventAssessment][1/adverseEventAssessment @classCode=INVTG][@typeCode=EVN/subject][@typeCode=SBJ][1/primaryRole][@class ode=INVSBJ/subject][@typeCode=SBJ][organizer/code][@code=2][@codeSystem=2.16.840.1 13883.3.989.2.1.1.20][1/organizer][@classCode=CATEGORY][@component @typeCode=COMP][substanceAdministration][1/substanceAdministration][@classCode=SBADM][@mo dCode=EVN/consumable][@typeCode=CSM][1/instanceOfKIND][@classCode=INSTI/KIND @typeCode=INSTI/KIND][@codeSystem=TBDF-PPIID]/@cod eSystemVersion </pre>

(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']/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'] 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'] 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'] 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'] 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

e	D.8.r.7b	副作用 (MedDRA コー)	8N	Coded With Equivalents (CE) code=Character String (ST)	種	<pre> MCCI_IN200100UV01[...]<\/pre> </pre>
h	D.9	死亡の場合				
e	D.9.1	死亡日	日付/時間	Point in Time (TS)	種	<pre> MCCI_IN200100UV01[...]<\/pre> </pre>
e					Null/favor	<pre> MCCI_IN200100UV01[...]<\/pre> </pre>
h	D.9.2.r	報告された死因 (必要に応じて繰り返す)			繰り返し	<pre> MCCI_IN200100UV01[...]<\/pre> </pre>
e	D.9.2.r.1a	報告された死因の MedDRA パーツ	4AN	Coded With Equivalents (CE) code=SystemVersion=Character String (ST)	種	<pre> MCCI_IN200100UV01[...]<\/pre> </pre>
e	D.9.2.r.1b	報告された死因 (MedDRA コー)	8N	Coded With Equivalents (CE) code=Character String (ST)	種	<pre> MCCI_IN200100UV01[...]<\/pre> </pre>

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='INVTG'][@moodCode='EVN']/component[@typeCode='COMP'] adverseEventAssessment[1]/adverseEventAssessment[@classCode='INVTG'][@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'] 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='INVTG'][@moodCode='EVN']/component[@typeCode='COMP'] adverseEventAssessment[1]/adverseEventAssessment[@classCode='INVTG'][@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'] 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='INVTG'][@moodCode='EVN']/component[@typeCode='COMP'] adverseEventAssessment[1]/adverseEventAssessment[@classCode='INVTG'][@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'] observation[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='BL'] [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='INVTG'][@moodCode='EVN']/component[@typeCode='COMP'] adverseEventAssessment[1]/adverseEventAssessment[@classCode='INVTG'][@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'] 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='INVTG'][@moodCode='EVN']/component[@typeCode='COMP'] adverseEventAssessment[1]/adverseEventAssessment[@classCode='INVTG'][@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'] observation[@classCode='OBS'][@moodCode='EVN']/outboundRelationship2[@typeCode='DRIV'] observation/code[@code='8'][@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						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']/birthTime/@nullFlavor
e	D.10.2.2a	親の年齢 (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']/player1[@classCode='PSN'][@determinerCode='INSTANCE']/role[@classCode='PRS'][1]/subjectOf2[@typeCode='SBJ'][observation/code[@code='3'][@codeSystem='2.16.840.1.11388.3.3.989.2.1.1.19']][1]/observation[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='PQ'][1]/@value
e	D.10.2.2b	親の年齢 (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']/player1[@classCode='PSN'][@determinerCode='INSTANCE']/role[@classCode='PRS'][1]/subjectOf2[@typeCode='SBJ'][observation/code[@code='3'][@codeSystem='2.16.840.1.11388.3.3.989.2.1.1.19']][1]/observation[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='PQ'][1]/@unit
e	D.10.3	親の最終月経日	日付/時間	Point in Time (TS)		値	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/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'][observation/code[@code='22'][@codeSystem='2.16.840.1.11388.3.3.989.2.1.1.19']][1]/observation[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='TS'][1]/@value
e						NullFlavor	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/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'][observation/code[@code='22'][@codeSystem='2.16.840.1.11388.3.3.989.2.1.1.19']][1]/observation[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='TS'][1]/@nullFlavor

<p>e</p>	<p>D.10.4</p>	<p>親の体重 (kg)</p>	<p>Physical Quantity (PQ)</p>	<p>value=Real Number (REAL)</p>	<p>値</p>	<p>M/CCL_IN200100UV01[1.0]@xsi:schemaLocation=urn:h7-org:v3/MCCL_IN200100UV01.xsd/PORR_IN049016UVI/controlAccess[@classCode=CACTI]@moode=EVN/subject[@typeCode=SUBJ][1]/investigationEvent[@classCode=INVTG][1]@moode=EVN/component[@typeCode=COMP][adverseEventAssessment]de=EVN/subject[@typeCode=EVN/subject[@typeCode=SBJ][1]/primaryRole[@classCode=INVSBJ/player1]@typeCode=PSN][determineInCode=INSTANACE]/role[@classCode=PR[S][1]/subject[@typeCode=SBJ][1]/observation/code[@code=7][1]@codeSystem=2.16.840.1.13883.3.989.2.1.1.19][1]@value</p>
<p>e</p>	<p>D.10.5</p>	<p>親の身長 (cm)</p>	<p>Physical Quantity (PQ)</p>	<p>value=Real Number (REAL)</p>	<p>値</p>	<p>M/CCL_IN200100UV01[1.0]@xsi:schemaLocation=urn:h7-org:v3/MCCL_IN200100UV01.xsd/PORR_IN049016UVI/controlAccess[@classCode=CACTI]@moode=EVN/subject[@typeCode=SUBJ][1]/investigationEvent[@classCode=INVTG][1]@moode=EVN/component[@typeCode=COMP][adverseEventAssessment]de=EVN/subject[@typeCode=EVN/subject[@typeCode=SBJ][1]/primaryRole[@classCode=INVSBJ/player1]@typeCode=PSN][determineInCode=INSTANACE]/role[@classCode=PR[S][1]/subject[@typeCode=SBJ][1]/observation/code[@code=17][1]@codeSystem=2.16.840.1.13883.3.989.2.1.1.19][1]@value</p>
<p>e</p>	<p>D.10.6</p>	<p>親の性別</p>	<p>Coded With Equivalents (CE)</p>	<p>code=Character String (ST)</p>	<p>値</p>	<p>M/CCL_IN200100UV01[1.0]@xsi:schemaLocation=urn:h7-org:v3/MCCL_IN200100UV01.xsd/PORR_IN049016UVI/controlAccess[@classCode=CACTI]@moode=EVN/subject[@typeCode=SUBJ][1]/investigationEvent[@classCode=INVTG][1]@moode=EVN/component[@typeCode=COMP][adverseEventAssessment]de=EVN/subject[@typeCode=EVN/subject[@typeCode=SBJ][1]/primaryRole[@classCode=INVSBJ/player1]@typeCode=PSN][determineInCode=INSTANACE]/role[@classCode=PR[S][1]/subject[@typeCode=SBJ][1]/observation/code[@code=1.0.52187]@codeSystem=1.0.52187</p>
<p>e</p>	<p>D.10.7</p>	<p>親の関連する治療歴及び随 伴症状</p>				
<p>h</p>	<p>D.10.7.1r</p>	<p>親の構造化された情報 (必要 に応じて繰り返し返す)</p>			<p>繰り返し返す</p>	<p>M/CCL_IN200100UV01[1.0]@xsi:schemaLocation=urn:h7-org:v3/MCCL_IN200100UV01.xsd/PORR_IN049016UVI/controlAccess[@classCode=CACTI]@moode=EVN/subject[@typeCode=SUBJ][1]/investigationEvent[@classCode=INVTG][1]@moode=EVN/component[@typeCode=COMP][adverseEventAssessment]de=EVN/subject[@typeCode=EVN/subject[@typeCode=SBJ][1]/primaryRole[@classCode=INVSBJ/player1]@typeCode=PSN][determineInCode=INSTANACE]/role[@classCode=PR[S][1]/subject[@typeCode=SBJ][1]/observation/code[@code=1]@codeSystem=2.16.840.1.13883.3.989.2.1.1.20][1]@value</p>

(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 パージョン	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][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	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][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
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][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[@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][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[@xsi:type=IVL_TS]/low/@nullFlavor

