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

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

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I. 序

本文書では、電子伝送のための有効な ICH ICSR メッセージまたは ICSR 確認応答メッセージの作成を支援するのに必要な技術的情報を示す。本文書の情報はすべて 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']/@codeSystem Version
e	N.1.2	バッチ番号	100AN	Instance Identifier (II)	extension=Character String (ST)	値	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/id[@root='2.16.840.1.113883.3.989.2.1.3.22']/@extension
e	N.1.3	バッチ送信者識別子	60AN	Instance Identifier (II)	extension=Character String (ST)	値	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/sender[@typeCode='SND']/device[@classCode='DEV'][@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='2.16.840.1.113883.3.989.2.1.3.1'][1]/@extension
e	N.2.r.2	メッセージ送信者識別子	60AN	Instance Identifier (II)	extension=Character String (ST)	値	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/sender[@typeCode='SND']/device[@classCode='DEV'][@determinerCode='INSTANCE']/id[@root='2.16.840.1.113883.3.989.2.1.3.11'][1]/@extension
e	N.2.r.3	メッセージ受信者識別子	60AN	Instance Identifier (II)	extension=Character String (ST)	値	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/receiver[@typeCode='RCV']/device[@classCode='DEV'][@determinerCode='INSTANCE']/id[@root='2.16.840.1.113883.3.989.2.1.3.12'][1]/@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					

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[@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[@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']][r]/document[@classCode='DOC'][@moodCode='EVN']/title/text()

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e	C.1.6.1.r.2	含まれる資料	N/A	Encapsulated Data (ED)		値	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/reference[@typeCode='REFR'][document/code[@code='1'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.27']][r]/document[@classCode='DOC'][@moodCode='EVN']/text/text()
e	C.1.7	本症例は当該国の緊急報告の基準を満たすか？	ブール型	Boolean (BL)		値	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][observationEvent/code[@code='23'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']][1]/observationEvent[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='BL']/@value
e						NullFlavor	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][observationEvent/code[@code='23'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']][1]/observationEvent[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='BL']/@nullFlavor
h	C.1.8	世界的に固有の症例識別子					
e	C.1.8.1	世界的に固有の症例識別子	100AN	Instance Identifier (II)	extension=Character String (ST)	値	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/id[@root='2.16.840.1.113883.3.989.2.1.3.2'][1]/@extension
e	C.1.8.2	本症例の第一送信者	1N	Coded With Equivalents (CE)	code=Character String (ST)	値	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/outboundRelationship[@typeCode='SPRT'][relatedInvestigation/code[@code='1'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.22']][1]/relatedInvestigation[@classCode='INVSTG'][@moodCode='EVN']/subjectOf2[@typeCode='SUBJ'][1]/controlActEvent[@classCode='CACT'][@moodCode='EVN']/author[@typeCode='AUT']/assignedEntity[@classCode='ASSIGNED']/code[@codeSystem='2.16.840.1.113883.3.989.2.1.1.3']/@code
e		本症例の第一送信者に関するICHコードリストのバージョン					/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/outboundRelationship[@typeCode='SPRT'][relatedInvestigation/code[@code='1'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.22']][1]/relatedInvestigation[@classCode='INVSTG'][@moodCode='EVN']/subjectOf2[@typeCode='SUBJ'][1]/controlActEvent[@classCode='CACT'][@moodCode='EVN']/author[@typeCode='AUT']/assignedEntity[@classCode='ASSIGNED']/code[@codeSystem='2.16.840.1.113883.3.989.2.1.1.3']/@codeSystemVersion
h	C.1.9	その他の症例識別子					
e	C.1.9.1	過去の伝送で記載されたその他の症例識別子はあるか？	ブール型	Boolean (BL)		値	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/subjectOf2[@typeCode='SUBJ'][investigationCharacteristic/code[@code='2'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.23']][1]/investigationCharacteristic[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='BL']/@value

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']/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']/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']/subject[@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']/subject[@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']/subject[@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 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[@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']/subject[@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 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']/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()

ICH ICSR 技術的情報

2014 年 11 月 10 日

						繰り返し ノード	
h	C.2.r	第一次情報源（必要に応じ繰り返す）				繰り返し ノード	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/outboundRelationship[@typeCode='SPRT'][relatedInvestigation/code[@code='2'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.22']]
h	C.2.r.1	報告者の氏名					
e	C.2.r.1.1	報告者の職名	50AN	Person Name (PN)	prefix=Entity Name Part (ENXP)	値	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/outboundRelationship[@typeCode='SPRT'][relatedInvestigation/code[@code='2'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.22']][r]/relatedInvestigation[@classCode='INVSTG'][@moodCode='EVN']/subjectOf2[@typeCode='SUBJ']/controlActEvent[@classCode='CACT'][@moodCode='EVN']/author[@typeCode='AUT']/assignedEntity[@classCode='ASSIGNED']/assignedPerson[@classCode='PSN'][@determinerCode='INSTANCE']/name/prefix[1]/text()
e						NullFlavor	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/outboundRelationship[@typeCode='SPRT'][relatedInvestigation/code[@code='2'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.22']][r]/relatedInvestigation[@classCode='INVSTG'][@moodCode='EVN']/subjectOf2[@typeCode='SUBJ']/controlActEvent[@classCode='CACT'][@moodCode='EVN']/author[@typeCode='AUT']/assignedEntity[@classCode='ASSIGNED']/assignedPerson[@classCode='PSN'][@determinerCode='INSTANCE']/name/prefix[1]/@nullFlavor
e	C.2.r.1.2	報告者の名前	60AN	Person Name (PN)	given=Entity Name Part (ENXP)	値	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/outboundRelationship[@typeCode='SPRT'][relatedInvestigation/code[@code='2'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.22']][r]/relatedInvestigation[@classCode='INVSTG'][@moodCode='EVN']/subjectOf2[@typeCode='SUBJ']/controlActEvent[@classCode='CACT'][@moodCode='EVN']/author[@typeCode='AUT']/assignedEntity[@classCode='ASSIGNED']/assignedPerson[@classCode='PSN'][@determinerCode='INSTANCE']/name/given[1]/text()
e						NullFlavor	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/outboundRelationship[@typeCode='SPRT'][relatedInvestigation/code[@code='2'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.22']][r]/relatedInvestigation[@classCode='INVSTG'][@moodCode='EVN']/subjectOf2[@typeCode='SUBJ']/controlActEvent[@classCode='CACT'][@moodCode='EVN']/author[@typeCode='AUT']/assignedEntity[@classCode='ASSIGNED']/assignedPerson[@classCode='PSN'][@determinerCode='INSTANCE']/name/given[1]/@nullFlavor
e	C.2.r.1.3	報告者の中間名	60AN	Person Name (PN)	given=Entity Name Part (ENXP)	値	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/outboundRelationship[@typeCode='SPRT'][relatedInvestigation/code[@code='2'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.22']][r]/relatedInvestigation[@classCode='INVSTG'][@moodCode='EVN']/subjectOf2[@typeCode='SUBJ']/controlActEvent[@classCode='CACT'][@moodCode='EVN']/author[@typeCode='AUT']/assignedEntity[@classCode='ASSIGNED']/assignedPerson[@classCode='PSN'][@determinerCode='INSTANCE']/name/given[2]/text()

e						NullFlavor	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/outboundRelationship[@typeCode='SPRT'][relatedInvestigation/code[@code='2'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.22']][r]/relatedInvestigation[@classCode='INVSTG'][@moodCode='EVN']/subjectOf2[@typeCode='SUBJ']/controlActEvent[@classCode='CACT'][@moodCode='EVN']/author[@typeCode='AUT']/assignedEntity[@classCode='ASSIGNED']/assignedPerson[@classCode='PSN'][@determinerCode='INSTANCE']/name/given[2]/@nullFlavor
e	C.2.r.1.4	報告者の姓	60AN	Person Name (PN)	family=Entity Name Part (ENXP)	値	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/outboundRelationship[@typeCode='SPRT'][relatedInvestigation/code[@code='2'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.22']][r]/relatedInvestigation[@classCode='INVSTG'][@moodCode='EVN']/subjectOf2[@typeCode='SUBJ']/controlActEvent[@classCode='CACT'][@moodCode='EVN']/author[@typeCode='AUT']/assignedEntity[@classCode='ASSIGNED']/assignedPerson[@classCode='PSN'][@determinerCode='INSTANCE']/name/family[1]/text()
e						NullFlavor	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/outboundRelationship[@typeCode='SPRT'][relatedInvestigation/code[@code='2'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.22']][r]/relatedInvestigation[@classCode='INVSTG'][@moodCode='EVN']/subjectOf2[@typeCode='SUBJ']/controlActEvent[@classCode='CACT'][@moodCode='EVN']/author[@typeCode='AUT']/assignedEntity[@classCode='ASSIGNED']/assignedPerson[@classCode='PSN'][@determinerCode='INSTANCE']/name/family[1]/@nullFlavor
h	C.2.r.2	報告者の住所及び電話番号					
e	C.2.r.2.1	報告者の組織	60AN	Organization Name (ON)	name=Entity Name Part (ENXP)	値	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/outboundRelationship[@typeCode='SPRT'][relatedInvestigation/code[@code='2'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.22']][r]/relatedInvestigation[@classCode='INVSTG'][@moodCode='EVN']/subjectOf2[@typeCode='SUBJ']/controlActEvent[@classCode='CACT'][@moodCode='EVN']/author[@typeCode='AUT']/assignedEntity[@classCode='ASSIGNED']/representedOrganization[@classCode='ORG'][@determinerCode='INSTANCE']/assignedEntity[@classCode='ASSIGNED']/representedOrganization[@classCode='ORG'][@determinerCode='INSTANCE']/name/text()
e						NullFlavor	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/outboundRelationship[@typeCode='SPRT'][relatedInvestigation/code[@code='2'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.22']][r]/relatedInvestigation[@classCode='INVSTG'][@moodCode='EVN']/subjectOf2[@typeCode='SUBJ']/controlActEvent[@classCode='CACT'][@moodCode='EVN']/author[@typeCode='AUT']/assignedEntity[@classCode='ASSIGNED']/representedOrganization[@classCode='ORG'][@determinerCode='INSTANCE']/assignedEntity[@classCode='ASSIGNED']/representedOrganization[@classCode='ORG'][@determinerCode='INSTANCE']/name/@nullFlavor

e	C.2.r.2.2	報告者の部署	60AN	Organization Name (ON)	name=Entity Name Part (ENXP)	値	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/outboundRelationship[@typeCode='SPRT'][relatedInvestigation/code[@code='2'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.22']][r]/relatedInvestigation[@classCode='INVSTG'][@moodCode='EVN']/subjectOf2[@typeCode='SUBJ']/controlActEvent[@classCode='CACT'][@moodCode='EVN']/author[@typeCode='AUT']/assignedEntity[@classCode='ASSIGNED']/representedOrganization[@classCode='ORG'][@determinerCode='INSTANCE']/name/text()
e						NullFlavor	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/outboundRelationship[@typeCode='SPRT'][relatedInvestigation/code[@code='2'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.22']][r]/relatedInvestigation[@classCode='INVSTG'][@moodCode='EVN']/subjectOf2[@typeCode='SUBJ']/controlActEvent[@classCode='CACT'][@moodCode='EVN']/author[@typeCode='AUT']/assignedEntity[@classCode='ASSIGNED']/representedOrganization[@classCode='ORG'][@determinerCode='INSTANCE']/name/@nullFlavor
e	C.2.r.2.3	報告者の住所（番地）	100AN	Postal Address (AD)	streetAddressLine=Address Part (ADXP)	値	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/outboundRelationship[@typeCode='SPRT'][relatedInvestigation/code[@code='2'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.22']][r]/relatedInvestigation[@classCode='INVSTG'][@moodCode='EVN']/subjectOf2[@typeCode='SUBJ']/controlActEvent[@classCode='CACT'][@moodCode='EVN']/author[@typeCode='AUT']/assignedEntity[@classCode='ASSIGNED']/addr[1]/streetAddressLine[1]/text()
e						NullFlavor	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/outboundRelationship[@typeCode='SPRT'][relatedInvestigation/code[@code='2'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.22']][r]/relatedInvestigation[@classCode='INVSTG'][@moodCode='EVN']/subjectOf2[@typeCode='SUBJ']/controlActEvent[@classCode='CACT'][@moodCode='EVN']/author[@typeCode='AUT']/assignedEntity[@classCode='ASSIGNED']/addr[1]/streetAddressLine[1]/@nullFlavor
e	C.2.r.2.4	報告者の住所（市町村等）	35AN	Postal Address (AD)	city=Address Part (ADXP)	値	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/outboundRelationship[@typeCode='SPRT'][relatedInvestigation/code[@code='2'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.22']][r]/relatedInvestigation[@classCode='INVSTG'][@moodCode='EVN']/subjectOf2[@typeCode='SUBJ']/controlActEvent[@classCode='CACT'][@moodCode='EVN']/author[@typeCode='AUT']/assignedEntity[@classCode='ASSIGNED']/addr[1]/city[1]/text()
e						NullFlavor	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/outboundRelationship[@typeCode='SPRT'][relatedInvestigation/code[@code='2'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.22']][r]/relatedInvestigation[@classCode='INVSTG'][@moodCode='EVN']/subjectOf2[@typeCode='SUBJ']/controlActEvent[@classCode='CACT'][@moodCode='EVN']/author[@typeCode='AUT']/assignedEntity[@classCode='ASSIGNED']/addr[1]/city[1]/@nullFlavor

ICH ICSR 技術的情報

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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	C.2.r.3	報告者の国コード	2A	Concept Descriptor (CD)	code=Character String (ST)	値	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/outboundRelationship[@typeCode='SPRT'][relatedInvestigation/code[@code='2'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.22']][r]/relatedInvestigation[@classCode='INVSTG'][@moodCode='EVN']/subjectOf2[@typeCode='SUBJ']/controlActEvent[@classCode='CACT'][@moodCode='EVN']/author[@typeCode='AUT']/assignedEntity[@classCode='ASSIGNED']/assignedPerson[@classCode='PSN'][@determinerCode='INSTANCE']/asLocatedEntity[@classCode='LOCE'][1]/location[@classCode='COUNTRY'][@determinerCode='INSTANCE']/code[@codeSystem='1.0.3166.1.2.2']/@code
e						NullFlavor	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/outboundRelationship[@typeCode='SPRT'][relatedInvestigation/code[@code='2'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.22']][r]/relatedInvestigation[@classCode='INVSTG'][@moodCode='EVN']/subjectOf2[@typeCode='SUBJ']/controlActEvent[@classCode='CACT'][@moodCode='EVN']/author[@typeCode='AUT']/assignedEntity[@classCode='ASSIGNED']/assignedPerson[@classCode='PSN'][@determinerCode='INSTANCE']/asLocatedEntity[@classCode='LOCE'][1]/location[@classCode='COUNTRY'][@determinerCode='INSTANCE']/code[@codeSystem='1.0.3166.1.2.2']/@nullFlavor
e	C.2.r.4	資格	1N	Coded With Equivalents (CE)	code=Character String (ST)	値	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/outboundRelationship[@typeCode='SPRT'][relatedInvestigation/code[@code='2'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.22']][r]/relatedInvestigation[@classCode='INVSTG'][@moodCode='EVN']/subjectOf2[@typeCode='SUBJ']/controlActEvent[@classCode='CACT'][@moodCode='EVN']/author[@typeCode='AUT']/assignedEntity[@classCode='ASSIGNED']/assignedPerson[@classCode='PSN'][@determinerCode='INSTANCE']/asQualifiedEntity[@classCode='QUAL'][1]/code[@codeSystem='2.16.840.1.113883.3.989.2.1.1.6']/@code
		資格に関する ICH コードリストのバージョン					/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/outboundRelationship[@typeCode='SPRT'][relatedInvestigation/code[@code='2'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.22']][r]/relatedInvestigation[@classCode='INVSTG'][@moodCode='EVN']/subjectOf2[@typeCode='SUBJ']/controlActEvent[@classCode='CACT'][@moodCode='EVN']/author[@typeCode='AUT']/assignedEntity[@classCode='ASSIGNED']/assignedPerson[@classCode='PSN'][@determinerCode='INSTANCE']/asQualifiedEntity[@classCode='QUAL'][1]/code[@codeSystem='2.16.840.1.113883.3.989.2.1.1.6']/@codeSystemVersion
e						NullFlavor	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/outboundRelationship[@typeCode='SPRT'][relatedInvestigation/code[@code='2'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.22']][r]/relatedInvestigation[@classCode='INVSTG'][@moodCode='EVN']/subjectOf2[@typeCode='SUBJ']/controlActEvent[@classCode='CACT'][@moodCode='EVN']/author[@typeCode='AUT']/assignedEntity[@classCode='ASSIGNED']/assignedPerson[@classCode='PSN'][@determinerCode='INSTANCE']/asQualifiedEntity[@classCode='QUAL'][1]/code[@codeSystem='2.16.840.1.113883.3.989.2.1.1.6']/@nullFlavor

ICH ICSR 技術的情報

2014 年 11 月 10 日

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	60AN	Person Name (PN)	given=Entity Name Part (ENXP)	値	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/subjectOf1[@typeCode='SUBJ'][controlActEvent/author/assignedEntity/code[@codeSystem='2.16.840.1.113883.3.989.2.1.1.7']][1]/controlActEvent[@classCode='CACT'][@moodCode='EVN']/author[@typeCode='AUT']/assignedEntity[@classCode='ASSIGNED']/assignedPerson[@classCode='PSN'][@determinerCode='INSTANCE']/name/given[1]/text()
e	C.3.3.4	送信者の中間名	60AN	Person Name (PN)	given=Entity Name Part (ENXP)	値	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/subjectOf1[@typeCode='SUBJ'][controlActEvent/author/assignedEntity/code[@codeSystem='2.16.840.1.113883.3.989.2.1.1.7']][1]/controlActEvent[@classCode='CACT'][@moodCode='EVN']/author[@typeCode='AUT']/assignedEntity[@classCode='ASSIGNED']/assignedPerson[@classCode='PSN'][@determinerCode='INSTANCE']/name/given[2]/text()
e	C.3.3.5	送信者の姓	60AN	Person Name (PN)	family=Entity Name Part (ENXP)	値	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/subjectOf1[@typeCode='SUBJ'][controlActEvent/author/assignedEntity/code[@codeSystem='2.16.840.1.113883.3.989.2.1.1.7']][1]/controlActEvent[@classCode='CACT'][@moodCode='EVN']/author[@typeCode='AUT']/assignedEntity[@classCode='ASSIGNED']/assignedPerson[@classCode='PSN'][@determinerCode='INSTANCE']/name/family[1]/text()
h	C.3.4	送信者の住所、FAX番号、電話番号及び電子メールアドレス					
e	C.3.4.1	送信者の住所（番地）	100AN	Postal Address (AD)	streetAddressLine=Address Part (ADXP)	値	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/subjectOf1[@typeCode='SUBJ'][controlActEvent/author/assignedEntity/code[@codeSystem='2.16.840.1.113883.3.989.2.1.1.7']][1]/controlActEvent[@classCode='CACT'][@moodCode='EVN']/author[@typeCode='AUT']/assignedEntity[@classCode='ASSIGNED']/addr[1]/streetAddressLine[1]/text()
e	C.3.4.2	送信者の住所（市町村等）	35AN	Postal Address (AD)	city=Address Part (ADXP)	値	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/subjectOf1[@typeCode='SUBJ'][controlActEvent/author/assignedEntity/code[@codeSystem='2.16.840.1.113883.3.989.2.1.1.7']][1]/controlActEvent[@classCode='CACT'][@moodCode='EVN']/author[@typeCode='AUT']/assignedEntity[@classCode='ASSIGNED']/addr[1]/city[1]/text()
e	C.3.4.3	送信者の住所（都道府県等）	40AN	Postal Address (AD)	state=Address Part (ADXP)	値	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/subjectOf1[@typeCode='SUBJ'][controlActEvent/author/assignedEntity/code[@codeSystem='2.16.840.1.113883.3.989.2.1.1.7']][1]/controlActEvent[@classCode='CACT'][@moodCode='EVN']/author[@typeCode='AUT']/assignedEntity[@classCode='ASSIGNED']/addr[1]/state[1]/text()

e	C.3.4.4	送信者の住所（郵便番号）	15AN	Postal Address (AD)	postalCode=Address Part (ADXP)	値	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/subjectOf1[@typeCode='SUBJ'][controlActEvent/author/assignedEntity/code[@codeSystem='2.16.840.1.113883.3.989.2.1.1.7']][1]/controlActEvent[@classCode='CACT'][@moodCode='EVN']/author[@typeCode='AUT']/assignedEntity[@classCode='ASSIGNED']/addr[1]/postalCode[1]/text()
e	C.3.4.5	送信者の住所（国コード）	2A	Concept Descriptor (CD)	code=Character String (ST)	値	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/subjectOf1[@typeCode='SUBJ'][controlActEvent/author/assignedEntity/code[@codeSystem='2.16.840.1.113883.3.989.2.1.1.7']][1]/controlActEvent[@classCode='CACT'][@moodCode='EVN']/author[@typeCode='AUT']/assignedEntity[@classCode='ASSIGNED']/assignedPerson[@classCode='PSN'][@determinerCode='INSTANCE']/asLocatedEntity[@classCode='LOCE'][1]/location[@classCode='COUNTRY'][@determinerCode='INSTANCE']/code[@codeSystem='1.0.3166.1.2.2']/@code
e	C.3.4.6	送信者の電話番号	33AN	Telecommunication Address (TEL)		値	substring(/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/subjectOf1[@typeCode='SUBJ'][controlActEvent/author/assignedEntity/code[@codeSystem='2.16.840.1.113883.3.989.2.1.1.7']][1]/controlActEvent[@classCode='CACT'][@moodCode='EVN']/author[@typeCode='AUT']/assignedEntity[@classCode='ASSIGNED']/telecom[starts-with(@value,'tel:')][1]/@value, 5)
e	C.3.4.7	送信者のFAX番号	33AN	Telecommunication Address (TEL)		値	substring(/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/subjectOf1[@typeCode='SUBJ'][controlActEvent/author/assignedEntity/code[@codeSystem='2.16.840.1.113883.3.989.2.1.1.7']][1]/controlActEvent[@classCode='CACT'][@moodCode='EVN']/author[@typeCode='AUT']/assignedEntity[@classCode='ASSIGNED']/telecom[starts-with(@value,'fax:')][1]/@value, 5)
e	C.3.4.8	送信者の電子メールアドレス	100AN	Telecommunication Address (TEL)		値	substring(/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/subjectOf1[@typeCode='SUBJ'][controlActEvent/author/assignedEntity/code[@codeSystem='2.16.840.1.113883.3.989.2.1.1.7']][1]/controlActEvent[@classCode='CACT'][@moodCode='EVN']/author[@typeCode='AUT']/assignedEntity[@classCode='ASSIGNED']/telecom[starts-with(@value,'mailto:')][1]/@value, 8)
h	C.4.r	引用文献（必要に応じ繰り返す）				繰り返しノード	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/reference[@typeCode='REFR'][document/code[@code='2'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.27']]
e	C.4.r.1	引用文献	500AN	Encapsulated Data (ED)		値	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/reference[@typeCode='REFR'][document/code[@code='2'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.27']][r]/document[@classCode='DOC'][@moodCode='EVN']/bibliographicDesignationText/text()

e						NullFlavor	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/reference[@typeCode='REFR'][document/code[@code='2'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.27']][r]/document[@classCode='DOC'][@moodCode='EVN']/bibliographicDesignationText/@nullFlavor
e	C.4.r.2	含まれる資料	N/A	Encapsulated Data (ED)		値	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/reference[@typeCode='REFR'][document/code[@code='2'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.27']][r]/document[@classCode='DOC'][@moodCode='EVN']/text/text()
h	C.5	試験の識別					
h	C.5.1.r	試験の登録情報（必要に応じ繰り返す）				繰り返しノード	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf1[@typeCode='SBJ'][1]/researchStudy[@classCode='CLNTRL'][@moodCode='EVN']/authorization[@typeCode='AUTH']
e	C.5.1.r.1	試験の登録番号	50AN	Instance Identifier (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']/authorization[@typeCode='AUTH'][r]/studyRegistration[@classCode='ACT'][@moodCode='EVN']/id[@root='2.16.840.1.113883.3.989.2.1.3.6']/@extension
e						NullFlavor	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/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']/id[@root='2.16.840.1.113883.3.989.2.1.3.6']/@nullFlavor
e	C.5.1.r.2	試験の登録国	2A	Concept Descriptor (CD)	code=Character String (ST)	値	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/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']/@code

e						NullFlavor	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf1[@typeCode='SBJ'][1]/researchStudy[@classCode='CLNTRL'][@moodCode='EVN']/authorization[@typeCode='AUTH'][r]/studyRegistration[@classCode='ACT'][@moodCode='EVN']/author[@typeCode='AUT']/territorialAuthority[@classCode='TERR']/governingPlace[@classCode='COUNTRY'][@determinerCode='INSTANCE']/code[@codeSystem='1.0.3166.1.2.2']/@nullFlavor
e	C.5.2	試験名	2000AN	Character String (ST)		値	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf1[@typeCode='SBJ'][1]/researchStudy[@classCode='CLNTRL'][@moodCode='EVN']/title/text()
e						NullFlavor	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf1[@typeCode='SBJ'][1]/researchStudy[@classCode='CLNTRL'][@moodCode='EVN']/title/@nullFlavor
e	C.5.3	試験依頼者（スポンサー）の試験番号	50AN	Instance Identifier (II)	extension=Character String (ST)	値	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf1[@typeCode='SBJ'][1]/researchStudy[@classCode='CLNTRL'][@moodCode='EVN']/id[@root='2.16.840.1.113883.3.989.2.1.3.5']/@extension
e						NullFlavor	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf1[@typeCode='SBJ'][1]/researchStudy[@classCode='CLNTRL'][@moodCode='EVN']/id[@root='2.16.840.1.113883.3.989.2.1.3.5']/@nullFlavor
e	C.5.4	副作用／有害事象が観察された試験の種類	1N	Coded With Equivalents (CE)	code=Character String (ST)	値	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf1[@typeCode='SBJ'][1]/researchStudy[@classCode='CLNTRL'][@moodCode='EVN']/code[@codeSystem='2.16.840.1.113883.3.989.2.1.1.8']/@code