e	D.10.7.1.r.3	継続	ブーリアン (BL)	値	<p>MCCL_IN200100UV01[TSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd/PORR_IN049016UVI/controlActProcess@classCode=CACTI@mo dCode=EVN/subject/@typeCode=SUBJ][1/InvestigationEvent@classCode=INVESTG][@mo dCode=EVN/component/@typeCode=COMP][1/adverseEventAssessment][1/primaryRole@class Code=INVSBJ/player/@classCode=PSN][@determineInCode=INSTANCE/role@classCode=PR S][1/subject/@typeCode=SBJ][1/organizer/@code=1][@codeSystem=2,16,840,1,113883, 3,989,2,1,1,20][1/organizer/@classCode=CATEGORV][@code=EVN/component/@typeCo de=COMP][observation/code@typeCode=EVN/observation/code@classCode=OBS][@mo dCode=OBS][@moCode=EVN/roundRelationship@typeCode=REFR][observation/code@classCo de=OBS][@codeSystem=2,16,840,1,113883,3,989,2,1,1,19][1][1/observation/@classCode=OBS][@</p>
e	D.10.7.1.r.4	終了日	日時/時間 Interval of Point in Time (VL<TS>)	値	<p>MCCL_IN200100UV01[TSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd/PORR_IN049016UVI/controlActProcess@classCode=CACTI@mo dCode=EVN/subject/@typeCode=SUBJ][1/InvestigationEvent@classCode=INVESTG][@mo dCode=EVN/component/@typeCode=COMP][1/adverseEventAssessment][1/primaryRole@class Code=INVSBJ/player/@classCode=PSN][@determineInCode=INSTANCE/role@classCode=PR S][1/subject/@typeCode=SBJ][1/organizer/@code=1][@codeSystem=2,16,840,1,113883, 3,989,2,1,1,20][1/organizer/@classCode=CATEGORV][@code=EVN/component/@typeCo de=COMP][observation/code@typeCode=EVN/observation/code@classCode=OBS][@mo dCode=OBS][@moCode=EVN/roundRelationship@typeCode=REFR][observation/code@classCo de=OBS][@codeSystem=2,16,840,1,113883,3,989,2,1,1,19][1][1/observation/@classCode=OBS][@</p>
e	D.10.7.1.r.4	終了日	日時/時間 Interval of Point in Time (VL<TS>)	値	<p>MCCL_IN200100UV01[TSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd/PORR_IN049016UVI/controlActProcess@classCode=CACTI@mo dCode=EVN/subject/@typeCode=SUBJ][1/InvestigationEvent@classCode=INVESTG][@mo dCode=EVN/component/@typeCode=COMP][1/adverseEventAssessment][1/primaryRole@class Code=INVSBJ/player/@classCode=PSN][@determineInCode=INSTANCE/role@classCode=PR S][1/subject/@typeCode=SBJ][1/organizer/@code=1][@codeSystem=2,16,840,1,113883, 3,989,2,1,1,20][1/organizer/@classCode=CATEGORV][@code=EVN/component/@typeCo de=COMP][observation/code@typeCode=EVN/observation/code@classCode=OBS][@mo dCode=OBS][@moCode=EVN/roundRelationship@typeCode=REFR][observation/code@classCo de=OBS][@codeSystem=2,16,840,1,113883,3,989,2,1,1,19][1][1/observation/@classCode=OBS][@</p>
e	D.10.7.1.r.5	備考	2000AN	値	<p>MCCL_IN200100UV01[TSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd/PORR_IN049016UVI/controlActProcess@classCode=CACTI@mo dCode=EVN/subject/@typeCode=SUBJ][1/InvestigationEvent@classCode=INVESTG][@mo dCode=EVN/component/@typeCode=COMP][1/adverseEventAssessment][1/primaryRole@class Code=INVSBJ/player/@classCode=PSN][@determineInCode=INSTANCE/role@classCode=PR S][1/subject/@typeCode=SBJ][1/organizer/@code=1][@codeSystem=2,16,840,1,113883, 3,989,2,1,1,20][1/organizer/@classCode=CATEGORV][@code=EVN/component/@typeCo de=COMP][observation/code@typeCode=EVN/observation/code@classCode=OBS][@mo dCode=OBS][@moCode=EVN/roundRelationship@typeCode=REFR][observation/code@classCo de=OBS][@codeSystem=2,16,840,1,113883,3,989,2,1,1,19][1][1/observation/@classCode=OBS][@</p>
e	D.10.7.1.r.5	備考	2000AN	値	<p>MCCL_IN200100UV01[TSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd/PORR_IN049016UVI/controlActProcess@classCode=CACTI@mo dCode=EVN/subject/@typeCode=SUBJ][1/InvestigationEvent@classCode=INVESTG][@mo dCode=EVN/component/@typeCode=COMP][1/adverseEventAssessment][1/primaryRole@class Code=INVSBJ/player/@classCode=PSN][@determineInCode=INSTANCE/role@classCode=PR S][1/subject/@typeCode=SBJ][1/organizer/@code=1][@codeSystem=2,16,840,1,113883, 3,989,2,1,1,20][1/organizer/@classCode=CATEGORV][@code=EVN/component/@typeCo de=COMP][observation/code@typeCode=EVN/observation/code@classCode=OBS][@mo dCode=OBS][@moCode=EVN/roundRelationship@typeCode=REFR][observation/code@classCo de=OBS][@codeSystem=2,16,840,1,113883,3,989,2,1,1,19][1][1/observation/@classCode=OBS][@</p>
e	D.10.7.1.r.5	備考	2000AN	値	<p>MCCL_IN200100UV01[TSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd/PORR_IN049016UVI/controlActProcess@classCode=CACTI@mo dCode=EVN/subject/@typeCode=SUBJ][1/InvestigationEvent@classCode=INVESTG][@mo dCode=EVN/component/@typeCode=COMP][1/adverseEventAssessment][1/primaryRole@class Code=INVSBJ/player/@classCode=PSN][@determineInCode=INSTANCE/role@classCode=PR S][1/subject/@typeCode=SBJ][1/organizer/@code=1][@codeSystem=2,16,840,1,113883, 3,989,2,1,1,20][1/organizer/@classCode=CATEGORV][@code=EVN/component/@typeCo de=COMP][observation/code@typeCode=EVN/observation/code@classCode=OBS][@mo dCode=OBS][@moCode=EVN/roundRelationship@typeCode=REFR][observation/code@classCo de=OBS][@codeSystem=2,16,840,1,113883,3,989,2,1,1,19][1][1/observation/@classCode=OBS][@</p>

(別添3)

(別添 3)

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']][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()
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']][1]/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']][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']/name[1]/text()
e	D.10.8.r.2a	MPID バージョン日付/番号	M5 ガイドラインを参照	Coded With Equivalents (CE)	codeSystemVersion=Character String (ST)	値	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@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']/consumable[@typeCode='CSM'][1]/instanceOfKind[@classCode='INST']/kindOfProduct[@classCode='MMAT'][@determinerCode='KIND']/code[@codeSystem='TBD-MPID'][@codeSystemVersion]

e						NullFlavor	/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']/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/@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'][@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']/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']/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'][@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']/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']/high/@nullFlavor
e	D.10.8.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'][@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']/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']/outboundRelationship2[@typeCode='RSON'][observation/code[@code='19'][@codeSy stem='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

h	E11	第一情報源により報告された副作用/有害事象		
h	E1	副作用/有害事象(必要に応じて繰り返す)	副作用/有害事象(必要に応じて繰り返す)	副作用/有害事象(必要に応じて繰り返す)
e	D.10.8.1.7b	副作用 (MedDRA コー)	Coded With Equivalents (CE)	8N
e	D.10.8.1.7a	副作用の MedDRA / 理由	Coded With Equivalents (CE)	4AN
e	D.10.8.1.6b	使用理由 (MedDRA コー)	Coded With Equivalents (CE)	8N
h	E1	副作用/有害事象(必要に応じて繰り返す)	副作用/有害事象(必要に応じて繰り返す)	副作用/有害事象(必要に応じて繰り返す)
h	E11	第一情報源により報告された副作用/有害事象		

(別添 3)

e	E.i.1.1a	母国語で記載された、第一次情報源により報告された副作用／有害事象	250AN	Coded With Equivalents (CE)	originalText = Encapsulated Data (ED)	値	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@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

e	E1.3.1	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	M/CCL_IN200100UV01[TSVersion=XML_1.0][XSI:schemaLocation=urn:hl7-org:v3 MCCl_IN200100UV01.xsd/PORR_IN049016UV1/controlActProcess[classCode=CACTI][mo ode=EVEN/subject][typeCode=SUBJ][investigationEvent][classCode=INVTG][@mo ode=EVEN/component][typeCode=COMP][adverseEventAssessment][1/adverseEventAssessment][classCode=INVTG][@moode=EVEN/subject][typeCode=EVN/subject][@typeCode=SBJ][1/primaryRole][class][classCode=INVTG][@moode=EVEN/subject][typeCode=SBJ][1/primaryRole][class ode=INVSBJ/subject][typeCode=SBJ][observation[id][code=29][@codeSystem=2.1 6.840.1.113883.3.9892.1.1.19][][/observation][classCode=OBS][@moode=EVEN/round Relationship2][typeCode=FER][observation/code][code=37][@codeSystem=2.16.840.1.1138 83.3.9892.1.1.19][][/observation][classCode=OBS][@moode=EVEN/value][XSI:type=CE][@ codeSystem=2.16.840.1.113883.3.9892.1.1.10][1/][@codeSystemVersion
e	E1.3.2	報告者にとって重要とされ た副作用/有害事象に 関するICH コーピライターの コメント					M/CCL_IN200100UV01[TSVersion=XML_1.0][XSI:schemaLocation=urn:hl7-org:v3 MCCl_IN200100UV01.xsd/PORR_IN049016UV1/controlActProcess[classCode=CACTI][mo ode=EVEN/subject][typeCode=SUBJ][investigationEvent][classCode=INVTG][@mo ode=EVEN/component][typeCode=COMP][adverseEventAssessment][1/adverseEventAssessment][classCode=INVTG][@moode=EVEN/subject][typeCode=EVN/subject][@typeCode=SBJ][1/primaryRole][class][classCode=INVTG][@moode=EVEN/subject][typeCode=SBJ][1/primaryRole][class ode=INVSBJ/subject][typeCode=SBJ][observation[id][code=29][@codeSystem=2.1 6.840.1.113883.3.9892.1.1.19][][/observation][classCode=OBS][@moode=EVEN/round Relationship2][typeCode=FER][observation/code][code=34][@codeSystem=2.16.840.1.11388 3.3.9892.1.1.19][][/observation][classCode=OBS][@moode=EVEN/value][XSI:type=BL][1/]
e	E1.3.2a	死に至るもの	ブール型 (Boolean (BL))			値	M/CCL_IN200100UV01[TSVersion=XML_1.0][XSI:schemaLocation=urn:hl7-org:v3 MCCl_IN200100UV01.xsd/PORR_IN049016UV1/controlActProcess[classCode=CACTI][mo ode=EVEN/subject][typeCode=SUBJ][investigationEvent][classCode=INVTG][@mo ode=EVEN/component][typeCode=COMP][adverseEventAssessment][1/adverseEventAssessment][classCode=INVTG][@moode=EVEN/subject][typeCode=EVN/subject][@typeCode=SBJ][1/primaryRole][class][classCode=INVTG][@moode=EVEN/subject][typeCode=SBJ][1/primaryRole][class ode=INVSBJ/subject][typeCode=SBJ][observation[id][code=29][@codeSystem=2.1 6.840.1.113883.3.9892.1.1.19][][/observation][classCode=OBS][@moode=EVEN/round Relationship2][typeCode=FER][observation/code][code=34][@codeSystem=2.16.840.1.11388 3.3.9892.1.1.19][][/observation][classCode=OBS][@moode=EVEN/value][XSI:type=BL][1/]
e						NullFlavor	M/CCL_IN200100UV01[TSVersion=XML_1.0][XSI:schemaLocation=urn:hl7-org:v3 MCCl_IN200100UV01.xsd/PORR_IN049016UV1/controlActProcess[classCode=CACTI][mo ode=EVEN/subject][typeCode=SUBJ][investigationEvent][classCode=INVTG][@mo ode=EVEN/component][typeCode=COMP][adverseEventAssessment][1/adverseEventAssessment][classCode=INVTG][@moode=EVEN/subject][typeCode=EVN/subject][@typeCode=SBJ][1/primaryRole][class][classCode=INVTG][@moode=EVEN/subject][typeCode=SBJ][1/primaryRole][class ode=INVSBJ/subject][typeCode=SBJ][observation[id][code=29][@codeSystem=2.1 6.840.1.113883.3.9892.1.1.19][][/observation][classCode=OBS][@moode=EVEN/round Relationship2][typeCode=FER][observation/code][code=34][@codeSystem=2.16.840.1.11388 3.3.9892.1.1.19][][/observation][classCode=OBS][@moode=EVEN/value][XSI:type=BL][1/]
h	E1.3.2	有害事象ごとの重篤性の基 準					