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		副作用／有害事象が観察された試験の種類に関するICH コードリストのバージョン					/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/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']/@codeSytemVersion
h	D	患者特性					
e	D.1	患者（名前又はイニシャル）	60AN	Entity Name (EN)	name=Entity Name Part (ENXP)	値	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/player1[@classCode='PSN'][@determinerCode='INSTANCE']/name[1]/text()
e						NullFlavor	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/player1[@classCode='PSN'][@determinerCode='INSTANCE']/name[1]/@nullFlavor
h	D.1.1	患者の診療記録番号及びその情報源（記載が許可されている場合）					
e	D.1.1:1	患者の診療記録番号及びその情報源（開業医診療記録番号）	20AN	Instance Identifier (II)	extension=Character String (ST)	値	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/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='1'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.4']][1]/id[@root='2.16.840.1.113883.3.989.2.1.3.7'][1]/@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='1'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.4']][1]/id[@root='2.16.840.1.113883.3.989.2.1.3.7'][1]/@nullFlavor
e	D.1.1.2	患者の診療記録番号及びその情報源（専門医診療記録番号）	20AN	Instance Identifier (II)	extension=Character String (ST)	値	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/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]/@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='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

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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']/birthTime/@nullFlavor
h	D.2.2	副作用／有害事象発現時の年齢					
e	D.2.2a	副作用／有害事象発現時の年齢（数）	5N	Physical Quantity (PQ)	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='3'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']][1]/observation[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='PQ'][1]/@value
e	D.2.2b	副作用／有害事象発現時の年齢（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']/subjectOf2[@typeCode='SBJ'][observation/code[@code='3'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']][1]/observation[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='PQ'][1]/@unit
e	D.2.2.1a	胎児での副作用／有害事象発現時の妊娠期間（数）	3N	Physical Quantity (PQ)	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='16'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']][1]/observation[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='PQ'][1]/@value
e	D.2.2.1b	胎児での副作用／有害事象発現時の妊娠期間（単位）	50AN	Physical Quantity (PQ)	unit=Coded Simple Value (CS)	値	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][observation/code[@code='16'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']][1]/observation[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='PQ'][1]/@unit
e	D.2.3	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	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/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]/@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'][@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]/@nullFlavor
h	D.7	関連する治療歴及び随伴症状（副作用／有害事象を除く）					
h	D.7.1.r	関連する治療歴及び随伴症状の構造化された情報（必要に応じ繰り返す）				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='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']]
e	D.7.1.r.1a	関連する治療歴及び随伴症状の MedDRA バージョン	4AN	Concept Descriptor (CD)	codeSystemVersion=Character String (ST)	値	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/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.7.1.r.1b	関連する治療歴及び随伴症状（疾病／手術処置／その他）（MedDRA コード）	8N	Concept Descriptor (CD)	code=Character String (ST)	値	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][organizer/code[@code='1'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][observation/code[@codeSystem='2.16.840.1.113883.6.163']][r]/observation[@classCode='OBS'][@moodCode='EVN']/code/@code
e	D.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']/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

ICH ICSR 技術的情報

2014 年 11 月 10 日

e						NullFlavor	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][organizer/code[@code='1'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][observation/code[@codeSystem='2.16.840.1.113883.6.163']][r]/observation[@classCode='OBS'][@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'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][organizer/code[@code='1'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][observation/code[@codeSystem='2.16.840.1.113883.6.163']][r]/observation[@classCode='OBS'][@moodCode='EVN']/inboundRelationship[@typeCode='REFR'][observation/code[@code='13'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']][1]/observation[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='BL'][1]/@value
e						NullFlavor	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][organizer/code[@code='1'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][observation/code[@codeSystem='2.16.840.1.113883.6.163']][r]/observation[@classCode='OBS'][@moodCode='EVN']/inboundRelationship[@typeCode='REFR'][observation/code[@code='13'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']][1]/observation[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='BL'][1]/@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'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][organizer/code[@code='1'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][observation/code[@codeSystem='2.16.840.1.113883.6.163']][r]/observation[@classCode='OBS'][@moodCode='EVN']/effectiveTime[@xsi:type='IVL_TS']/high/@value
e						NullFlavor	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][organizer/code[@code='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']/high/@nullFlavor

e	D.7.1.r.5	備考	2000AN	Encapsulated Data (ED)		値	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][organizer/code[@code='1'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][observation/code[@codeSystem='2.16.840.1.113883.6.163']][r]/observation[@classCode='OBS'][@moodCode='EVN']/outboundRelationship2[@typeCode='COMP'][observation/code[@code='10'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']][1]/observation[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='ED'][1]/text()
e	D.7.1.r.6	家族歴	ブール型	Boolean (BL)		値	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][organizer/code[@code='1'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][observation/code[@codeSystem='2.16.840.1.113883.6.163']][r]/observation[@classCode='OBS'][@moodCode='EVN']/outboundRelationship2[@typeCode='EXPL'][observation/code[@code='38'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']][1]/observation[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='BL'][1]/@value
e	D.7.2	関連する治療歴及び随伴症状（副作用／有害事象を除く）の記述情報	10000AN	Encapsulated Data (ED)		値	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][organizer/code[@code='1'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][observation/code[@code='18'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']][1]/observation[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='ED'][1]/text()
e						NullFlavor	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][organizer/code[@code='1'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][observation/code[@code='18'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']][1]/observation[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='ED'][1]/@nullFlavor
e	D.7.3	併用療法	ブール型	Boolean (BL)		値	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][organizer/code[@code='1'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][observation/code[@code='11'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']][1]/observation[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='BL'][1]/@value

h	D.8.r	関連する過去の医薬品使用歴（必要に応じ繰り返す）				繰り返しノード	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][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]
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='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][organizer/code[@code='2'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][substanceAdministration][r]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/consumable[@typeCode='CSM'][1]/instanceOfKind[@classCode='INST']/kindOfProduct[@classCode='MMAT'][@determinerCode='KIND']/name[1]/text()
e						NullFlavor	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/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]/@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='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][organizer/code[@code='2'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][substanceAdministration][r]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/consumable[@typeCode='CSM'][1]/instanceOfKind[@classCode='INST']/kindOfProduct[@classCode='MMAT'][@determinerCode='KIND']/code[@codeSystem='TBD-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='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][organizer/code[@code='2'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][substanceAdministration][r]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/consumable[@typeCode='CSM'][1]/instanceOfKind[@classCode='INST']/kindOfProduct[@classCode='MMAT'][@determinerCode='KIND']/code[@codeSystem='TBD-MPID']/@code

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e	D.8.r.3a	PhPID 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='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ']/organizer/code[@code='2'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][substanceAdministration][r]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/consumable[@typeCode='CSM'][1]/instanceOfKind[@classCode='INST']/kindOfProduct[@classCode='MMAT'][@determinerCode='KIND']/code[@codeSystem='TBD-PhPID']/@codeSystemVersion
e	D.8.r.3b	製剤識別子（PhPID）	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='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ']/organizer/code[@code='2'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][substanceAdministration][r]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/consumable[@typeCode='CSM'][1]/instanceOfKind[@classCode='INST']/kindOfProduct[@classCode='MMAT'][@determinerCode='KIND']/code[@codeSystem='TBD-PhPID']/@code
e	D.8.r.4	開始日	日付／時間	Interval of Point in Time (IVL<TS>)	low=Interval Boundary (IVXB)	値	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ']/organizer/code[@code='2'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][substanceAdministration][r]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/effectiveTime[@xsi:type='IVL_TS']/low/@value
e						NullFlavor	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ']/organizer/code[@code='2'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][substanceAdministration][r]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/effectiveTime[@xsi:type='IVL_TS']/low/@nullFlavor
e	D.8.r.5	終了日	日付／時間	Interval of Point in Time (IVL<TS>)	high=Interval Boundary (IVXB)	値	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ']/organizer/code[@code='2'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][substanceAdministration][r]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/effectiveTime[@xsi:type='IVL_TS']/high/@value

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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']/subjectOf2[@typeCode='SBJ'][organizer/code[@code='2'][@codeSystem='2.16.840.1 .113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][substanceAdministration][r]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/effectiveTime[@xsi:type='IVL_TS']/high/@nullFlavor
e	D.8.r.6a	使用理由の MedDRA バージョン	4AN	Coded With Equivalents (CE)	codeSystemVersion= Character String (ST)	値	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moo dCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCo de='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment [@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classC ode='INVSBJ']/subjectOf2[@typeCode='SBJ'][organizer/code[@code='2'][@codeSystem='2.16.840.1 .113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][substanceAdministration][r]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/outboundRelationship2[@typeCode='RSON'][observation/code[@code='19'][@ codeSystem='2.16.840.1.113883.3.989.2.1.1.19']][1]/observation[@classCode='OBS'][@moodCode ='EVN']/value[@xsi:type='CE'][@codeSystem='2.16.840.1.113883.6.163'][1]/@codeSystemVersion
e	D.8.r.6b	使用理由（MedDRA コード）	8N	Coded With Equivalents (CE)	code=Character String (ST)	値	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moo dCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCo de='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment [@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classC ode='INVSBJ']/subjectOf2[@typeCode='SBJ'][organizer/code[@code='2'][@codeSystem='2.16.840.1 .113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][substanceAdministration][r]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/outboundRelationship2[@typeCode='RSON'][observation/code[@code='19'][@ codeSystem='2.16.840.1.113883.3.989.2.1.1.19']][1]/observation[@classCode='OBS'][@moodCode ='EVN']/value[@xsi:type='CE'][@codeSystem='2.16.840.1.113883.6.163'][1]/@code
e	D.8.r.7a	副作用の MedDRA バージョン	4AN	Coded With Equivalents (CE)	codeSystemVersion= Character String (ST)	値	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moo dCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCo de='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment [@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classC ode='INVSBJ']/subjectOf2[@typeCode='SBJ'][organizer/code[@code='2'][@codeSystem='2.16.840.1 .113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][substanceAdministration][r]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/outboundRelationship2[@typeCode='CAUS'][observation/code[@code='29'][@ codeSystem='2.16.840.1.113883.3.989.2.1.1.19']][1]/observation[@classCode='OBS'][@moodCode ='EVN']/value[@xsi:type='CE'][@codeSystem='2.16.840.1.113883.6.163'][1]/@codeSystemVersion

e	D.8.r.7b	副作用（MedDRA コード）	8N	Coded With Equivalents (CE)	code=Character String (ST)	値	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ']/organizer/code[@code='2'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20'][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][substanceAdministration][r]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/outboundRelationship2[@typeCode='CAUS'][observation/code[@code='29'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19'][1]/observation[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='CE'][@codeSystem='2.16.840.1.113883.6.163'][1]/@code
h	D.9	死亡の場合					
e	D.9.1	死亡日	日付／時間	Point in Time (TS)		値	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='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']/deceasedTime/@value
e						NullFlavor	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='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']/deceasedTime/@nullFlavor
h	D.9.2.r	報告された死因（必要に応じ繰り返す）				繰り返しノード	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][observation/code[@code='32'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']]
e	D.9.2.r.1a	報告された死因の MedDRA バージョン	4AN	Coded With Equivalents (CE)	codeSystemVersion=Character String (ST)	値	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][observation/code[@code='32'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']][r]/observation[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='CE'][@codeSystem='2.16.840.1.113883.6.163'][1]/@codeSystemVersion
e	D.9.2.r.1b	報告された死因（MedDRA コード）	8N	Coded With Equivalents (CE)	code=Character String (ST)	値	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][observation/code[@code='32'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']][r]/observation[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='CE'][@codeSystem='2.16.840.1.113883.6.163'][1]/@code

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e	D.9.2.r.2	報告された死因（自由記載）	250AN	Coded With Equivalents (CE)	originalText = Encapsulated Data (ED)	値	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][observation/code[@code='32'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']]][r]/observation[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='CE'][@codeSystem='2.16.840.1.113883.6.163'][1]/originalText/text()
e	D.9.3	剖検は実施されたか？	ブール型	Boolean (BL)		値	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][observation/code[@code='5'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']][1]/observation[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='BL'][1]/@value
e						NullFlavor	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][observation/code[@code='5'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']][1]/observation[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='BL'][1]/@nullFlavor
h	D.9.4.r	剖検による死因（必要に応じ繰り返す）				繰り返しノード	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][observation/code[@code='5'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']][1]/observation[@classCode='OBS'][@moodCode='EVN']/outboundRelationship2[@typeCode='DRIV'][observation/code[@code='8'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']]
e	D.9.4.r.1a	剖検による死因の MedDRA バージョン	4AN	Coded With Equivalents (CE)	codeSystemVersion= Character String (ST)	値	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][observation/code[@code='5'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']][1]/observation[@classCode='OBS'][@moodCode='EVN']/outboundRelationship2[@typeCode='DRIV'][observation/code[@code='8'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']][r]/observation[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='CE'][@codeSystem='2.16.840.1.113883.6.163'][1]/@codeSystemVersion

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e	D.9.4.r.1b	剖検による死因（MedDRA コード）	8N	Coded With Equivalents (CE)	code=Character String (ST)	値	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ']/observation/code[@code='5'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']][1]/observation[@classCode='OBS'][@moodCode='EVN']/outboundRelationship2[@typeCode='DRIV'][observation/code[@code='8'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']][r]/observation[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='CE'][@codeSystem='2.16.840.1.113883.6.163'][1]/@code
e	D.9.4.r.2	剖検による死因（自由記載）	250AN	Coded With Equivalents (CE)	originalText = Encapsulated Data (ED)	値	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ']/observation/code[@code='5'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']][1]/observation[@classCode='OBS'][@moodCode='EVN']/outboundRelationship2[@typeCode='DRIV'][observation/code[@code='8'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']][r]/observation[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='CE'][@codeSystem='2.16.840.1.113883.6.163'][1]/originalText/text()
h	D.10	親ー子／胎児報告における、親に関する情報					
e	D.10.1	親の識別	60AN	Entity Name (EN)	name=Entity Name Part (ENXP)	値	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/player1[@classCode='PSN'][@determinerCode='INSTANCE']/role[@classCode='PRS'][1]/associatedPerson[@classCode='PSN'][@determinerCode='INSTANCE']/name[1]/text()
e						NullFlavor	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/player1[@classCode='PSN'][@determinerCode='INSTANCE']/role[@classCode='PRS'][1]/associatedPerson[@classCode='PSN'][@determinerCode='INSTANCE']/name[1]/@nullFlavor
h	D.10.2	親の年齢情報					
e	D.10.2.1	親の生年月日	日付／時間	Point in Time (TS)		値	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/player1[@classCode='PSN'][@determinerCode='INSTANCE']/role[@classCode='PRS'][1]/associatedPerson[@classCode='PSN'][@determinerCode='INSTANCE']/birthTime/@value

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='2.16.840.1.113883.3.989.2.1.1.19']][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='2.16.840.1.113883.3.989.2.1.1.19']][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='2.16.840.1.113883.3.989.2.1.1.19']][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'][@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='2.16.840.1.113883.3.989.2.1.1.19']][1]/observation[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='TS'][1]/@nullFlavor

e	D.10.4	親の体重（kg）	6N	Physical Quantity (PQ)	value=Real Number (REAL)	値	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/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='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.10.5	親の身長（cm）	3N	Physical Quantity (PQ)	value=Real Number (REAL)	値	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='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='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.10.6	親の性別	1N	Coded With Equivalents (CE)	code=Character String (ST)	値	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='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']/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']/role[@classCode='PRS'][1]/associatedPerson[@classCode='PSN'][@determinerCode='INSTANCE']/administrativeGenderCode[@codeSystem='1.0.5218']/@nullFlavor
h	D.10.7	親の関連する治療歴及び随伴症状				-	
h	D.10.7.1.r	親の構造化された情報（必要に応じ繰り返す）				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='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']]

e	D.10.7.1.r.1a	親の関連する治療歴及び随伴症状の MedDRA バージョン	4AN	Concept Descriptor (CD)	codeSystemVersion=Character String (ST)	値	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/player1[@classCode='PSN'][@determinerCode='INSTANCE']/role[@classCode='PRS'][1]/subjectOf2[@typeCode='SBJ'][organizer/code[@code='1'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][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

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e	D.10.7.1.r.3	継続	ブール型	Boolean (BL)		値	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/player1[@classCode='PSN'][@determinerCode='INSTANCE']/role[@classCode='PRS'][1]/subjectOf2[@typeCode='SBJ'][organizer/code[@code='1'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][observation/code[@codeSystem='2.16.840.1.113883.6.163']][r]/observation[@classCode='OBS'][@moodCode='EVN']/inboundRelationship[@typeCode='REFR'][observation/code[@code='13'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']][1]/observation[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='BL'][1]/@value
e	D.10.7.1.r.4	終了日	日付／時間	Interval of Point in Time (IVL<TS>)	high=Interval Boundary (IVXB)	値	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/player1[@classCode='PSN'][@determinerCode='INSTANCE']/role[@classCode='PRS'][1]/subjectOf2[@typeCode='SBJ'][organizer/code[@code='1'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][observation/code[@codeSystem='2.16.840.1.113883.6.163']][r]/observation[@classCode='OBS'][@moodCode='EVN']/effectiveTime[@xsi:type='IVL_TS']/high/@value
e						NullFlavor	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/player1[@classCode='PSN'][@determinerCode='INSTANCE']/role[@classCode='PRS'][1]/subjectOf2[@typeCode='SBJ'][organizer/code[@code='1'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][observation/code[@codeSystem='2.16.840.1.113883.6.163']][r]/observation[@classCode='OBS'][@moodCode='EVN']/effectiveTime[@xsi:type='IVL_TS']/high/@nullFlavor
e	D.10.7.1.r.5	備考	2000AN	Encapsulated Data (ED)		値	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/player1[@classCode='PSN'][@determinerCode='INSTANCE']/role[@classCode='PRS'][1]/subjectOf2[@typeCode='SBJ'][organizer/code[@code='1'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][observation/code[@codeSystem='2.16.840.1.113883.6.163']][r]/observation[@classCode='OBS'][@moodCode='EVN']/outboundRelationship2[@typeCode='COMP'][observation/code[@code='10'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']][1]/observation[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='ED'][1]/text()

e	D.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	D.10.8.r.2b	医薬品製品識別子（MPID）	M5 ガイドラインを参照	Coded With Equivalents (CE)	code=Character String (ST)	値	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/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']/@code
e	D.10.8.r.3a	PhPID バージョン日付／番号	M5 ガイドラインを参照	Coded With Equivalents (CE)	codeSystemVersion= Character String (ST)	値	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/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-PhPID']/@codeSystemVersion
e	D.10.8.r.3b	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']/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-PhPID']/@code
e	D.10.8.r.4	開始日	日付／時間	Interval of Point in Time (IVL<TS>)	low=Interval Boundary (IVXB)	値	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/player1[@classCode='PSN'][@determinerCode='INSTANCE']/role[@classCode='PRS'][1]/subjectOf2[@typeCode='SBJ'][organizer/code[@code='2'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][substanceAdministration][r]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/effectiveTime[@xsi:type='IVL_TS']/low/@value

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e						NullFlavor	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3. MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/player1[@classCode='PSN'][@determinerCode='INSTANCE']/role[@classCode='PRS'][1]/subjectOf2[@typeCode='SBJ'][organizer/code[@code='2'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][substanceAdministration][r]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/effectiveTime[@xsi:type='IVL_TS']/low/@nullFlavor
e	D.10.8.r.5	終了日	日付／時間	Interval of Point in Time (IVL<TS>)	high=Interval Boundary (IVXB)	値	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/player1[@classCode='PSN'][@determinerCode='INSTANCE']/role[@classCode='PRS'][1]/subjectOf2[@typeCode='SBJ'][organizer/code[@code='2'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][substanceAdministration][r]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/effectiveTime[@xsi:type='IVL_TS']/high/@value
e						NullFlavor	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/player1[@classCode='PSN'][@determinerCode='INSTANCE']/role[@classCode='PRS'][1]/subjectOf2[@typeCode='SBJ'][organizer/code[@code='2'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][substanceAdministration][r]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/effectiveTime[@xsi:type='IVL_TS']/high/@nullFlavor
e	D.10.8.r.6a	使用理由の MedDRA 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']/player1[@classCode='PSN'][@determinerCode='INSTANCE']/role[@classCode='PRS'][1]/subjectOf2[@typeCode='SBJ'][organizer/code[@code='2'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][substanceAdministration][r]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/outboundRelationship2[@typeCode='RSON'][observation/code[@code='19'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']][1]/observation[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='CE'][@codeSystem='2.16.840.1.113883.6.163'][1]/@codeSystemVersion

e	D.10.8.r.6b	使用理由（MedDRA コード）	8N	Coded With Equivalents (CE)	code=Character String (ST)	値	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/player1[@classCode='PSN'][@determinerCode='INSTANCE']/role[@classCode='PRS'][1]/subjectOf2[@typeCode='SBJ'][organizer/code[@code='2'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][substanceAdministration][r]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/outboundRelationship2[@typeCode='RSON'][observation/code[@code='19'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']][1]/observation[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='CE'][@codeSystem='2.16.840.1.113883.6.163'][1]/@code
e	D.10.8.r.7a	副作用の MedDRA バージョン	4AN	Coded With Equivalents (CE)	codeSystemVersion= Character String (ST)	値	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/player1[@classCode='PSN'][@determinerCode='INSTANCE']/role[@classCode='PRS'][1]/subjectOf2[@typeCode='SBJ'][organizer/code[@code='2'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][substanceAdministration][r]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/outboundRelationship2[@typeCode='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.10.8.r.7b	副作用（MedDRA コード）	8N	Coded With Equivalents (CE)	code=Character String (ST)	値	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/player1[@classCode='PSN'][@determinerCode='INSTANCE']/role[@classCode='PRS'][1]/subjectOf2[@typeCode='SBJ'][organizer/code[@code='2'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][substanceAdministration][r]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/outboundRelationship2[@typeCode='CAUS'][observation/code[@code='29'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']][1]/observation[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='CE'][@codeSystem='2.16.840.1.113883.6.163'][1]/@code
h	E.i	副作用／有害事象（必要に応じ繰り返す）				繰り返しノード	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][observation[id]/code[@code='29'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']]]
h	E.i.1	第一次情報源により報告された副作用／有害事象					

e	E.i.1.1a	母国語で記載された、第一次情報源により報告された副作用／有害事象	250AN	Coded With Equivalents (CE)	originalText = Encapsulated Data (ED)	値	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][observation[id][code[@code='29'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']]][i]/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／有害事象の営語	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']]][i]/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']]][i]/observation[@classCode='OBS'][@moodCode='EVN']/outboundRelationship2[@typeCode='PERT'][observation/code[@code='30'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']][1]/observation[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='ED'][1]/text()
e	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']]][i]/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']]][i]/observation[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='CE'][@codeSystem='2.16.840.1.113883.6.163'][1]/@code

e	E.i.3.1	報告者によって重要とされた副作用／有害事象	1N	Coded With Equivalents (CE)	code=Character String (ST)	値	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ']/observation[id][code[@code='29'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']]][i]/observation[@classCode='OBS'][@moodCode='EVN']/outboundRelationship2[@typeCode='PERT'][observation/code[@code='37'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']][1]/observation[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='CE'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.10'][1]/@code
		報告者によって重要とされた副作用／有害事象に関する ICH コードリストのバージョン					/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][observation[id][code[@code='29'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']]][i]/observation[@classCode='OBS'][@moodCode='EVN']/outboundRelationship2[@typeCode='PERT'][observation/code[@code='37'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']][1]/observation[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='CE'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.10'][1]/@codeSystemVersion
h	E.i.3.2	有害事象ごとの重篤性の基準					
e	E.i.3.2a	死に至るもの	ブール型	Boolean (BL)		値	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][observation[id][code[@code='29'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']]][i]/observation[@classCode='OBS'][@moodCode='EVN']/outboundRelationship2[@typeCode='PERT'][observation/code[@code='34'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']][1]/observation[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='BL'][1]/@value
e						NullFlavor	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][observation[id][code[@code='29'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']]][i]/observation[@classCode='OBS'][@moodCode='EVN']/outboundRelationship2[@typeCode='PERT'][observation/code[@code='34'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']][1]/observation[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='BL'][1]/@nullFlavor

e	E.i.3.2b	生命を脅かすもの	ブール型	Boolean (BL)		値	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][observation[id][code[@code='29'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']]][i]/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']]][i]/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']]][i]/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']]][i]/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']]][i]/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