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']]]/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']]]/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']]]/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']]]/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']]]/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

						<p>NullFlavor</p> <p>MCCI_IN200100UV01@TSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd/PORR_IN049016UVI/controlActProcess[classCode=CACT][@moodCode=EVN/subject][@typeCode=SUBJ][1/investigationEvent][@classCode=INVESTG][@componentTypeCode=COMP][adverseEventAssessment][1/adverseEventAssessment][@classCode=INVESTG][@typeCode=EVN/subject][@typeCode=SBJ][1/primaryRole][@classCode=INVSBJ/subject][@typeCode=SBJ][observationId][code=29][@codeSystem=2.16.840.1.113883.3.989.2.1.1.19][observationCode][code=26][@codeSystem=2.16.840.1.113883.3.989.2.1.1.19][observationCode][code=26][@codeSystem=2.16.840.1.113883.3.989.2.1.1.19][value]</p>
e	E1.3.2f	その他の医学的に重要な状態	ブール型	Boolean (BL)	値	<p>NullFlavor</p> <p>MCCI_IN200100UV01@TSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd/PORR_IN049016UVI/controlActProcess[classCode=CACT][@moodCode=EVN/subject][@typeCode=SUBJ][1/investigationEvent][@classCode=INVESTG][@componentTypeCode=COMP][adverseEventAssessment][1/adverseEventAssessment][@classCode=INVESTG][@typeCode=EVN/subject][@typeCode=SBJ][1/primaryRole][@classCode=INVSBJ/subject][@typeCode=SBJ][observationId][code=29][@codeSystem=2.16.840.1.113883.3.989.2.1.1.19][observationCode][code=26][@codeSystem=2.16.840.1.113883.3.989.2.1.1.19][observationCode][code=26][@codeSystem=2.16.840.1.113883.3.989.2.1.1.19][value]</p>
e						<p>NullFlavor</p> <p>MCCI_IN200100UV01@TSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd/PORR_IN049016UVI/controlActProcess[classCode=CACT][@moodCode=EVN/subject][@typeCode=SUBJ][1/investigationEvent][@classCode=INVESTG][@componentTypeCode=COMP][adverseEventAssessment][1/adverseEventAssessment][@classCode=INVESTG][@typeCode=EVN/subject][@typeCode=SBJ][1/primaryRole][@classCode=INVSBJ/subject][@typeCode=SBJ][observationId][code=29][@codeSystem=2.16.840.1.113883.3.989.2.1.1.19][observationCode][code=12][@codeSystem=2.16.840.1.113883.3.989.2.1.1.19][value]</p>
e	E1.3.2e	先天異常を来すもの	ブール型	Boolean (BL)	値	<p>NullFlavor</p> <p>MCCI_IN200100UV01@TSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd/PORR_IN049016UVI/controlActProcess[classCode=CACT][@moodCode=EVN/subject][@typeCode=SUBJ][1/investigationEvent][@classCode=INVESTG][@componentTypeCode=COMP][adverseEventAssessment][1/adverseEventAssessment][@classCode=INVESTG][@typeCode=EVN/subject][@typeCode=SBJ][1/primaryRole][@classCode=INVSBJ/subject][@typeCode=SBJ][observationId][code=29][@codeSystem=2.16.840.1.113883.3.989.2.1.1.19][observationCode][code=12][@codeSystem=2.16.840.1.113883.3.989.2.1.1.19][observationCode][code=12][@codeSystem=2.16.840.1.113883.3.989.2.1.1.19][value]</p>
e						<p>NullFlavor</p> <p>MCCI_IN200100UV01@TSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd/PORR_IN049016UVI/controlActProcess[classCode=CACT][@moodCode=EVN/subject][@typeCode=SUBJ][1/investigationEvent][@classCode=INVESTG][@componentTypeCode=COMP][adverseEventAssessment][1/adverseEventAssessment][@classCode=INVESTG][@typeCode=EVN/subject][@typeCode=SBJ][1/primaryRole][@classCode=INVSBJ/subject][@typeCode=SBJ][observationId][code=29][@codeSystem=2.16.840.1.113883.3.989.2.1.1.19][observationCode][code=35][@codeSystem=2.16.840.1.113883.3.989.2.1.1.19][value]</p>

(別添 3)

(別添3)

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='INVTG'][@moodCode='EVN']/component[@typeCode='COMP'][@adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][@observation][d][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']/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='INVTG'][@moodCode='EVN']/component[@typeCode='COMP'][@adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][@observation][d][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']/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 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/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='INVTG'][@moodCode='EVN']/component[@typeCode='COMP'][@adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][@observation][d][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']/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='INVTG'][@moodCode='EVN']/component[@typeCode='COMP'][@adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][@observation][d][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']/low/@nullFlavor

						<p>NullFlavor</p> <p>MCC1_IN200100UV01.xsd/PORR_IN049016UVI/controlActForces[classCode=CACTI][@moodCode=EVN]/subject[@typeCode=SUBJ][1]/investigationEvent[classCode=INVESTG][@moodCode=EVN]/component[@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment[classCode=INVESTG][@typeCode=SBJ][1]/primaryRole[classCode=INVSBJ/subjectOrZ[@typeCode=SBJ][observationId][code@code=29][@codeSystem=2.16.840.1.113883.3.989.2.1.1.19]][/observation][@classCode=OBS][@moodCode=EVN]/effectiveTime[xsi:type=VL_TS][high/@value</p>
e	E.15	副作用/有害事象の終了日	日付/時間	HL7 子タイプ: Interval of Point in Time (VL<TS>)	<p>high=Interval Boundary (VXB)</p> <p>示されない場合 のすべての項目が表</p>	<p>MCC1_IN200100UV01.xsd/PORR_IN049016UVI/controlActForces[classCode=CACTI][@moodCode=EVN]/subject[@typeCode=SUBJ][1]/investigationEvent[classCode=INVESTG][@moodCode=EVN]/component[@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment[classCode=INVESTG][@typeCode=SBJ][1]/primaryRole[classCode=INVSBJ/subjectOrZ[@typeCode=SBJ][observationId][code@code=29][@codeSystem=2.16.840.1.113883.3.989.2.1.1.19]][/observation][@classCode=OBS][@moodCode=EVN]/effectiveTime[xsi:type=VL_TS][high/@value</p>
						<p>NullFlavor</p> <p>MCC1_IN200100UV01.xsd/PORR_IN049016UVI/controlActForces[classCode=CACTI][@moodCode=EVN]/subject[@typeCode=SUBJ][1]/investigationEvent[classCode=INVESTG][@moodCode=EVN]/component[@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment[classCode=INVESTG][@typeCode=SBJ][1]/primaryRole[classCode=INVSBJ/subjectOrZ[@typeCode=SBJ][observationId][code@code=29][@codeSystem=2.16.840.1.113883.3.989.2.1.1.19]][/observation][@classCode=OBS][@moodCode=EVN]/effectiveTime[xsi:type=VL_TS][high/@value</p>
				HL7 子タイプ: Parenthetic Set Expression of Point in Time (SXPRTS>)	<p>compLow=Interval Boundary (VXB)</p> <p>1. E.14, E.15 及び E.16 のすべての項目が表示されない場合</p>	<p>MCC1_IN200100UV01.xsd/PORR_IN049016UVI/controlActForces[classCode=CACTI][@moodCode=EVN]/subject[@typeCode=SUBJ][1]/investigationEvent[classCode=INVESTG][@moodCode=EVN]/component[@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment[classCode=INVESTG][@typeCode=SBJ][1]/primaryRole[classCode=INVSBJ/subjectOrZ[@typeCode=SBJ][observationId][code@code=29][@codeSystem=2.16.840.1.113883.3.989.2.1.1.19]][/observation][@classCode=OBS][@moodCode=EVN]/effectiveTime[xsi:type=VL_TS][high/@value</p>

(別添 3)

e			<p>2.E.i.4、E.i.5及びE.i.6のすべての項目が表示される場合</p> <p>データ型 SXPR を伴う最初の comp 項目</p> <p>HL7 データ型：Parenthetic Set Expression of Point in Time (SXPR<TS>)</p>	<p>2.E.i.4、E.i.5及びE.i.6のすべての項目が表示される場合</p> <p>データ型 SXPR を伴う最初の comp 項目</p> <p>comp/high=Interval Boundary (IVXB)</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']{1}/observation[id][code[@code='29']][codeSystem='2.16.840.1.113883.3.989.2.1.1.19']{1}/observation[@classCode='OBS'][@moodCode='EVN']/effectiveTime[@xsi:type='SXPR_TS']/comp[@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']{1}/adverseEventAssessment{1}/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ']{1}/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ']{1}/observation[id][code[@code='29']][codeSystem='2.16.840.1.113883.3.989.2.1.1.19']{1}/observation[@classCode='OBS'][@moodCode='EVN']/effectiveTime[@xsi:type='SXPR_TS']/comp[@xsi:type='IVL_TS']/high/@nullFlavor</pre>
			<p>3.E.i.4、E.i.5及びE.i.6のすべての項目が表示される場合</p> <p>データ型 SXPR を伴う2番目の comp 項目</p> <p>HL7 データ型：Parenthetic Set Expression of Point in Time (SXPR<TS>)</p>	<p>3.E.i.4、E.i.5及びE.i.6のすべての項目が表示される場合</p> <p>データ型 SXPR を伴う2番目の comp 項目</p> <p>comp/high=Interval Boundary (IVXB)</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']{1}/observation[id][code[@code='29']][codeSystem='2.16.840.1.113883.3.989.2.1.1.19']{1}/observation[@classCode='OBS'][@moodCode='EVN']/effectiveTime[@xsi:type='SXPR_TS']/comp[@xsi:type='IVL_TS']/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'][@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']{1}/observation[id][code[@code='29']][codeSystem='2.16.840.1.113883.3.989.2.1.1.19']{1}/observation[@classCode='OBS'][@moodCode='EVN']/effectiveTime[@xsi:type='SXPR_TS']/comp[@xsi:type='IVL_TS']/operator='A'/high/@nullFlavor</pre>

<p>e</p> <p>E.1.6b</p> <p>副作用／有害事象の持続期 間(単位)</p>	<p>50AN</p>	<p>1.E.1.4, E.1.5 及び E.1.6 のすべての項目が表示されない場合</p> <p>H.7 子タイプ: Interval of Point in Time (IVL<TS>)</p> <p>width/unit=Coded Simple Value (CS)</p>	<p>1.E.1.4, E.1.5 及び E.1.6 のすべての項目が表示されない場合</p> <p>H.7 子タイプ: Parenthetic Set in Time (SXPRTS>)</p> <p>compwidth/value= Real Number (REAL)</p>	<p>1.E.1.4, E.1.5 及び E.1.6 のすべての項目が表示されない場合</p> <p>H.7 子タイプ: Parenthetic Set in Time (SXPRTS>)</p> <p>compwidth/value= Real Number (REAL)</p>	<p>1.E.1.4, E.1.5 及び E.1.6 のすべての項目が表示されない場合</p> <p>H.7 子タイプ: Parenthetic Set in Time (SXPRTS>)</p> <p>compwidth/value= Real Number (REAL)</p>
<p>e</p> <p>E.1.6a</p> <p>副作用／有害事象の持続期 間(数)</p>	<p>5N</p>	<p>1.E.1.4, E.1.5 及び E.1.6 のすべての項目が表示されない場合</p> <p>H.7 子タイプ: Interval of Point in Time (IVL<TS>)</p> <p>width/value=Real Number (REAL)</p>	<p>2.E.1.4, E.1.5 及び E.1.6 のすべての項目が表示されない場合</p> <p>H.7 子タイプ: Parenthetic Set in Time (SXPRTS>)</p> <p>compwidth/value= Real Number (REAL)</p>	<p>2.E.1.4, E.1.5 及び E.1.6 のすべての項目が表示されない場合</p> <p>H.7 子タイプ: Parenthetic Set in Time (SXPRTS>)</p> <p>compwidth/value= Real Number (REAL)</p>	<p>2.E.1.4, E.1.5 及び E.1.6 のすべての項目が表示されない場合</p> <p>H.7 子タイプ: Parenthetic Set in Time (SXPRTS>)</p> <p>compwidth/value= Real Number (REAL)</p>

(別添 3)

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']{1}/adverseEventAssessment{1}/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ']{1}/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ']{1}/observation[id][code][@code='29'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']{1}/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']{1}/adverseEventAssessment{1}/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ']{1}/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ']{1}/observation[id][code][@code='29'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']{1}/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']{1}/adverseEventAssessment{1}/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ']{1}/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ']{1}/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']{1}/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']{1}/adverseEventAssessment{1}/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ']{1}/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ']{1}/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']{1}/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

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

e	F.1.2	検査結果 (値/限定子)	50N	Internal of Physical Quantity (VL<PQ>)	1.EQ Center=Physical Quantity (PQ)	種	MCCI_IN200100UV01@TSVersion=XML_1.0][@xsi:schemaLocation=um:h7-org.v3 MCCI_IN200100UV01@TSVersion=XML_1.0][@xsi:schemaLocation=um:h7-org.v3 MCCI_IN200100UV01@TSVersion=XML_1.0][@xsi:schemaLocation=um:h7-org.v3 MCCI_IN200100UV01@TSVersion=XML_1.0][@xsi:schemaLocation=um:h7-org.v3
e						種	MCCI_IN200100UV01@TSVersion=XML_1.0][@xsi:schemaLocation=um:h7-org.v3 MCCI_IN200100UV01@TSVersion=XML_1.0][@xsi:schemaLocation=um:h7-org.v3 MCCI_IN200100UV01@TSVersion=XML_1.0][@xsi:schemaLocation=um:h7-org.v3 MCCI_IN200100UV01@TSVersion=XML_1.0][@xsi:schemaLocation=um:h7-org.v3
e						種	MCCI_IN200100UV01@TSVersion=XML_1.0][@xsi:schemaLocation=um:h7-org.v3 MCCI_IN200100UV01@TSVersion=XML_1.0][@xsi:schemaLocation=um:h7-org.v3 MCCI_IN200100UV01@TSVersion=XML_1.0][@xsi:schemaLocation=um:h7-org.v3 MCCI_IN200100UV01@TSVersion=XML_1.0][@xsi:schemaLocation=um:h7-org.v3
e						種	MCCI_IN200100UV01@TSVersion=XML_1.0][@xsi:schemaLocation=um:h7-org.v3 MCCI_IN200100UV01@TSVersion=XML_1.0][@xsi:schemaLocation=um:h7-org.v3 MCCI_IN200100UV01@TSVersion=XML_1.0][@xsi:schemaLocation=um:h7-org.v3 MCCI_IN200100UV01@TSVersion=XML_1.0][@xsi:schemaLocation=um:h7-org.v3
e						種	MCCI_IN200100UV01@TSVersion=XML_1.0][@xsi:schemaLocation=um:h7-org.v3 MCCI_IN200100UV01@TSVersion=XML_1.0][@xsi:schemaLocation=um:h7-org.v3 MCCI_IN200100UV01@TSVersion=XML_1.0][@xsi:schemaLocation=um:h7-org.v3 MCCI_IN200100UV01@TSVersion=XML_1.0][@xsi:schemaLocation=um:h7-org.v3
e						種	MCCI_IN200100UV01@TSVersion=XML_1.0][@xsi:schemaLocation=um:h7-org.v3 MCCI_IN200100UV01@TSVersion=XML_1.0][@xsi:schemaLocation=um:h7-org.v3 MCCI_IN200100UV01@TSVersion=XML_1.0][@xsi:schemaLocation=um:h7-org.v3 MCCI_IN200100UV01@TSVersion=XML_1.0][@xsi:schemaLocation=um:h7-org.v3
e						種	MCCI_IN200100UV01@TSVersion=XML_1.0][@xsi:schemaLocation=um:h7-org.v3 MCCI_IN200100UV01@TSVersion=XML_1.0][@xsi:schemaLocation=um:h7-org.v3 MCCI_IN200100UV01@TSVersion=XML_1.0][@xsi:schemaLocation=um:h7-org.v3 MCCI_IN200100UV01@TSVersion=XML_1.0][@xsi:schemaLocation=um:h7-org.v3

(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

e	F.3.4	検査結果に関する非構造化 子一夕 (自由記載)	2000AN	Encapsulated Data (ED)	種	<pre> M/CCL_IN200100UV01.xsd?P/ORA_IN049016UV1/controlActProcss@classCode=CACT[@mooc dCode=EVN/subjct[@typeCode=SUBJ][investigationEvent@classCode=INVTG][@mooc dCode=EVN/subjct[@typeCode=COMP][adverseEventAssessment][adverseEventAssessment de=EVN/component[@typeCode=COMP][adverseEventAssessment][adverseEventAssessment de=EVN/subjct[@typeCode=EVN/subjct[@typeCode=SBJ][primaryRole@classC ode=INVSBJ/subjctOZ[@typeCode=SBJ]organizer/code@code=3][@codeSystem=2,16,840,1 .13883,3,989,2,1,1,20][organization@classCode=CATGORV][@moocCode=EVN/component @typeCode=COMP][observation/code@codeSystem=2,16,840,1,13883,6,163][r/observation] [classCode=OBS][@moocCode=EVN/referenceRange@typeCode=REFV][observationRange/int erpretationCode@code=L][@codeSystem=2,16,840,1,13883,5,83][r/value@value Code=OBS][@moocCode=EVN.CRTI/value@value </pre>
e	F.3.4	検査結果に関する非構造化 子一夕 (自由記載)	2000AN	Encapsulated Data (ED)	種	<pre> M/CCL_IN200100UV01.xsd?P/ORA_IN049016UV1/controlActProcss@classCode=CACT[@mooc dCode=EVN/subjct[@typeCode=SUBJ][investigationEvent@classCode=INVTG][@mooc dCode=EVN/subjct[@typeCode=COMP][adverseEventAssessment][adverseEventAssessment de=EVN/component[@typeCode=COMP][adverseEventAssessment][adverseEventAssessment de=EVN/subjct[@typeCode=EVN/subjct[@typeCode=SBJ][primaryRole@classC ode=INVSBJ/subjctOZ[@typeCode=SBJ]organizer/code@code=3][@codeSystem=2,16,840,1 .13883,3,989,2,1,1,20][organization@classCode=CATGORV][@moocCode=EVN/component @typeCode=COMP][observation/code@codeSystem=2,16,840,1,13883,6,163][r/observation] [classCode=OBS][@moocCode=EVN.CRTI/value@value </pre>
e	F.3.4	検査結果に関する非構造化 子一夕 (自由記載)	2000AN	Encapsulated Data (ED)	種	<pre> M/CCL_IN200100UV01.xsd?P/ORA_IN049016UV1/controlActProcss@classCode=CACT[@mooc dCode=EVN/subjct[@typeCode=SUBJ][investigationEvent@classCode=INVTG][@mooc dCode=EVN/subjct[@typeCode=COMP][adverseEventAssessment][adverseEventAssessment de=EVN/component[@typeCode=COMP][adverseEventAssessment][adverseEventAssessment de=EVN/subjct[@typeCode=EVN/subjct[@typeCode=SBJ][primaryRole@classC ode=INVSBJ/subjctOZ[@typeCode=SBJ]organizer/code@code=3][@codeSystem=2,16,840,1 .13883,3,989,2,1,1,20][organization@classCode=CATGORV][@moocCode=EVN/component @typeCode=COMP][observation/code@codeSystem=2,16,840,1,13883,6,163][r/observation] [classCode=OBS][@moocCode=EVN.CRTI/value@value </pre>
e	F.3.5	正常範囲 高値	50AN	Physical Quantity (PQ)	種	<pre> M/CCL_IN200100UV01.xsd?P/ORA_IN049016UV1/controlActProcss@classCode=CACT[@mooc dCode=EVN/subjct[@typeCode=SUBJ][investigationEvent@classCode=INVTG][@mooc dCode=EVN/subjct[@typeCode=COMP][adverseEventAssessment][adverseEventAssessment de=EVN/component[@typeCode=COMP][adverseEventAssessment][adverseEventAssessment de=EVN/subjct[@typeCode=EVN/subjct[@typeCode=SBJ][primaryRole@classC ode=INVSBJ/subjctOZ[@typeCode=SBJ]organizer/code@code=3][@codeSystem=2,16,840,1 .13883,3,989,2,1,1,20][organization@classCode=CATGORV][@moocCode=EVN/component @typeCode=COMP][observation/code@codeSystem=2,16,840,1,13883,6,163][r/observation] [classCode=OBS][@moocCode=EVN/referenceRange@typeCode=REFV][observationRange/int erpretationCode@code=H][@codeSystem=2,16,840,1,13883,5,83][r/value@value Code=OBS][@moocCode=EVN.CRTI/value@value </pre>