ICH ICSR 技術的情報

2014 年 11 月 10 日

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']]][i]/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]/@nullFlavor
e	E.i.3.2e	先天異常を来すもの	ブール型	Boolean (BL)		値	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][observation[id][code[@code='29'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']]][i]/observation[@classCode='OBS'][@moodCode='EVN']/outboundRelationship2[@typeCode='PERT'][observation/code[@code='12'][@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']]][i]/observation[@classCode='OBS'][@moodCode='EVN']/outboundRelationship2[@typeCode='PERT'][observation/code[@code='12'][@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.3.2f	その他の医学的に重要な状態	ブール型	Boolean (BL)		値	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][observation[id][code[@code='29'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']]][i]/observation[@classCode='OBS'][@moodCode='EVN']/outboundRelationship2[@typeCode='PERT'][observation/code[@code='26'][@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']]][i]/observation[@classCode='OBS'][@moodCode='EVN']/outboundRelationship2[@typeCode='PERT'][observation/code[@code='26'][@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.4	副作用／有害事象の発現日	日付／時間	1.E.i.4、E.i.5 及び E.i.6 のすべての項目が表示されない場合 HL7 データ型: Interval of Point in Time (IVL<TS>)	1.E.i.4、E.i.5 及び E.i.6 のすべての項目が表示されない場合 low=Interval Boundary (IVXB)	値	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][observation[id][code[@code='29'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']]][i]/observation[@classCode='OBS'][@moodCode='EVN']/effectiveTime[@xsi:type='IVL_TS']/low/@value
e						NullFlavor	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][observation[id][code[@code='29'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']]][i]/observation[@classCode='OBS'][@moodCode='EVN']/effectiveTime[@xsi:type='IVL_TS']/low/@nullFlavor
e				2.E.i.4、E.i.5 及び E.i.6 のすべての項目が表示される場合 データ型 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='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][observation[id][code[@code='29'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']]][i]/observation[@classCode='OBS'][@moodCode='EVN']/effectiveTime[@xsi:type='SXPR_TS']/comp[@xsi:type='IVL_TS']/low/@value
e						NullFlavor	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][observation[id][code[@code='29'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']]][i]/observation[@classCode='OBS'][@moodCode='EVN']/effectiveTime[@xsi:type='SXPR_TS']/comp[@xsi:type='IVL_TS']/low/@nullFlavor

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				3.E.i.4、E.i.5 及び E.i.6 のすべての項目が表示される場合 データ型 SXPR を伴う2番目の comp 項目 HL7 データ型：Parenthetic Set Expression of Point in Time (SXPR<TS>)	3.E.i.4、E.i.5 及び E.i.6 のすべての項目が表示される場合 データ型 SXPR を伴う2番目の comp 項目 comp/low=Interval Boundary (IVXB)	値	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ']/observation[id][code[@code='29'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']]]][i]/observation[@classCode='OBS'][@moodCode='EVN']/effectiveTime[@xsi:type='SXPR_TS']/comp[@xsi:type='IVL_TS'][@operator='A']/low/@value
						NullFlavor	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ']/observation[id][code[@code='29'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']]]][i]/observation[@classCode='OBS'][@moodCode='EVN']/effectiveTime[@xsi:type='SXPR_TS']/comp[@xsi:type='IVL_TS'][@operator='A']/low/@nullFlavor
e	E.i.5	副作用／有害事象の終了日	日付／時間	1.E.i.4、E.i.5 及び E.i.6 のすべての項目が表示されない場合 HL7 データ型:Interval of Point in Time (IVL<TS>)	1.E.i.4、E.i.5 及び E.i.6 のすべての項目が表示されない場合 high=Interval Boundary (IVXB)	値	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ']/observation[id][code[@code='29'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']]]][i]/observation[@classCode='OBS'][@moodCode='EVN']/effectiveTime[@xsi:type='IVL_TS']/high/@value
e						NullFlavor	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ']/observation[id][code[@code='29'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']]]][i]/observation[@classCode='OBS'][@moodCode='EVN']/effectiveTime[@xsi:type='IVL_TS']/high/@nullFlavor

e				2.E.i.4、E.i.5 及び E.i.6 のすべての項目が表示される場合 データ型 SXPR を伴う最初の comp 項目 HL7 データ型： Parenthetic Set Expression of Point in Time (SXPR<TS>)	2.E.i.4、E.i.5 及び E.i.6 のすべての項目が表示される場合 データ型 SXPR を伴う最初の comp 項目 comp/high=Interval Boundary (IVXB)	値	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][observation[id][code[@code='29'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']]][i]/observation[@classCode='OBS'][@moodCode='EVN']/effectiveTime[@xsi:type='SXPR_TS']/comp[@xsi:type='IVL_TS']/high/@value
e						NullFlavor	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][observation[id][code[@code='29'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']]][i]/observation[@classCode='OBS'][@moodCode='EVN']/effectiveTime[@xsi:type='SXPR_TS']/comp[@xsi:type='IVL_TS']/high/@nullFlavor
				3.E.i.4、E.i.5 及び E.i.6 のすべての項目が表示される場合 データ型 SXPR を伴う 2 番目の comp 項目 HL7 データ型： Parenthetic Set Expression of Point in Time (SXPR<TS>)	3.E.i.4、E.i.5 及び E.i.6 のすべての項目が表示される場合 データ型 SXPR を伴う 2 番目の comp 項目 comp/high=Interval Boundary (IVXB)	値	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][observation[id][code[@code='29'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']]][i]/observation[@classCode='OBS'][@moodCode='EVN']/effectiveTime[@xsi:type='SXPR_TS']/comp[@xsi:type='IVL_TS'][@operator='A']/high/@value
						NullFlavor	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][observation[id][code[@code='29'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']]][i]/observation[@classCode='OBS'][@moodCode='EVN']/effectiveTime[@xsi:type='SXPR_TS']/comp[@xsi:type='IVL_TS'][@operator='A']/high/@nullFlavor

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e	E.i.6a	副作用／有害事象の持続期間（数）	5N	1.E.i.4、E.i.5 及び E.i.6 のすべての項目が表示されない場合 HL7 データ型: Interval of Point in Time (IVL<TS>)	1.E.i.4、E.i.5 及び E.i.6 のすべての項目が表示されない場合 width/value=Real Number (REAL)	値	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][observation[id][code[@code='29'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']]][i]/observation[@classCode='OBS'][@moodCode='EVN']/effectiveTime[@xsi:type='IVL_TS']/width/@value
e				2.E.i.4、E.i.5 及び E.i.6 のすべての項目が表示される場合 データ型 SXPR を伴う最初の comp 項目 HL7 データ型： Parenthetic Set Expression of Point in Time (SXPR<TS>)	2.E.i.4、E.i.5 及び E.i.6 のすべての項目が表示される場合 データ型 SXPR を伴う最初の comp 項目 comp/width/value= Real Number (REAL)	値	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][observation[id][code[@code='29'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']]][i]/observation[@classCode='OBS'][@moodCode='EVN']/effectiveTime[@xsi:type='SXPR_TS']/comp[@xsi:type='IVL_TS']/width/@value
e				3.E.i.4、E.i.5 及び E.i.6 のすべての項目が表示される場合 データ型 SXPR を伴う 2番目の comp 項目 HL7 データ型： Parenthetic Set Expression of Point in Time (SXPR<TS>)	3.E.i.4、E.i.5 及び E.i.6 のすべての項目が表示される場合 データ型 SXPR を伴う 2番目の comp 項目 comp/width/value= Real Number (REAL)	値	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][observation[id][code[@code='29'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']]][i]/observation[@classCode='OBS'][@moodCode='EVN']/effectiveTime[@xsi:type='SXPR_TS']/comp[@xsi:type='IVL_TS'][@operator='A']/width/@value
e	E.i.6b	副作用／有害事象の持続期間（単位）	50AN	1.E.i.4、E.i.5 及び E.i.6 のすべての項目が表示されない場合 HL7 データ型: Interval of Point in Time (IVL<TS>)	1.E.i.4、E.i.5 及び E.i.6 のすべての項目が表示されない場合 width/unit=Coded Simple Value (CS)	値	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][observation[id][code[@code='29'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']]][i]/observation[@classCode='OBS'][@moodCode='EVN']/effectiveTime[@xsi:type='IVL_TS']/width/@unit

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						値	
e				2.E.i.4、E.i.5 及び E.i.6 のすべての項目が表示される場合 データ型 SXPR を伴う最初の comp 項目 HL7 データ型：Parenthetic Set Expression of Point in Time (SXPR<TS>)	2.E.i.4、E.i.5 及び E.i.6 のすべての項目が表示される場合データ型 SXPR を伴う最初の comp 項目 comp/width/unit=Coded Simple Value (CS)	値	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ']/observation[id][code[@code='29'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']]][i]/observation[@classCode='OBS'][@moodCode='EVN']/effectiveTime[@xsi:type='SXPR_TS']/comp[@xsi:type='IVL_TS']/width/@unit
				3.E.i.4、E.i.5 及び E.i.6 のすべての項目が表示される場合 データ型 SXPR を伴う 2 番目の comp 項目 HL7 データ型：Parenthetic Set Expression of Point in Time (SXPR<TS>)	3.E.i.4、E.i.5 及び E.i.6 のすべての項目が表示される場合 データ型 SXPR を伴う 2 番目の comp 項目 comp/width/unit=Coded Simple Value (CS)	値	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ']/observation[id][code[@code='29'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']]][i]/observation[@classCode='OBS'][@moodCode='EVN']/effectiveTime[@xsi:type='SXPR_TS']/comp[@xsi:type='IVL_TS'][@operator='A']/width/@unit
e	E.i.7	最終観察時の副作用／有害事象の転帰	1N	Coded With Equivalents (CE)	code=Character String (ST)	値	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ']/observation[id][code[@code='29'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']]][i]/observation[@classCode='OBS'][@moodCode='EVN']/outboundRelationship2[@typeCode='PERT'][observation/code[@code='27'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']][1]/observation[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='CE'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.11'][1]/@code
		最終観察時の副作用／有害事象の転帰の ICH コードリストのバージョン					/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ']/observation[id][code[@code='29'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']]][i]/observation[@classCode='OBS'][@moodCode='EVN']/outboundRelationship2[@typeCode='PERT'][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	E.i.8	医療専門家による医学的確認	ブール型	Boolean (BL)		値	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][observation[id][code[@code='29'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']]][i]/observation[@classCode='OBS'][@moodCode='EVN']/outboundRelationship2[@typeCode='PERT'][observation/code[@code='24'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']][1]/observation[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='BL']/@value
e	E.i.9	副作用／有害事象が発現した国の識別	2A	Concept Descriptor (CD)	code=Character String (ST)	値	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][observation[id][code[@code='29'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']]][i]/observation[@classCode='OBS'][@moodCode='EVN']/location[@typeCode='LOC'][1]/locatedEntity[@classCode='LOCE']/locatedPlace[@classCode='COUNTRY'][@determinerCode='INSTANCE']/code[@codeSystem='1.0.3166.1.2.2']/@code
h	F.r	患者の診断に関連する検査及び処置の結果（必要に応じ繰り返す）				繰り返しノード	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][organizer/code[@code='3'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][observation/code[@codeSystem='2.16.840.1.113883.6.163']]
e	F.r.1	日付（検査）	日付／時間	Point in Time (TS)		値	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][organizer/code[@code='3'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][observation/code[@codeSystem='2.16.840.1.113883.6.163']][r]/observation[@classCode='OBS'][@moodCode='EVN']/effectiveTime/@value
e						NullFlavor	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][organizer/code[@code='3'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][observation/code[@codeSystem='2.16.840.1.113883.6.163']][r]/observation[@classCode='OBS'][@moodCode='EVN']/effectiveTime/@nullFlavor
h	F.r.2	検査名					

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

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e	F.r.3.2	検査結果（値／限定子）	50N	Interval of Physical Quantity (IVL<PQ>)	1.EQ center=Physical Quantity (PQ)	値	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/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/@value
e					2.GT low=Interval Boundary (IVXB)	値	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][organizer/code[@code='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']/@value
e					3.GE low=Interval Boundary (IVXB)	値	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][organizer/code[@code='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']/@value
e					4.LT high=Interval Boundary (IVXB)	値	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][organizer/code[@code='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']/@value
e					5.LEhigh=Interval Boundary (IVXB)	値	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][organizer/code[@code='3'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][observation/code[@codeSystem='2.16.840.1.113883.6.163']][r]/observation[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='IVL_PQ'][low/@nullFlavor='NINF'][1]/high[@inclusive='true']/@value