(別添3)

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

e	Gk.2.1.2a	PHPD パーソナル日付/番号	M5 カイト ライツを参照	Coded With Equivalents (CE)	codesystemVersion= Character String (ST)	種	<pre> /MCCL_IN200100UV01@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 /MCCL_IN200100UV01.xsd/PORR_IN049016UV1/controlActForces[@classCode=CACTI][@mo dCode=EVN]/subject[@typeCode=SUBJ][1]/investigationEvent[@classCode=INVTG][@mo dCode=EVN]/component[@typeCode=COMP][adverseEventAssessment][1]/adverseEventAssessment de=EVN]/component[@typeCode=COMP][adverseEventAssessment][1]/primaryRole[@class de=EVN/subject[@typeCode=EVN]/subject[@typeCode=SBJ][1]/primaryRole[@class de=EVN/subject[@typeCode=EVN]/subject[@typeCode=SBJ][1]/organizer[@code=4][@codeSystem=2.16.840.1 .13883.3.989.2.1.1.20][1]/organizer[@classCode=CATEGORY][@modCode=EVN]/component @typeCode=COMP][substanceAdministration/@k/sid][substanceAdministration/@classCode=SBADM N][@modCode=EVN/consuable[@typeCode=CSM][1]/instanceOfKind[@classCode=INSTJ/kin dOfProduct[@classCode=MMA][1]/determineCode=KIND]/code[@codeSystem=TBDM-MPID]/co desystemVersion</pre>
e	Gk.2.1.1b	医薬品製品識別子 (MPID)	M5 カイト ライツを参照	Coded With Equivalents (CE)	code=Character String (ST)	種	<pre> /MCCL_IN200100UV01@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 /MCCL_IN200100UV01.xsd/PORR_IN049016UV1/controlActForces[@classCode=CACTI][@mo dCode=EVN]/subject[@typeCode=SUBJ][1]/investigationEvent[@classCode=INVTG][@mo dCode=EVN]/component[@typeCode=COMP][adverseEventAssessment][1]/adverseEventAssessment de=EVN]/component[@typeCode=COMP][adverseEventAssessment][1]/primaryRole[@class de=EVN/subject[@typeCode=EVN]/subject[@typeCode=SBJ][1]/primaryRole[@class de=EVN/subject[@typeCode=EVN]/subject[@typeCode=SBJ][1]/organizer[@code=4][@codeSystem=2.16.840.1 .13883.3.989.2.1.1.20][1]/organizer[@classCode=CATEGORY][@modCode=EVN]/component @typeCode=COMP][substanceAdministration/@k/sid][substanceAdministration/@classCode=SBADM N][@modCode=EVN/consuable[@typeCode=CSM][1]/instanceOfKind[@classCode=INSTJ/kin dOfProduct[@classCode=MMA][1]/determineCode=KIND]/code[@codeSystem=TBDM-MPID]/co desystemVersion</pre>
e	Gk.2.1.1a	MPID パーソナル日付/番号	M5 カイト ライツを参照	Coded With Equivalents (CE)	codesystemVersion= Character String (ST)	種	<pre> /MCCL_IN200100UV01@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 /MCCL_IN200100UV01.xsd/PORR_IN049016UV1/controlActForces[@classCode=CACTI][@mo dCode=EVN]/subject[@typeCode=SUBJ][1]/investigationEvent[@classCode=INVTG][@mo dCode=EVN]/component[@typeCode=COMP][adverseEventAssessment][1]/adverseEventAssessment de=EVN]/component[@typeCode=COMP][adverseEventAssessment][1]/primaryRole[@class de=EVN/subject[@typeCode=EVN]/subject[@typeCode=SBJ][1]/primaryRole[@class de=EVN/subject[@typeCode=EVN]/subject[@typeCode=SBJ][1]/organizer[@code=4][@codeSystem=2.16.840.1 .13883.3.989.2.1.1.20][1]/organizer[@classCode=CATEGORY][@modCode=EVN]/component @typeCode=COMP][substanceAdministration/@k/sid][substanceAdministration/@classCode=SBADM N][@modCode=EVN/consuable[@typeCode=CSM][1]/instanceOfKind[@classCode=INSTJ/kin dOfProduct[@classCode=MMA][1]/determineCode=KIND]/code[@codeSystem=TBDM-MPID]/co desystemVersion</pre>
h	Gk.2.1	医薬品の固有識別子/製剤					
h	Gk.2	医薬品の識別					
		医薬品固有の位置付けに する ICH コーフレットの パーソナル					<pre> /MCCL_IN200100UV01@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 /MCCL_IN200100UV01.xsd/PORR_IN049016UV1/controlActForces[@classCode=CACTI][@mo dCode=EVN]/subject[@typeCode=SUBJ][1]/investigationEvent[@classCode=INVTG][@mo dCode=EVN]/component[@typeCode=COMP][adverseEventAssessment][1]/adverseEventAssessment de=EVN]/component[@typeCode=COMP][adverseEventAssessment][1]/causalityAssessment ntCode[@code=20][@codeSystem=2.16.840.1.13883.3.989.2.1.1.19][1]/causalityAssessment[1] @code=OBS][@modCode=EVN]/subject[@typeCode=SUBJ][productUserReference[@classC ode=SBADM][@modCode=EVN]/id[@root=UID of k-h drug][value[@xsi:type=CE][@codeSystem=2.16.840.1.13883.3.989.2.1.1.13]/@codeSystemVer sion</pre>

(別添 3)

e	G.k.2.1.2b	製剤識別子 (PhPID)	M5 ガイド ラインを参 照	Coded With Equivalents (CE)	code=Character String (ST)	値	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@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')/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'][(@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')/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'][(@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')/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'][(@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')/consumable[@typeCode='CSM']][1]/instanceOfKind[@classCode='INST']/kind OfProduct[@classCode='MMAT'][(@determinerCode='KIND')/ingredient[@classCode='ACTI']][1]/ingre dientSubstance[@classCode='MMAT'][(@determinerCode='KIND')/name[1]/text()

<p>e</p>	<p>G.K.2.3.r.3b</p>	<p>数量 (単位)</p>	<p>50AN</p>	<p>Physical Quantity (PQ)</p>	<p>unit=Coded Simple Value (CS)</p>	<p>値 /MCCI_IN200100UV01[@TSVersion='XML_1.0'][@xsi:schemaLocation='urn:h7-org:v3...]</p>
<p>e</p>	<p>G.K.2.3.r.3a</p>	<p>数量 (数)</p>	<p>10N</p>	<p>Physical Quantity (PQ)</p>	<p>value=Real Number (REAL)</p>	<p>値 /MCCI_IN200100UV01[@TSVersion='XML_1.0'][@xsi:schemaLocation='urn:h7-org:v3...]</p>
<p>e</p>	<p>G.K.2.3.r.2b</p>	<p>成分 / 特定成分の ID</p>	<p>M5 ガイド ライク参照</p>	<p>Coded With Equivalents (CE)</p>	<p>code=Character String (ST)</p>	<p>値 /MCCI_IN200100UV01[@TSVersion='XML_1.0'][@xsi:schemaLocation='urn:h7-org:v3...]</p>
<p>e</p>	<p>G.K.2.3.r.2a</p>	<p>成分 / 特定成分の ID / パー ション日付 / 番号</p>	<p>M5 ガイド ライク参照</p>	<p>Coded With Equivalents (CE)</p>	<p>code=SystemVersion Character String (ST)</p>	<p>値 /MCCI_IN200100UV01[@TSVersion='XML_1.0'][@xsi:schemaLocation='urn:h7-org:v3...]</p>

(別添 3)

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	試験薬の盲検状況	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.1.2	投与量(数)	8N	Physical Quantity (PQ)	value=Real Number (REAL)	値	<pre>MCCL_IN200100UV01@ITSVersion=XML_1.0]@xmlns:schemaLocation=urn:hit-org:vs @code=EVBN/subjct[@typeCode=SUBJ][1]/investigationEvent[@classCode=CACT][@mo @code=EVBN/component[@typeCode=COMP][adverseEventAssessment @code=EVBN/subjct[@typeCode=EVNSTG][1]/primaryRole[@classC @code=INVSBJ/subjct[@typeCode=SBJ][1]/organizer/@code=4][@codeSystem=2,16,840,1 13883,3,989,2,1,1,20][1]/organizer/@classCode=CATEGORRY][@modeCode=EVBN/component @typeCode=COMP][substanceAdministration/@k]/substanceAdministration/@classCode=SBADM]@modeCode=EVBN/outboundRelationshp2][@typeCode=COMP][substanceAdministration]]@modeCode=EVBN/outboundRelationshp2][@typeCode=COMP][substanceAdministration]</pre>
h	G.k.1	投与量及び関連情報(必要に 応じ繰り返す)				繰り返し	<pre>MCCL_IN200100UV01@ITSVersion=XML_1.0]@xmlns:schemaLocation=urn:hit-org:vs @code=EVBN/subjct[@typeCode=SUBJ][1]/investigationEvent[@classCode=CACT][@mo @code=EVBN/component[@typeCode=COMP][adverseEventAssessment @code=EVBN/subjct[@typeCode=EVNSTG][1]/primaryRole[@classC @code=INVSBJ/subjct[@typeCode=SBJ][1]/organizer/@code=4][@codeSystem=2,16,840,1 13883,3,989,2,1,1,20][1]/organizer/@classCode=CATEGORRY][@modeCode=EVBN/component @typeCode=COMP][substanceAdministration/@k]/substanceAdministration/@classCode=SBADM]@modeCode=EVBN/outboundRelationshp2][@typeCode=COMP][substanceAdministration]</pre>
e	G.k.3.3	承認の取持者/申請者の名 称	60AN	Organization Name (ON)	name=Entry Name (ENXP)	値	<pre>MCCL_IN200100UV01@ITSVersion=XML_1.0]@xmlns:schemaLocation=urn:hit-org:vs @code=EVBN/subjct[@typeCode=SUBJ][1]/investigationEvent[@classCode=CACT][@mo @code=EVBN/component[@typeCode=COMP][adverseEventAssessment @code=EVBN/subjct[@typeCode=EVNSTG][1]/primaryRole[@classC @code=INVSBJ/subjct[@typeCode=SBJ][1]/organizer/@code=4][@codeSystem=2,16,840,1 13883,3,989,2,1,1,20][1]/organizer/@classCode=CATEGORRY][@modeCode=EVBN/component @typeCode=COMP][substanceAdministration/@k]/substanceAdministration/@classCode=SBADM]@modeCode=EVBN/consumable/@typeCode=CSM][1]/instanceOKind[@classCode=INST/kind @code=INST/kind/@classCode=INST/kind/@typeCode=CSM][1]/instanceOKind/@classCode= @code=OFFproduct[@classCode=MMAAT]/@deleteMinerCode=KIND]/asmManufacturedProduct/@classCode= MANU/subjctOr[@typeCode=SBJ][1]/approval/@classCode=CENTRCT][@modeCode=EVBN/hol der/@typeCode=HLDD]/role/@classCode=HLDD]/playingOrganization/@classCode=ORG][@date MinerCode=INSTANCE]/code[System=1,0,3166,1,2,2]@code</pre>
e	G.k.3.2	承認/申請国	2A	Coded With Equivalents (CE)	code=Character String (ST)	値	<pre>MCCL_IN200100UV01@ITSVersion=XML_1.0]@xmlns:schemaLocation=urn:hit-org:vs @code=EVBN/subjct[@typeCode=SUBJ][1]/investigationEvent[@classCode=CACT][@mo @code=EVBN/component[@typeCode=COMP][adverseEventAssessment @code=EVBN/subjct[@typeCode=EVNSTG][1]/primaryRole[@classC @code=INVSBJ/subjct[@typeCode=SBJ][1]/organizer/@code=4][@codeSystem=2,16,840,1 13883,3,989,2,1,1,20][1]/organizer/@classCode=CATEGORRY][@modeCode=EVBN/component @typeCode=COMP][substanceAdministration/@k]/substanceAdministration/@classCode=SBADM]@modeCode=EVBN/consumable/@typeCode=CSM][1]/instanceOKind[@classCode=INST/kind @code=INST/kind/@classCode=INST/kind/@typeCode=CSM][1]/instanceOKind/@classCode= @code=OFFproduct[@classCode=MMAAT]/@deleteMinerCode=KIND]/asmManufacturedProduct/@classCode= MANU/subjctOr[@typeCode=SBJ][1]/approval/@classCode=CENTRCT][@modeCode=EVBN/hol der/@typeCode=HLDD]/role/@classCode=HLDD]/playingOrganization/@classCode=ORG][@date MinerCode=INSTANCE]/code[System=1,0,3166,1,2,2]@code</pre>

(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']/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']/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']/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/@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']/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']/doseCheckQuantity[denominator[@xsi:type='PQ'][@nullFlavor='UNK']/numerator[@xsi:type='PQ']]/@unit

						<p>2.以下の子-タ項目の2つを超える権が表示される場合：</p> <p>1) G.K.4.r.2, G.K.4.r.3, 2) G.K.4.r.4, 3) G.K.4.r.5, 4) G.K.4.r.6a, G.K.4.r.6b</p> <p>子-タ型 SXPР を伴う 2 番目の comp 項目</p> <p>Paranthetic Set (SXPR_TS) Expression of Time [Periodic Interval of Time (PVL_TS)]</p>				<p>権</p>	
						<p>1.以下の子-タ項目の2つを超える権が表示される場合：</p> <p>1) G.K.4.r.2, G.K.4.r.3, 2) G.K.4.r.4, 3) G.K.4.r.5, 4) G.K.4.r.6a, G.K.4.r.6b</p> <p>子-タ型 SXPР を伴う最初の comp 項目</p> <p>Paranthetic Set (SXPR_TS) Expression of Time [Periodic Interval of Time (PVL_TS)]</p>		<p>権</p>		<p>権</p>	

(別添 3)

e				<p>3.以下のデータ項目の1つの値のみが表示される場合</p> <p>1) G.k.4.r.2、 G.k.4.r.3 2) G.k.4.r.4 3) G.k.4.r.5 4) G.k.4.r.6a、 G.k.4.r.6b</p> <p>Periodic Interval of Time (PIVL_TS)</p>	<p>period/value=Real Number (REAL)</p>	<p>値</p>	<p>/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@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='PIVL_TS']/period/@value</p>
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>	<p>/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@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='PIVL_TS']/period/@unit</p>

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='um: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']/low/@value</pre>
e						NullFlavor	<pre>/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='um: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']/low/@nullFlavor</pre>

	<p>2.以下の子一々項目の2つを超える権が表示される場合:</p> <ol style="list-style-type: none"> 1) G.K.4.r.2. 2) G.K.4.r.4 3) G.K.4.r.5 4) G.K.4.r.6a, G.K.4.r.6b <p>子一々型 XPR を伴う 2 番目の comp 項目 Parenthetic Set Expression of Time (SXP_R_TS) Interval of Point in Time (VL_TS)]</p>	
	<p>値</p>	
<p>Null Favor</p>		<pre> MCCI_IN200100UV01@TSVersion=XML_1.0][@xmlns:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd/PORR_IN049016UV1/controlActProcess[@classCode=CACT][@mo odCode=EVN/subject[@typeCode=SUBJ][1/investigationEvent[@classCode=INVSTG][@mo odCode=EVN/component[@typeCode=COMP][adverseEventAssessment[1/adverseEventAssessment [classCode=INVSTG][@typeCode=EVN/subject1[@typeCode=SUBJ][1/primaryRole[@class ode=INVSBJ/subject0/2[@typeCode=SBJ][organizer/code[@code=4][@codesSystem=2.16.840.1 .13883.3.989.2.1.1.20][1/organizer[@classCode=CATEGORY][@typeCode=EVN/component [@typeCode=COMP][substanceAdministration/2[@typeCode=SBADMI][substanceAdministration][sub stanceAdministration[@classCode=EVN/outboundRelationship2[@typeCode=SBADM][@mo odCode=COMP][substanceAdministration/id][k/substanceAdministration][classCode=SBADM][typeCode=EVN/subject[@typeCode=EVN/subject1[@typeCode=SBJ][1/primaryRole[@class ode=INVSBJ/subject0/2[@typeCode=SBJ][organizer/code[@code=4][@codesSystem=2.16.840.1 .13883.3.989.2.1.1.20][1/organizer[@classCode=CATEGORY][@typeCode=EVN/component [@typeCode=COMP][substanceAdministration/2[@typeCode=SBADMI][substanceAdministration][sub stanceAdministration[@classCode=EVN/outboundRelationship2[@typeCode=SBADM][@mo odCode=COMP][substanceAdministration/id][k/substanceAdministration][classCode=SBADM][typeCode=EVN/subject[@typeCode=EVN/subject1[@typeCode=SBJ][1/primaryRole[@class ode=INVSBJ/subject0/2[@typeCode=SBJ][organizer/code[@code=4][@codesSystem=2.16.840.1 .13883.3.989.2.1.1.20][1/organizer[@classCode=CATEGORY][@typeCode=EVN/component TS/comp[@xsi:type=VL_TS][@operator=A/low/@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> <ol style="list-style-type: none"> 1) G.k.4.r.2、G.k.4.r.3 2) G.k.4.r.4 3) G.k.4.r.5 4) G.k.4.r.6a、G.k.4.r.6b <p>Interval of Point in Time (IVL_TS)</p>	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/d][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>/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@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']/low/@nullFlavor</pre>
e	G.k.4.r.5	医薬品の投与終了日	<p>1.以下のデータ項目の2つを超える値が表示される場合：</p> <ol style="list-style-type: none"> 1) G.k.4.r.2、G.k.4.r.3 2) G.k.4.r.4 3) G.k.4.r.5 4) G.k.4.r.6a、G.k.4.r.6b <p>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>	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/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']/high/@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>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/d[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/d[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 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>	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='SXPR_TS']/comp[@xsi:type='IVL_TS']/width/@value</pre>

	<p>MCCI_IN200100UV01[TSVersion=XML_1.0][@xmlns:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd/PORR_IN049016UV[controlActProcess@classCode=CACT][@moodCode=EVTN/subject[@typeCode=SUBJ][1]/investigationEvent[@classCode=INVTG][@moodCode=EVTN/component[@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment[@classCode=EVNTG][@moodCode=EVNTG][@moodCode=EVNTG][1]/subject[1]/primaryRole[@classCode=INVSBJ/subjectC2[@typeCode=SBJ][organizer/code[@code=4][@codeSystem=2.16.840.1.13883.3.989.2.1.1.20][1]/organizer[@classCode=CATEGORY][@moodCode=EVNTG/component[@typeCode=COMP][substanceAdministration[k]/substanceAdministration[@classCode=SBADM][@moodCode=EVNTG][@moodCode=EVNTG][1]/outboundRelationship[@typeCode=COMP][substanceAdministration][f/substanceAdministration[@classCode=EVNTG][@moodCode=EVNTG][@moodCode=EVNTG][1]/width@value</p>
<p>値</p>	<p>値</p>
<p>3.以下の子-々項目 の1つの値のみが表 示される場合</p>	<p>width/value=Real Number (REAL)</p>
<p>2.以下の子-々項目 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>子-々型 SXPR を持 た 2 番目の comp 項 目 Parenthetic Set Expression of Time (SXPR_TS) [Interval of Point in Time (IVL_TS)]</p>	<p>Interval of Point in Time (IVL_TS) 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>