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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					5.LE 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='true']/@unit
e	F.r.3.4	検査結果に関する非構造化データ（自由記載）	2000AN	Encapsulated Data (ED)		値	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='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='ED'][1]/text()
e	F.r.4	正常範囲　低値	50AN	Physical Quantity (PQ)	value=Real Number (REAL)	値	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='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']/referenceRange[@typeCode='REFV'][observationRange/interpretationCode[@code='L'][@codeSystem='2.16.840.1.113883.5.83']][1]/observationRange[@classCode='OBS'][@moodCode='EVN.CRT']/value[@xsi:type='PQ']/@value
e	F.r.5	正常範囲　高値	50AN	Physical Quantity (PQ)	value=Real Number (REAL)	値	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='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']/referenceRange[@typeCode='REFV'][observationRange/interpretationCode[@code='H'][@codeSystem='2.16.840.1.113883.5.83']][1]/observationRange[@classCode='OBS'][@moodCode='EVN.CRT']/value[@xsi:type='PQ']/@value

e	F.r.6	備考	2000AN	Encapsulated Data (ED)		値	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ']/organizer/code[@code='3'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][observation/code[@codeSystem='2.16.840.1.113883.6.163']][r]/observation[@classCode='OBS'][@moodCode='EVN']/outboundRelationship2[@typeCode='PERT'][observation/code[@code='10'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']]/observation[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='ED'][1]/text()
e	F.r.7	その他の情報	ブール型	Boolean (BL)		値	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ']/organizer/code[@code='3'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][observation/code[@codeSystem='2.16.840.1.113883.6.163']][r]/observation[@classCode='OBS'][@moodCode='EVN']/outboundRelationship2[@typeCode='REFR'][observation/code[@code='25'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']]/observation[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='BL'][1]/@value
h	G.k	医薬品情報（必要に応じ繰り返す）				繰り返しノード	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ']/organizer/code[@code='4'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][substanceAdministration/id]
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='2.16.840.1.113883.3.989.2.1.13']/@code

		医薬品関与の位置付けに関する ICH コードリストのバージョン					/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][causalityAssessment[@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']/@codeSystemVersion
h	G.k.2	医薬品の識別					
h	G.k.2.1	医薬品の固有識別子／製剤の固有識別子					
e	G.k.2.1.1a	MPID バージョン日付／番号	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'][@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']/code[@codeSystem='TBD-MPID']/@codeSystemVersion
e	G.k.2.1.1b	医薬品製品識別子（MPID）	M5 ガイドラインを参照	Coded With Equivalents (CE)	code=Character String (ST)	値	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/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']/code[@codeSystem='TBD-MPID']/@code
e	G.k.2.1.2a	PhPID バージョン日付／番号	M5 ガイドラインを参照	Coded With Equivalents (CE)	codeSystemVersion= Character String (ST)	値	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/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']/code[@codeSystem='TBD-PhPID']/@codeSystemVersion

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2014 年 11 月 10 日

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/id][k]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/consumable[@typeCode='CSM'][1]/instanceOfKind[@classCode='INST']/kindOfProduct[@classCode='MMAT'][@determinerCode='KIND']/code[@codeSystem='TBD-PhPID']/@code
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/id][k]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/consumable[@typeCode='CSM'][1]/instanceOfKind[@classCode='INST']/kindOfProduct[@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/id][k]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/consumable[@typeCode='CSM'][1]/instanceOfKind[@classCode='INST']/kindOfProduct[@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/id][k]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/consumable[@typeCode='CSM'][1]/instanceOfKind[@classCode='INST']/kindOfProduct[@classCode='MMAT'][@determinerCode='KIND']/ingredient[@classCode='ACTI'][r]/ingredientSubstance[@classCode='MMAT'][@determinerCode='KIND']/name[1]/text()

ICH ICSR 技術的情報

e	G.k.2.3.r.2a	成分／特定成分の 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'][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']/ingredient[@classCode='ACTI'][r]/ingredientSubstance[@classCode='MMAT'][@determinerCode='KIND']/code[@codeSystem='TBD-Substance']/@codeSystemVersion
e	G.k.2.3.r.2b	成分／特定成分の 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'][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']/ingredient[@classCode='ACTI'][r]/ingredientSubstance[@classCode='MMAT'][@determinerCode='KIND']/code[@codeSystem='TBD-Substance']/@code
e	G.k.2.3.r.3a	含量（数）	10N	Physical Quantity (PQ)	value=Real Number (REAL)	値	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@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']/ingredient[@classCode='ACTI'][r]/quantity[denominator/@value='1']/numerator/@value
e	G.k.2.3.r.3b	含量（単位）	50AN	Physical Quantity (PQ)	unit=Coded Simple Value (CS)	値	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@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']/ingredient[@classCode='ACTI'][r]/quantity[denominator/@value='1']/numerator/@unit

e	G.k.2.4	医薬品を入手した国の識別	2A	Postal Address (AD)	country=Address Part (ADXP)	値	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][organizer/code[@code='4'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][substanceAdministration/id][k]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/consumable[@typeCode='CSM'][1]/instanceOfKind[@classCode='INST']/subjectOf[@typeCode='SBJ'][1]/productEvent[@classCode='ACT'][@moodCode='EVN'][code[@code='1'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.18']]/performer[@typeCode='PRF']/assignedEntity[@classCode='ASSIGNED']/representedOrganization[@classCode='ORG'][@determinerCode='INSTANCE']/addr/country[1]/text()
e	G.k.2.5	治験薬の盲検状況	ブール型	Boolean (BL)		値	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][organizer/code[@code='4'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][substanceAdministration/id][k]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/outboundRelationship2[@typeCode='PERT'][observation/code[@code='6'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']][1]/observation[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='BL'][1]/@value
h	G.k.3	医薬品の承認の取得者及び承認／申請番号					
e	G.k.3.1	承認／申請番号	35AN	Instance Identifier (II)	extension=Character String (ST)	値	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][organizer/code[@code='4'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][substanceAdministration/id][k]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/consumable[@typeCode='CSM'][1]/instanceOfKind[@classCode='INST']/kindOfProduct[@classCode='MMAT'][@determinerCode='KIND']/asManufacturedProduct[@classCode='MANU']/subjectOf[@typeCode='SBJ'][1]/approval[@classCode='CNTRCT'][@moodCode='EVN']/id[@root='2.16.840.1.113883.3.989.2.1.3.4']/@extension

e	G.k.3.2	承認／申請国	2A	Coded With Equivalents (CE)	code=Character String (ST)	値	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][organizer/code[@code='4'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][substanceAdministration/id][k]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/consumable[@typeCode='CSM'][1]/instanceOfKind[@classCode='INST']/kindOfProduct[@classCode='MMAT'][@determinerCode='KIND']/asManufacturedProduct[@classCode='MANU']/subjectOf[@typeCode='SBJ'][1]/approval[@classCode='CNTRCT'][@moodCode='EVN']/author[@typeCode='AUT']/territorialAuthority[@classCode='TERR']/territory[@classCode='NAT'][@determinerCode='INSTANCE']/code[@codeSystem='1.0.3166.1.2.2']/@code
e	G.k.3.3	承認の取得者／申請者の名称	60AN	Organization Name (ON)	name=Entity Name Part (ENXP)	値	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][organizer/code[@code='4'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][substanceAdministration/id][k]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/consumable[@typeCode='CSM'][1]/instanceOfKind[@classCode='INST']/kindOfProduct[@classCode='MMAT'][@determinerCode='KIND']/asManufacturedProduct[@classCode='MANU']/subjectOf[@typeCode='SBJ'][1]/approval[@classCode='CNTRCT'][@moodCode='EVN']/holder[@typeCode='HLD'][1]/role[@classCode='HLD']/playingOrganization[@classCode='ORG'][@determinerCode='INSTANCE']/name/text()
h	G.k.4.r	投与量及び関連情報（必要に応じ繰り返す）				繰り返しノード	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][organizer/code[@code='4'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][substanceAdministration/id][k]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/outboundRelationship2[@typeCode='COMP'][substanceAdministration]
e	G.k.4.r.1a	投与量（数）	8N	Physical Quantity (PQ)	value=Real Number (REAL)	値	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][organizer/code[@code='4'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][substanceAdministration/id][k]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/outboundRelationship2[@typeCode='COMP'][substanceAdministration][r]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/doseQuantity/@value

ICH ICSR 技術的情報

2014 年 11 月 10 日

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

| e | G.k.4.r.2 | 投与間隔の単位数 | 4N | 1.以下のデータ項目の２つを超える値が表示される場合：

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

データ型 SXPR を伴う最初の comp 項目

Parenthetic Set Expression of Time (SXPR_TS) [Periodic Interval of Time (PIVL_TS)] | period/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']/effectiveTime[@xsi:type='SXPR_TS']/comp[@xsi:type='PIVL_TS']/period/@value |
| | | | | 2.以下のデータ項目の２つを超える値が表示される場合：

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

データ型 SXPR を伴う２番目の comp 項目

Parenthetic Set Expression of Time (SXPR_TS) [Periodic Interval of Time (PIVL_TS)] | | 値 | /MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][organizer/code[@code='4'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][substanceAdministration/id][k]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/outboundRelationship2[@typeCode='COMP'][substanceAdministration][r]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/effectiveTime[@xsi:type='SXPR_TS']/comp[@xsi:type='PIVL_TS'][@operator='A']/period/@value |

| e | | | | 3.以下のデータ項目の１つの値のみが表示される場合

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

Periodic Interval of Time (PIVL_TS) | period/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']/effectiveTime[@xsi:type='PIVL_TS']/period/@value |
| e | G.k.4.r.3 | 投与間隔の定義 | 50AN | 1.以下のデータ項目の２つの値が表示される場合

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

データ型 SXPR を伴う最初の comp 項目

Parenthetic Set Expression of Time (SXPR_TS)
[Periodic Interval of Time (PIVL_TS)] | period/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']/effectiveTime[@xsi:type='SXPR_TS']/comp[@xsi:type='PIVL_TS']/period/@unit |

			2.以下のデータ項目の２つを超える値が表示される場合： 1) G.k.4.r.2、G.k.4.r.3 2) G.k.4.r.4 3) G.k.4.r.5 4) G.k.4.r.6a、G.k.4.r.6b データ型 SXPR を伴う２番目の comp 項目 Parenthetic Set Expression of Time (SXPR_TS) [Periodic Interval of Time (PIVL_TS)]		値	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][organizer/code[@code='4'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][substanceAdministration/id][k]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/outboundRelationship2[@typeCode='COMP'][substanceAdministration][r]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/effectiveTime[@xsi:type='SXPR_TS']/comp[@xsi:type='PIVL_TS'][@operator='A']/period/@unit
e			3.以下のデータ項目の１つの値のみが表示される場合 1) G.k.4.r.2、G.k.4.r.3 2) G.k.4.r.4 3) G.k.4.r.5 4) G.k.4.r.6a、G.k.4.r.6b Periodic Interval of Time (PIVL_TS)	period/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']/effectiveTime[@xsi:type='PIVL_TS']/period/@unit

				1.以下のデータ項目の２つを超える値が表示される場合： 1) G.k.4.r.2、G.k.4.r.3 2) G.k.4.r.4 3) G.k.4.r.5 4) G.k.4.r.6a、G.k.4.r.6b データ型 SXPR を伴う最初の comp 項目 Parenthetic Set Expression of Time (SXPR_TS) [Intervale of Point in Time (IVL_TS)]			
e	G.k.4.r.4	医薬品の投与開始日	日付／時間		low=Interval Boundary (IVXB)	値	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][organizer/code[@code='4'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][substanceAdministration/id][k]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/outboundRelationship2[@typeCode='COMP'][substanceAdministration][r]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/effectiveTime[@xsi:type='SXPR_TS']/comp[@xsi:type='IVL_TS']/low/@value
e						NullFlavor	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][organizer/code[@code='4'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][substanceAdministration/id][k]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/outboundRelationship2[@typeCode='COMP'][substanceAdministration][r]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/effectiveTime[@xsi:type='SXPR_TS']/comp[@xsi:type='IVL_TS']/low/@nullFlavor

| | | | | | 2.以下のデータ項目の２つを超える値が表示される場合：

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

データ型 SXPR を伴う２番目の comp 項目

Parenthetic Set Expression of Time (SXPR_TS)
[Intervale of Point in Time (IVL_TS)] | | 値 | /MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][organizer/code[@code='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']/low/@value |
| | | | | | | | NullFlavor | /MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][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']/low/@nullFlavor |

ICH ICSR 技術的情報

2014 年 11 月 10 日

				3.以下のデータ項目の１つの値のみが表示される場合 1) G.k.4.r.2、G.k.4.r.3 2) G.k.4.r.4 3) G.k.4.r.5 4) G.k.4.r.6a、G.k.4.r.6b Interval of Point in Time (IVL_TS)	low=Interval Boundary (IVXB)	値	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][organizer/code[@code='4'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][substanceAdministration/id][k]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/outboundRelationship2[@typeCode='COMP'][substanceAdministration][r]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/effectiveTime[@xsi:type='IVL_TS']/low/@value
e						NullFlavor	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][organizer/code[@code='4'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][substanceAdministration/id][k]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/outboundRelationship2[@typeCode='COMP'][substanceAdministration][r]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/effectiveTime[@xsi:type='IVL_TS']/low/@nullFlavor
e	G.k.4.r.5	医薬品の投与終了日	日付／時間	1.以下のデータ項目の２つを超える値が表示される場合： 1) G.k.4.r.2、G.k.4.r.3 2) G.k.4.r.4 3) G.k.4.r.5 4) G.k.4.r.6a、G.k.4.r.6b データ型 SXPR を伴う最初の comp 項目 Parenthetic Set Expression of Time (SXPR_TS) [Intervale of Point in Time (IVL_TS)]	high=Interval Boundary (IVXB)	値	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][organizer/code[@code='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']/high/@value

e						NullFlavor	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ']/organizer/code[@code='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']/high/@nullFlavor
				2.以下のデータ項目の２つを超える値が表示される場合： 1) G.k.4.r.2、 G.k.4.r.3 2) G.k.4.r.4 3) G.k.4.r.5 4) G.k.4.r.6a、 G.k.4.r.6b データ型 SXPR を伴う２番目の comp 項目 Parenthetic Set Expression of Time (SXPR_TS) [Intervale of Point in Time (IVL_TS)]		値	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ']/organizer/code[@code='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']/high/@value
						NullFlavor	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ']/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']/high/@nullFlavor

				3.以下のデータ項目の１つの値のみが表示される場合 1) G.k.4.r.2、G.k.4.r.3 2) G.k.4.r.4 3) G.k.4.r.5 4) G.k.4.r.6a、G.k.4.r.6b Interval of Point in Time (IVL_TS)	high=Interval Boundary (IVXB)	値	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][organizer/code[@code='4'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][substanceAdministration/id][k]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/outboundRelationship2[@typeCode='COMP'][substanceAdministration][r]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/effectiveTime[@xsi:type='IVL_TS']/high/@value
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']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][organizer/code[@code='4'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][substanceAdministration/id][k]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/outboundRelationship2[@typeCode='COMP'][substanceAdministration][r]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/effectiveTime[@xsi:type='IVL_TS']/high/@nullFlavor
e	G.k.4.r.6a	医薬品投与期間（数）	5N	1.以下のデータ項目の２つを超える値が表示される場合： 1) G.k.4.r.2、G.k.4.r.3 2) G.k.4.r.4 3) G.k.4.r.5 4) G.k.4.r.6a、G.k.4.r.6b データ型 SXPR を伴う最初の comp 項目 Parenthetic Set Expression of Time (SXPR_TS) [Intervale of Point in Time (IVL_TS)]	width/value=Real Number (REAL)	値	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][organizer/code[@code='4'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][substanceAdministration/id][k]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/outboundRelationship2[@typeCode='COMP'][substanceAdministration][r]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/effectiveTime[@xsi:type='SXPR_TS']/comp[@xsi:type='IVL_TS']/width/@value

				2.以下のデータ項目の２つを超える値が表示される場合： 1) G.k.4.r.2、G.k.4.r.3 2) G.k.4.r.4 3) G.k.4.r.5 4) G.k.4.r.6a、G.k.4.r.6b データ型 SXPR を伴う２番目の comp 項目 Parenthetic Set Expression of Time (SXPR_TS) [Intervale of Point in Time (IVL_TS)]		値	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][organizer/code[@code='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/@value
e				3.以下のデータ項目の１つの値のみが表示される場合 1) G.k.4.r.2、G.k.4.r.3 2) G.k.4.r.4 3) G.k.4.r.5 4) G.k.4.r.6a、G.k.4.r.6b Interval of Point in Time (IVL_TS)	width/value=Real Number (REAL)	値	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][organizer/code[@code='4'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][substanceAdministration/id][k]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/outboundRelationship2[@typeCode='COMP'][substanceAdministration][r]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/effectiveTime[@xsi:type='IVL_TS']/width/@value

ICH ICSR 技術的情報

2014 年 11 月 10 日

| e | G.k.4.r.6b | 医薬品投与期間（単位） | 50AN | 1.以下のデータ項目の２つを超える値が表示される場合：

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

データ型 SXPR を伴う最初の comp 項目

Parenthetic Set Expression of Time (SXPR_TS)
[Intervale of Point in Time (IVL_TS)] | width/unit=Coded Simple Value (CS) | 値 | /MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ']/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 |
| | | | | 2.以下のデータ項目の２つを超える値が表示される場合：
1) G.k.4.r.2、G.k.4.r.3
2) G.k.4.r.4
3) G.k.4.r.5
4) G.k.4.r.6a、G.k.4.r.6b
データ型 SXPR を伴う２番目の comp 項目
Parenthetic Set Expression of Time (SXPR_TS)[Intervale of Point in Time (IVL_TS)] | | 値 | /MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ']/organizer/code[@code='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 |

e				3.以下のデータ項目の１つの値のみが表示される場合 1) G.k.4.r.2、G.k.4.r.3 2) G.k.4.r.4 3) G.k.4.r.5 4) G.k.4.r.6a、G.k.4.r.6b Interval of Point in Time (IVL_TS)	width/unit=Coded Simple Value (CS)	値	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][organizer/code[@code='4'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][substanceAdministration/id][k]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/outboundRelationship2[@typeCode='COMP'][substanceAdministration][r]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/effectiveTime[@xsi:type='IVL_TS']/width/@unit
e	G.k.4.r.7	バッチ／ロット番号	35AN	Character String (ST)		値	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][organizer/code[@code='4'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][substanceAdministration/id][k]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/outboundRelationship2[@typeCode='COMP'][substanceAdministration][r]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/consumable[@typeCode='CSM'][1]/instanceOfKind[@classCode='INST']/productInstanceInstance[@classCode='MMAT'][@determinerCode='INSTANCE']/lotNumberText/text()
e	G.k.4.r.8	投与量を表す記述情報	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='4'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][substanceAdministration/id][k]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/outboundRelationship2[@typeCode='COMP'][substanceAdministration][r]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/text/text()
h	G.k.4.r.9	医薬品剤形					
e	G.k.4.r.9.1	医薬品剤形（自由記載）	60AN	Coded With Equivalents (CE)	originalText=Encapsulated Data (ED)	値	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][organizer/code[@code='4'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][substanceAdministration/id][k]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/outboundRelationship2[@typeCode='COMP'][substanceAdministration][r]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/consumable[@typeCode='CSM'][1]/instanceOfKind[@classCode='INST']/kindOfProduct[@classCode='MMAT'][@determinerCode='KIND']/formCode[@codeSystem='TBD-DoseForm']/originalText/text()

e						NullFlavor	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][organizer/code[@code='4'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][substanceAdministration/id][k]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/outboundRelationship2[@typeCode='COMP'][substanceAdministration][r]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/consumable[@typeCode='CSM'][1]/instanceOfKind[@classCode='INST']/kindOfProduct[@classCode='MMAT'][@determinerCode='KIND']/formCode[@codeSystem='TBD-DoseForm']/originalText/@nullFlavor
e	G.k.4.r.9.2a	医薬品剤形の ID バージョン日付／番号	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'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][substanceAdministration/id][k]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/outboundRelationship2[@typeCode='COMP'][substanceAdministration][r]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/consumable[@typeCode='CSM'][1]/instanceOfKind[@classCode='INST']/kindOfProduct[@classCode='MMAT'][@determinerCode='KIND']/formCode[@codeSystem='TBD-DoseForm']/@codeSystemVersion
e	G.k.4.r.9.2b	医薬品剤形の ID	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/id][k]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/outboundRelationship2[@typeCode='COMP'][substanceAdministration][r]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/consumable[@typeCode='CSM'][1]/instanceOfKind[@classCode='INST']/kindOfProduct[@classCode='MMAT'][@determinerCode='KIND']/formCode[@codeSystem='TBD-DoseForm']/@code
h	G.k.4.r.10	投与経路					
e	G.k.4.r.10.1	投与経路（自由記載）	60AN	Coded With Equivalents (CE)	originalText=Encapsulated Data (ED)	値	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][organizer/code[@code='4'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][substanceAdministration/id][k]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/outboundRelationship2[@typeCode='COMP'][substanceAdministration][r]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/routeCode[@codeSystem='2.16.840.1.113883.3.989.2.1.1.14']/originalText/text()

e						NullFlavor	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moo dCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCo de='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment [@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classC ode='INVSBJ']/subjectOf2[@typeCode='SBJ']/organizer/code[@code='4'][@codeSystem='2.16.840.1 .113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][substanceAdministration/id][k]/substanceAdministration[@classCode='SBADM '][@moodCode='EVN']/outboundRelationship2[@typeCode='COMP'][substanceAdministration][r]/sub stanceAdministration[@classCode='SBADM'][@moodCode='EVN']/routeCode[@codeSystem='2.16. 840.1.113883.3.989.2.1.1.14']/originalText/@nullFlavor
e	G.k.4.r.10.2a	投与経路の ID バージョン日付／番号	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'][@moo dCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCo de='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment [@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classC ode='INVSBJ']/subjectOf2[@typeCode='SBJ']/organizer/code[@code='4'][@codeSystem='2.16.840.1 .113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][substanceAdministration/id][k]/substanceAdministration[@classCode='SBADM '][@moodCode='EVN']/outboundRelationship2[@typeCode='COMP'][substanceAdministration][r]/sub stanceAdministration[@classCode='SBADM'][@moodCode='EVN']/routeCode[@codeSystem='2.16. 840.1.113883.3.989.2.1.1.14']/@codeSystemVersion
e	G.k.4.r.10.2b	投与経路の ID	M5 ガイドライン（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'][@moo dCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCo de='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment [@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classC ode='INVSBJ']/subjectOf2[@typeCode='SBJ']/organizer/code[@code='4'][@codeSystem='2.16.840.1 .113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][substanceAdministration/id][k]/substanceAdministration[@classCode='SBADM '][@moodCode='EVN']/outboundRelationship2[@typeCode='COMP'][substanceAdministration][r]/sub stanceAdministration[@classCode='SBADM'][@moodCode='EVN']/routeCode[@codeSystem='2.16. 840.1.113883.3.989.2.1.1.14']/@code
h	G.k.4.r.11	親への投与経路（親―子／胎児報告の場合）					
e	G.k.4.r.11.1	親への投与経路（自由記載）	60AN	Coded With Equivalents (CE)	originalText=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'][@moo dCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCo de='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment [@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classC ode='INVSBJ']/subjectOf2[@typeCode='SBJ']/organizer/code[@code='4'][@codeSystem='2.16.840.1 .113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][substanceAdministration/id][k]/substanceAdministration[@classCode='SBADM '][@moodCode='EVN']/outboundRelationship2[@typeCode='COMP'][substanceAdministration][r]/sub stanceAdministration[@classCode='SBADM'][@moodCode='EVN']/inboundRelationship[@typeCode ='REFR'][observation/code[@code='28'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']][1]/obse rvation[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='CE'][@codeSystem='2.16.840.1. 113883.3.989.2.1.1.14'][1]/originalText/text()

e						NullFlavor	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][organizer/code[@code='4'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][substanceAdministration/id][k]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/outboundRelationship2[@typeCode='COMP'][substanceAdministration][r]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/inboundRelationship[@typeCode='REFR'][observation/code[@code='28'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']][1]/observation[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='CE'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.14'][1]/originalText/@nullFlavor
e	G.k.4.r.11.2a	親への投与経路の ID バージョン日付／番号	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'][@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'][@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'][@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'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']][1]/observation[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='CE'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.14'][1]/@code
e	G.k.5a	副作用／有害事象発現までの累積総投与量（数）	10N	Physical Quantity (PQ)	value=Real Number (REAL)	値	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][organizer/code[@code='4'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][substanceAdministration/id][k]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/outboundRelationship2[@typeCode='SUMM'][observation/code[@code='14'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']][1]/observation[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='PQ'][1]/@value

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e	G.k.5b	副作用／有害事象発現までの累積総投与量（単位）	50AN	Physical Quantity (PQ)	unit=Coded Simple Value (CS)	値	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][organizer/code[@code='4'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][substanceAdministration/id][k]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/outboundRelationship2[@typeCode='SUMM'][observation/code[@code='14'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']][1]/observation[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='PQ'][1]/@unit
e	G.k.6a	曝露時の妊娠期間（数）	3N	Physical Quantity (PQ)	value=Real Number (REAL)	値	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][organizer/code[@code='4'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][substanceAdministration/id][k]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/outboundRelationship2[@typeCode='PERT'][observation/code[@code='16'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']][1]/observation[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='PQ'][1]/@value
e	G.k.6b	曝露時の妊娠期間（単位）	50AN	Physical Quantity (PQ)	unit=Coded Simple Value (CS)	値	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][organizer/code[@code='4'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][substanceAdministration/id][k]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/outboundRelationship2[@typeCode='PERT'][observation/code[@code='16'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']][1]/observation[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='PQ'][1]/@unit
h	G.k.7.r	医薬品使用理由（必要に応じ繰り返す）				繰り返しノード	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][organizer/code[@code='4'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][substanceAdministration/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']]