(別添 3)

e	G.k.4.r.6b	医薬品投与期間 (単位)	<p>50AN</p> <p>1.以下のデータ項目の2つを超える値が表示される場合：</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/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='SXPR_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</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[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'][@operator='A']/width/@unit</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']{1}/adverseEventAssessment{1}/adverseEventAssessment[@classCode='INVSTG'][@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='COMP']{1}/substanceAdministration[@classCode='SBADM']{1}[@moodCode='EVN']/consumable[@typeCode='CSM']{1}/instanceOfKind[@classCode='INST']/kindOfProduct[@classCode='MMAT']{1}[@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	M5 ガイド ラインを参 照	Coded With Equivalents (CE)	codeSystemVersion= Character String (ST)	値	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn: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']{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='COMP']{1}/substanceAdministration[@classCode='SBADM']{1}[@moodCode='EVN']/consumable[@typeCode='CSM']{1}/instanceOfKind[@classCode='INST']/kindOfProduct[@classCode='MMAT']{1}[@determinerCode='KIND']/formCode[@codeSystem='TBD-DoseForm']/@codeSystemVersion
e	G.k.4.r.9.2b	医薬品剤形の ID	M5 ガイド ラインを参 照	Coded With Equivalents (CE)	code=Character String (ST)	値	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@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']{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='COMP']{1}/substanceAdministration[@classCode='SBADM']{1}[@moodCode='EVN']/consumable[@typeCode='CSM']{1}/instanceOfKind[@classCode='INST']/kindOfProduct[@classCode='MMAT']{1}[@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']{1}/adverseEventAssessment{1}/adverseEventAssessment[@classCode='INVSTG'][@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='COMP']{1}/substanceAdministration[@classCode='SBADM']{1}[@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='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']][1][@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']/inboundRelationship[@typeCode='REFR'][observation/code[@code='28']][1][@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 パー ジョン日付/番号	M5 ガイド ラインを参 照	Coded With Equivalents (CE)	codeSystemVersion= Character String (ST)	値	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@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']][1][@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']/inboundRelationship[@typeCode='REFR'][observation/code[@code='28']][1][@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	M5 ガイド ライン (3N)を参 照	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']][1][@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']/inboundRelationship[@typeCode='REFR'][observation/code[@code='28']][1][@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']][1][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][substanceAdministration/id][k]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/outboundRelationship2[@typeCode='SUMM'][@observation/code[@code='14']][1][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']][1]/observation[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='PQ']][1]/@value

<p>h</p>	<p>G.k.7f</p>	<p>医薬品使用理由 (必要に応じ 繰り返し返す)</p>			<p>繰り返し / - f</p>
<p>e</p>	<p>G.k.6b</p>	<p>曝露時の妊娠期間 (単位)</p>	<p>SOAN Physical Quantity (PQ)</p>	<p>unit-Coded Simple Value (CS)</p>	<p>値</p>
<p>e</p>	<p>G.k.6a</p>	<p>曝露時の妊娠期間 (数)</p>	<p>3N Physical Quantity (PQ)</p>	<p>value=Real Number (REAL)</p>	<p>値</p>
<p>e</p>	<p>G.k.5b</p>	<p>副作用 / 有害事象発現まで の累積総投与量 (単位)</p>	<p>SOAN Physical Quantity (PQ)</p>	<p>unit-Coded Simple Value (CS)</p>	<p>値</p>

(別添 3)

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=um: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]][1][@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]/originalText/text()
e						NullFlavor	/MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=um: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]][1][@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]/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=um: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]][1][@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]/@codeSystemVersion

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'] 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='39'] [@codeSystem='2.16.840.1.113883.3.989.2.1.1.19'] [r]/causalityAssessment[@classCode='OBS'] [@moodCode='EVN'] [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']] author[@typeCode='AUT'] [1]/assignedEntity[@classCode='ASSIGNED'] code/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'] 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='39'] [@codeSystem='2.16.840.1.113883.3.989.2.1.1.19'] [r]/causalityAssessment[@classCode='OBS'] [@moodCode='EVN'] [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']] 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'] 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='39'] [@codeSystem='2.16.840.1.113883.3.989.2.1.1.19'] [r]/causalityAssessment[@classCode='OBS'] [@moodCode='EVN'] [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']] 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'] 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='SUBJ'] [1]/primaryRole[@classCode='INVSBJ'] subjectOf2[@typeCode='SUBJ'] organizer[@classCode='CATEGORY'] [@moodCode='EVN'] [code][@code='4'] [@codeSystem='2.16.840.1.113883.3.989.2.1.1.20'] [1]/component[@typeCode='COMP'] [substanceAdministration/id][k] substanceAdministration[@classCode='SBADM'] [@moodCode='EVN'] outboundRelationship1[@typeCode='SAS'] factReference[@classCode='OBS'] [@moodCode='EVN'] [id[@root='UUID of i-th reaction']] pauseQuantity/@value

<p>e</p> <p>G.K.9.1.4</p> <p>再投与で副作用は再発した か?</p>	<p>1N</p> <p>Coded With Equivalents (CE)</p>	<p>種</p> <p>code=Character String (ST)</p>	<p>MCC1_IN200100UV01[...] reaction][value][@xsi:type=CE][@codeSystem=2.16.840.1.113883.3.989.2.1.1.16][1][@code of @root=UID boundRelationship1[@typeCode=REFR][actReference][@classCode=OBS][@moodCode=EVN][id system=2.16.840.1.113883.3.989.2.1.1.19][observation][@classCode=OBS][@moodCode=EVN][out dCode=EVN/outboundRelationship2[@typeCode=PERT][observation/code=@code=31][@codeSys de=COMP][substanceAdministration/id][k/substanceAdministration/@classCode=SBADM][@moo EVN][code/@code=4][@codeSystem=2.16.840.1.113883.3.989.2.1.1.20][1][component][@typeCo de=INVSBJ/subjectO/RZ[@typeCode=SBJ/organizer][@classCode=CATEGORV][@moodCode= @classCode=INVSBJ][@typeCode=SBJ][1][primaryRole][@classC de=EVN][component][@typeCode=COMP][adverseEventAssessment][1][adverseEventAssessment dCode=EVN/subject][@typeCode=SUBJ][1][investigationEvent][@classCode=INVSBJ][@moodCo MCC1_IN200100UV01.xsd/PORR_IN049016UV1/controlActProcess][@classCode=CACT][@moo MCC1_IN200100UV01[...] @xsi:schemaLocation=urn:hl7-org:v3</p>
<p>e</p> <p>G.K.9.1.3.2b</p> <p>医薬品の最終投与から副作 用/有害事象発現までの時 間間隔 (単位)</p>	<p>50AN</p> <p>Physical Quantity (PQ)</p>	<p>種</p> <p>Unit-Coded Simple Value (CS)</p>	<p>MCC1_IN200100UV01[...] dCode=EVN/subject][@typeCode=SUBJ][1][investigationEvent][@classCode=INVSBJ][@moodCo de=EVN][component][@typeCode=COMP][adverseEventAssessment][1][adverseEventAssessment @classCode=INVSBJ][@typeCode=SBJ][1][primaryRole][@classC ode=INVSBJ/subjectO/RZ[@typeCode=SBJ/organizer][@classCode=CATEGORV][@moodCode= EVN][code/@code=4][@codeSystem=2.16.840.1.113883.3.989.2.1.1.20][1][component][@typeCo dCode=EVN/outboundRelationship1[@typeCode=SAE][actReference][@classCode=OBS][@moo MCC1_IN200100UV01.xsd/PORR_IN049016UV1/controlActProcess][@classCode=CACT][@moo MCC1_IN200100UV01[...] @xsi:schemaLocation=urn:hl7-org:v3</p>
<p>e</p> <p>G.K.9.1.3.2a</p> <p>医薬品の最終投与から副作 用/有害事象発現までの時 間間隔 (数)</p>	<p>5N</p> <p>Physical Quantity (PQ)</p>	<p>種</p> <p>Value-Real Number (REAL)</p>	<p>MCC1_IN200100UV01[...] dCode=EVN/subject][@typeCode=SUBJ][1][investigationEvent][@classCode=INVSBJ][@moodCo de=EVN][component][@typeCode=COMP][adverseEventAssessment][1][adverseEventAssessment @classCode=INVSBJ][@typeCode=SBJ][1][primaryRole][@classC ode=INVSBJ/subjectO/RZ[@typeCode=SBJ/organizer][@classCode=CATEGORV][@moodCode= EVN][code/@code=4][@codeSystem=2.16.840.1.113883.3.989.2.1.1.20][1][component][@typeCo dCode=EVN/outboundRelationship1[@typeCode=SAE][actReference][@classCode=OBS][@moo MCC1_IN200100UV01.xsd/PORR_IN049016UV1/controlActProcess][@classCode=CACT][@moo MCC1_IN200100UV01[...] @xsi:schemaLocation=urn:hl7-org:v3</p>
<p>e</p> <p>G.K.9.1.3.1b</p> <p>医薬品の投与開始から副作 用/有害事象発現までの時 間間隔 (単位)</p>	<p>50AN</p> <p>Physical Quantity (PQ)</p>	<p>種</p> <p>Unit-Coded Simple Value (CS)</p>	<p>MCC1_IN200100UV01[...] dCode=EVN/subject][@typeCode=SUBJ][1][investigationEvent][@classCode=INVSBJ][@moodCo de=EVN][component][@typeCode=COMP][adverseEventAssessment][1][adverseEventAssessment @classCode=INVSBJ][@typeCode=SBJ][1][primaryRole][@classC ode=INVSBJ/subjectO/RZ[@typeCode=SBJ/organizer][@classCode=CATEGORV][@moodCode= EVN][code/@code=4][@codeSystem=2.16.840.1.113883.3.989.2.1.1.20][1][component][@typeCo dCode=EVN/outboundRelationship1[@typeCode=SAE][actReference][@classCode=OBS][@moo MCC1_IN200100UV01.xsd/PORR_IN049016UV1/controlActProcess][@classCode=CACT][@moo MCC1_IN200100UV01[...] @xsi:schemaLocation=urn:hl7-org:v3</p>

(別添 3)

		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					/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@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[@classCode='CATEGORY'][@moodCode='EVN']/code[@code='4'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/component[@typeCode='COMP'][substanceAdministration[id][k]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/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]]/@codeSystemVersion
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	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@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='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='REFR'][observation/code[@code='9']][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']]/observation[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='CE'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.17']][1]]/@codeSystemVersion
		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					/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@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='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='REFR'][observation/code[@code='9']][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']]/observation[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='CE'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.17']][1]]/@codeSystemVersion
e						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']/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='REFR'][observation/code[@code='9']][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']]

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)	種	<pre> /MCCL_IN200100UV01[xmlns:schemaLocation="urn:h7-org:v3 @code=EVN/subject[@typeCode=SUBJ][1]/investigationEvent[@classCode=INVESTG][1]/adverseEventAssessment [classCode=INVESTG][@typeCode=EVN/subject1[@typeCode=SUBJ][1]/primaryRole[@classC ode=INVSBJ/subject/@typeCode=SBJ][1]/organizationCode=SBJ][organizationCode=4][[1]@codeSystem=2.16.840.1 .13883.3.989.2.1.1.20][1]/organizationCode=CATEGORY][1]/component[1]/substanceAdministration/@classCode=SBADM [1]@codeSystem=2.16.840.1.13883.3.989.2.1.1.19][1]/observation/@typeCode=REFF[1]/observation/@code=2][1] [1]@codeSystem=2.16.840.1.13883.3.989.2.1.1.19][1]observation[@typeCode=OBS][1]/value[xmlns:st="ST][1]/text() =EVN/value[xmlns:type=ST][1]/text() </pre>
h	H	症例概要及びその他の情報の記述				
e	H.1	臨床経過、治療計画、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)	種	<pre> /MCCL_IN200100UV01[xmlns:schemaLocation="urn:h7-org:v3 @code=EVN/subject[@typeCode=SUBJ][1]/investigationEvent[@classCode=INVESTG][1]/adverseEventAssessment [classCode=INVESTG][@typeCode=EVN/subject1[@typeCode=SUBJ][1]/investigationEvent[@classCode=CACT][1]/mo dcode=EVN/text/text() </pre>
e	H.2	報告者の意見	2000AN	Encapsulated Data (ED)	種	<pre> /MCCL_IN200100UV01[xmlns:schemaLocation="urn:h7-org:v3 @code=EVN/subject[@typeCode=SUBJ][1]/investigationEvent[@classCode=INVESTG][1]/adverseEventAssessment [classCode=INVESTG][@typeCode=EVN/subject1[@typeCode=SUBJ][1]/investigationEvent[@classCode=CACT][1]/mo dcode=EVN/component[1]/adverseEventAssessment[1]/observationEvent[1]/component[1]/typeCode=COMP[1]observationEvent [1]/adverseEventAssessment[1]/adverseEventAssessment[1]/adverseEventAssessment[1]/adverseEventAssessment[1] /classCode=COMP[1]observationEvent[1]@codeSystem=2.16.840.1.13883.3.989.2.1.1.19][1]author[@typeCode=AUT]/as signedEntry[1]@codeSystem=2.16.840.1.13883.3.989.2.1.1.19][1]text </pre>
e	H.3.f	送信者による診断名 (必要に 応じ繰り返す)			繰り返シ	<pre> /MCCL_IN200100UV01[xmlns:schemaLocation="urn:h7-org:v3 @code=EVN/subject[@typeCode=SUBJ][1]/investigationEvent[@classCode=INVESTG][1]/adverseEventAssessment [classCode=INVESTG][@typeCode=EVN/subject1[@typeCode=SUBJ][1]/investigationEvent[@classCode=CACT][1]/mo dcode=EVN/component[1]/adverseEventAssessment[1]/adverseEventAssessment[1]/adverseEventAssessment[1] /classCode=COMP[1]observationEvent[1]/component[1]/typeCode=COMP[1]observationEvent[1] /classCode=COMP[1]observationEvent[1]@codeSystem=2.16.840.1.13883.3.989.2.1.1.19][1]author[@typeCode=AUT]/as signedEntry[1]@codeSystem=2.16.840.1.13883.3.989.2.1.1.19][1]text </pre>
e	H.3.r.1a	送信者による診断名 / 症候 群及び / 又は副作用 / 有害 事象の再分類の MedDRA バージョン	4AN	Coded With Equivalents (CE)	種	<pre> /MCCL_IN200100UV01[xmlns:schemaLocation="urn:h7-org:v3 @code=EVN/subject[@typeCode=SUBJ][1]/investigationEvent[@classCode=INVESTG][1]/adverseEventAssessment [classCode=COMP[1]/adverseEventAssessment[1]/adverseEventAssessment[1]/adverseEventAssessment[1] /classCode=COMP[1]observationEvent[1]/component[1]/typeCode=COMP[1]observationEvent[1] /classCode=COMP[1]observationEvent[1]@codeSystem=2.16.840.1.13883.3.989.2.1.1.19][1]author[@typeCode=AUT]/as signedEntry[1]@codeSystem=2.16.840.1.13883.3.989.2.1.1.19][1]text </pre>

e	H.3.r.1b	送信者による診断名／症候群及び／又は副作用／有害事象の再分類 (MedDRA コード)	8N	Coded With Equivalents (CE)	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']/component1[@typeCode='COMP']observationEvent[code[@code='15'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']][author[@typeCode='AUT']/assignedEntity[@classCode='ASSIGNED']/code[@code='1'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.21']][r]/observationEvent[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='CE'][@codeSystem='2.16.840.1.113883.6.163']/@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'][adverseEventAssessment[1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/component1[@typeCode='COMP']observationEvent[code[@code='10'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']][author[@typeCode='AUT']/assignedEntity[@classCode='ASSIGNED']/code[@code='1'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.21']][1]/observationEvent[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='ED']/text0
h	H.5.r	母国語で記載された症例概要及び報告者の意見 (必要に応じ繰り返す)				繰り返すノード	/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']observationEvent[code[@code='36'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']][author[@typeCode='AUT']/assignedEntity[@classCode='ASSIGNED']/code[@code='2'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.21']]
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']observationEvent[code[@code='36'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']][author[@typeCode='AUT']/assignedEntity[@classCode='ASSIGNED']/code[@code='2'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.21']][r]/observationEvent[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='ED']/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']observationEvent[code[@code='36'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']][author[@typeCode='AUT']/assignedEntity[@classCode='ASSIGNED']/code[@code='2'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.21']][r]/observationEvent[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='ED']/@language

h: エン コード 番号	ICSR メッセージ における フィールド名	ICR チー タイプ 名	HL7 チー タイプ 名	HL7 チー タイプ 名 (下位構成要素)	分類	Xpath
e	ACK.M.1	確認応答パッチ番号	100AN	Instance Identifier (II)	値	/MCCI_IN200101UV01[@TSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3:3883.3.989.2.1.3.20']@extension
e	ACK.M.2	確認応答パッチ送信者識別子	60AN	Instance Identifier (II)	値	/MCCI_IN200101UV01[@TSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3:3883.3.989.2.1.3.17']@extension
e	ACK.M.3	確認応答パッチ受信者識別子	60AN	Instance Identifier (II)	値	/MCCI_IN200101UV01[@TSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3:3883.3.989.2.1.3.18']@extension
e	ACK.M.4	パッチ送信の確認応答日	日付/時間	Point in Time (TS)	値	/MCCI_IN200101UV01[@TSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3:3883.3.989.2.1.3.22']@extension
e	ACK.A.1	ICSRパッチ番号	100AN	Instance Identifier (II)	値	/MCCI_IN200101UV01[@TSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3:3883.3.989.2.1.3.21']@extension
e	ACK.A.2	確認応答地域メッセージ番号	100AN	Instance Identifier (II)	値	/MCCI_IN200101UV01[@TSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3:3883.3.989.2.1.1.24']@extension
e	ACK.A.3	ICSRパッチ送信日	N.1.5	Point in Time (TS)	値	/MCCI_IN200101UV01[@TSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3:3883.3.989.2.1.1.24']@extension
h	ACK.M/A	ICSRパッチ確認応答				

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='urn: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='urn:hl7-org:v3 MCCI_IN200101UV01.xsd']/acknowledgement[@typeCode]/acknowledgementDetail[1]/text/text()
h	ACK.B.r	ICH ICSR メッセージ確認応答					繰り返しノード	/MCCI_IN200101UV01[ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200101UV01.xsd']/MCCI_IN000002UV01
e	ACK.B.r.1	ICSR メッセージ番号	N.2.r.1 C.1.1	100AN	Instance Identifier (II)	extension=Character String (ST)	値	/MCCI_IN200101UV01[ITSVersion='XML_1.0'][@xsi:schemaLocation='urn: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='urn: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='urn: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='urn: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='urn: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='urn:hl7-org:v3 MCCI_IN200101UV01.xsd']/MCCI_IN000002UV01[r]/acknowledgement[1]/@typeCode

e	ACK.B.r.7	エラー/警告メッセージ又は意見	250AN	Encapsulated Data (ED)	値	<p>MCGI_IN200101UV01[1]@TSVersion='XML_1.0'[1]@xsi:schemaLocation='um:h7-org:v3 MCGI_IN200101UV01.xsd'/MCGI_IN00002UV01[r/acknowledgement[@typeCode][1/acknowledgementDetail[1]/text/text()]</p>
---	-----------	-----------------	-------	------------------------	---	--

(別添 3)

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」にするが、G.k.4.r.6にはしない

```

<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="SXPR_TS">
      <comp xsi:type="PIVL_TS">
        <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="SXPR_TS">
      <comp xsi:type="PIVL_TS">
        <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="MMAT" 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ザクション内の繰り返しの入れ子構造 (インバウンド及びアウトバンドの関係) を用いて入力する。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。