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e	G.k.7.r.1	第一次情報源により報告された使用理由	250AN	Coded With Equivalents (CE)	originalText=Encapsulated Data (ED)	値	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][organizer/code[@code='4'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][substanceAdministration/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='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][organizer/code[@code='4'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][substanceAdministration/id][k]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/inboundRelationship[@typeCode='RSON'][observation/code[@code='19'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']][r]/observation[@classCode='OBS'][@moodCode='EVN'][performer[@typeCode='PRF']/assignedEntity[@classCode='ASSIGNED']/code[@code='3'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.21']][1]/value[@xsi:type='CE'][@codeSystem='2.16.840.1.113883.6.163'][1]/originalText/@nullFlavor
e	G.k.7.r.2a	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='4'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][substanceAdministration/id][k]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/inboundRelationship[@typeCode='RSON'][observation/code[@code='19'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']][r]/observation[@classCode='OBS'][@moodCode='EVN'][performer[@typeCode='PRF']/assignedEntity[@classCode='ASSIGNED']/code[@code='3'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.21']][1]/value[@xsi:type='CE'][@codeSystem='2.16.840.1.113883.6.163'][1]/@codeSystemVersion

e	G.k.7.r.2b	使用理由（MedDRA コード）	8N	Coded With Equivalents (CE)	code=Character String (ST)	値	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][organizer/code[@code='4'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][substanceAdministration/id][k]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/inboundRelationship[@typeCode='RSON'][observation/code[@code='19'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']][r]/observation[@classCode='OBS'][@moodCode='EVN'][performer[@typeCode='PRF']/assignedEntity[@classCode='ASSIGNED']/code[@code='3'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.21']][1]/value[@xsi:type='CE'][@codeSystem='2.16.840.1.113883.6.163'][1]/@code
e	G.k.8	医薬品に対して取られた処置	1N	Concept Descriptor (CD)	code=Character String (ST)	値	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][organizer/code[@code='4'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][substanceAdministration/id][k]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/inboundRelationship[@typeCode='CAUS'][act/code[@codeSystem='2.16.840.1.113883.3.989.2.1.1.15']][1]/act[@classCode='ACT'][@moodCode='EVN']/code[@codeSystem='2.16.840.1.113883.3.989.2.1.1.15']/@code
		医薬品に対して取られた処置に関する ICH コードリストのバージョン					/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][organizer/code[@code='4'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][substanceAdministration/id][k]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/inboundRelationship[@typeCode='CAUS'][act/code[@codeSystem='2.16.840.1.113883.3.989.2.1.1.15']][1]/act[@classCode='ACT'][@moodCode='EVN']/code[@codeSystem='2.16.840.1.113883.3.989.2.1.1.15']/@codeSystemVersion
h	G.k.9.i	医薬品と副作用／有害事象のマトリックス（必要に応じ繰り返す）					
e	G.k.9.i.1	評価対象の副作用／有害事象	N/A			値	
h	G.k.9.i.2.r	医薬品と副作用／有害事象の因果関係（必要に応じ繰り返す）				繰り返しノード	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][causalityAssessment[code[@code='39'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']][subject1[@typeCode='SUBJ']/adverseEffectReference[@classCode='OBS'][@moodCode='EVN']/id[@root='UUID of i-th reaction']][subject2[@typeCode='SUBJ']/productUseReference[@classCode='SBADM'][@moodCode='EVN']/id[@root='UUID of k-th drug']]]

e	G.k.9.i.2.r.1	評価の情報源	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'][@moo dCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCo de='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment [@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][causalityAssessme nt/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[@cla ssCode='OBS'][@moodCode='EVN']/id[@root='UUID of i-th reaction']][subject2[@typeCode='SUBJ']/productUseReference[@classCode='SBADM'][@moodCod e='EVN']/id[@root='UUID of k-th drug']]/author[@typeCode='AUT'][1]/assignedEntity[@classCode='ASSIGNED']/code/originalText/tex t()
e	G.k.9.i.2.r.2	評価方法	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'][@moo dCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCo de='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment [@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][causalityAssessme nt/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[@cla ssCode='OBS'][@moodCode='EVN']/id[@root='UUID of i-th reaction']][subject2[@typeCode='SUBJ']/productUseReference[@classCode='SBADM'][@moodCod e='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'][@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']/component[@typeCode='COMP'][causalityAssessme nt/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[@cla ssCode='OBS'][@moodCode='EVN']/id[@root='UUID of i-th reaction']][subject2[@typeCode='SUBJ']/productUseReference[@classCode='SBADM'][@moodCod e='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'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moo dCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCo de='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment [@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classC ode='INVSBJ']/subjectOf2[@typeCode='SBJ']/organizer[@classCode='CATEGORY'][@moodCode=' EVN'][code[@code='4'][@codeSystem='2.16.840.1.113883.3.989.2.1.20']][1]/component[@typeCo de='COMP'][substanceAdministration/id][k]/substanceAdministration[@classCode='SBADM'][@moo dCode='EVN']/outboundRelationship1[@typeCode='SAS'][actReference[@classCode='OBS'][@moo dCode='EVN']/id[@root='UUID of i-th reaction']]/pauseQuantity/@value

e	G.k.9.i.3.1b	医薬品の投与開始から副作用／有害事象発現までの時間間隔（単位）	50AN	Physical Quantity (PQ)	unit=Coded Simple Value (CS)	値	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ']/organizer[@classCode='CATEGORY'][@moodCode='EVN'][code[@code='4'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/component[@typeCode='COMP'][substanceAdministration/id][k]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/outboundRelationship1[@typeCode='SAS'][actReference[@classCode='OBS'][@moodCode='EVN']/id[@root='UUID of i-th reaction']]/pauseQuantity/@unit
e	G.k.9.i.3.2a	医薬品の最終投与から副作用／有害事象発現までの時間間隔（数）	5N	Physical Quantity (PQ)	value=Real Number (REAL)	値	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ']/organizer[@classCode='CATEGORY'][@moodCode='EVN'][code[@code='4'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/component[@typeCode='COMP'][substanceAdministration/id][k]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/outboundRelationship1[@typeCode='SAE'][actReference[@classCode='OBS'][@moodCode='EVN']/id[@root='UUID of i-th reaction']]/pauseQuantity/@value
e	G.k.9.i.3.2b	医薬品の最終投与から副作用／有害事象発現までの時間間隔（単位）	50AN	Physical Quantity (PQ)	unit=Coded Simple Value (CS)	値	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ']/organizer[@classCode='CATEGORY'][@moodCode='EVN'][code[@code='4'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/component[@typeCode='COMP'][substanceAdministration/id][k]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/outboundRelationship1[@typeCode='SAE'][actReference[@classCode='OBS'][@moodCode='EVN']/id[@root='UUID of i-th reaction']]/pauseQuantity/@unit
e	G.k.9.i.4	再投与で副作用は再発したか？	1N	Coded With Equivalents (CE)	code=Character String (ST)	値	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ']/organizer[@classCode='CATEGORY'][@moodCode='EVN'][code[@code='4'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][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]/@code

		再投与で副作用は再発したか？に関する ICH コードリストのバージョン					/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ']/organizer[@classCode='CATEGORY'][@moodCode='EVN'][code[@code='4'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][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]/@codeSystemVerison
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='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='REFR'][observation/code[@code='9'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']][r]/observation[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='CE'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.17'][1]/@code
		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='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='REFR'][observation/code[@code='9'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']][r]/observation[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='CE'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.17'][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='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='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)		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='REFR'][observation/code[@code='2'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']][1]/observation[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='ST'][1]/text()
h	H	症例概要及びその他の情報の記述					
e	H.1	臨床経過、治療処置、転帰及びその他の関連情報を含む症例の記述情報	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']/text/text()
e	H.2	報告者の意見	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='3'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.21']]][1]/observationEvent[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='ED']/text()
h	H.3.r	送信者による診断名（必要に応じ繰り返す）				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']/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']]]
e	H.3.r.1a	送信者による診断名／症候群及び／又は副作用／有害事象の再分類の MedDRA バージョン	4AN	Coded With Equivalents (CE)	codeSystemVersion= Character String (ST)	値	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@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']/@codeSystemVersion

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']/text()
h	H.5.r	母国語で記載された症例概要及び報告者の意見（必要に応じ繰り返す）				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'][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='2.16.840.1.113883.2.989.2.1.1.21']]]
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='2.16.840.1.113883.2.1.1.21']]][r]/observationEvent[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='ED']/@language

h：ヘッダ e：エンティティ	フィールド番号	フィールド名	ICSR メッセージにおけるフィールド番号	ICH データ型	HL7 データ型	HL7 データ型（下位構成要素）	分類	Xpath
h	ACK.M/A	ICH ICSR バッチ確認応答						
e	ACK.M.1	確認応答バッチ番号		100AN	Instance Identifier (II)	extension=Character String (ST)	値	/MCCI_IN200101UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200101UV01.xsd']/id[@root='2.16.840.1.113883.3.989.2.1.3.20']/@extension
e	ACK.M.2	確認応答バッチ送信者識別子	N.1.4	60AN	Instance Identifier (II)	extension=Character String (ST)	値	/MCCI_IN200101UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200101UV01.xsd']/sender[@typeCode='SND']/device[@classCode='DEV'][@determinerCode='INSTANCE']/id[@root='2.16.840.1.113883.3.989.2.1.3.17'][1]/@extension
e	ACK.M.3	確認応答バッチ受信者識別子	N.1.3	60AN	Instance Identifier (II)	extension=Character String (ST)	値	/MCCI_IN200101UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200101UV01.xsd']/receiver[@typeCode='RCV']/device[@classCode='DEV'][@determinerCode='INSTANCE']/id[@root='2.16.840.1.113883.3.989.2.1.3.18'][1]/@extension
e	ACK.M.4	バッチ伝送の確認応答日		日付／時間	Point in Time (TS)		値	/MCCI_IN200101UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200101UV01.xsd']/creationTime/@value
e	ACK.A.1	ICSR バッチ番号	N.1.2	100AN	Instance Identifier (II)	extension=Character String (ST)	値	/MCCI_IN200101UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200101UV01.xsd']/acknowledgement[@typeCode]/targetBatch/id[@root='2.16.840.1.113883.3.989.2.1.3.22']/@extension
e	ACK.A.2	確認応答地域メッセージ番号		100AN	Instance Identifier (II)	extension=Character String (ST)	値	/MCCI_IN200101UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200101UV01.xsd']/attentionLine[keyWordText[@code='2'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.24']][1]/value[@xsi:type='II'][@root='2.16.840.1.113883.3.989.2.1.3.21']/@extension
e	ACK.A.3	ICSR バッチ伝送日	N.1.5	日付／時間	Point in Time (TS)		値	/MCCI_IN200101UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200101UV01.xsd']/attentionLine[keyWordText[@code='3'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.24']][1]/value[@xsi:type='TS']/@value

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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

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| e | ACK.B.r.7 | エラー／警告メッ
セージ又は意見 | | 250AN | Encapsulated
Data (ED) | | 値 | /MCCI_IN200101UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3
MCCI_IN200101UV01.xsd']/MCCI_IN000002UV01[r]/acknowledgement[@typeCode][1]/acknowle
dgementDetail[1]/text/text() |

2.　複数の XML 表現に関する XML 断片

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

2.1　開始日、終了日及び持続期間

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

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

```xml
<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

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

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

2.1.3. E.i.4「発現日」、E.i.5「終了日」、及び E.i.6「持続期間」に入力する

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

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

    <!-- E.i.1.1b: Reaction / Event as Reported by the Primary Source Language
-->

    </value>
```

2.1.4.　G.k.4.r.4「開始日」及び G.k.4.r.5「終了日」に入力するが、G.k.4.r.6 には入力しない

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

2.1.5.　G.k.4.r.4「開始日」（又は G.k.4.r.5「終了日」）及び G.k.4.r.6 に入力する

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

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

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

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

IVL_TSの例：

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

PIVL_TSのもう１つの例：

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

2.1.7. **G.k.4.r.4**「開始日」、**G.k.4.r.5**「終了日」、及び **G.k.4.r.8**「持続期間」に入力する

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

```
<effectiveTime xsi:type="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>
    <comp xsi:type="IVL_TS" 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="IVL_PQ" >
<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="IVL_PQ" >
    <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>
```

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>
```

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```
<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"/>
```

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"/>
```

2.3.13. 総投与量 20,000 mg、開始日、終了日

```
<substanceAdministrationclassCode="SBADM" moodCode="EVN">
    <effectiveTimexsi: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>
```

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セ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。