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日米 EU 医薬品規制調和国際会議

ICH E2B 専門家作業部会

個別症例安全性報告 (ICSR) の電子的伝送に
係る実装ガイド

付録 I (G)

技術的情報

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目次

I.	序.....	3
II.	技術的情報.....	3
1.	ICH データ型、HL7 データ型及び E2B (R3) データ項目の XPATH.....	3
2.	複数の XML 表現に関する XML 断片.....	84
2.1	開始日、終了日及び持続期間.....	84
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.....	84
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.....	84
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.....	85
2.1.4.	G.k.4.r.4 「開始日」及び G.k.4.r.5 「終了日」に入力するが、G.k.4.r.6 には入力しない.....	86
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.....	86
2.1.6.	G.k.4.r.2 及び G.k.4.r.3 には入力しないが、G.k.4.r.5、G.k.4.r.7 又は G.k.4.r.6 のいずれかに入力する.....	87
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.....	87
2.2.	F 検査結果.....	88
2.2.1.	F.r.3.2 値及び限定子.....	88
2.2.1.1.	値(例: "10 mg/dL").....	88
2.2.1.2.	値より大きい(例: "> 10 mg/dL").....	88
2.2.1.3.	値より小さい(例: "< 10 mg/dL").....	89
2.2.1.4.	値以上(例: "≥ 10 mg/dL").....	89
2.2.1.5.	値以下(例: "≤ 10 mg/dL").....	89
2.2.2.	F.r.3.2 及び F.r.3.3.....	89
2.2.3.	F.r.3.1.....	90
2.2.4.	F.r.3.4.....	90
2.3.	G.k.4 投与量の例.....	90
2.3.1.	1 日当たり 1/回.....	90
2.3.2.	1 日当たり 1錠/回.....	91
2.3.3.	1 日 1 回、1/4 錠/回.....	91

(別添3)

2.3.4.	週1回、6錠/回.....	92
2.3.5.	1日2回、1錠/回.....	92
2.3.6.	1日4回、7.5 mg/回.....	93
2.3.7.	1日1回、15 mL/回.....	94
2.3.8.	2日に1回、1錠/回.....	94
2.3.9.	頓用、1錠/回、開始日、終了日.....	95
2.3.10.	頓用、20 mg/回.....	95
2.3.11.	周期的、500 mg/回、開始日、終了日.....	96
2.3.12.	周期的、500 mg/回.....	96
2.3.13.	総投与量 20,000 mg、開始日、終了日.....	96
2.4.	電話、Fax、電子メール (C.3.4.6、C.3.4.7、及びC.3.4.8).....	97
2.5.	報告者の電話番号に対して"Privacy"を示す (C.2.r.2.7).....	97
2.6.	トライメスターを使用した妊娠期間 (D.2.2.1b).....	97
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).....	97
2.8.	各副作用に関する因果関係情報の例.....	98
III.	参照インスタンスについての注意事項.....	99
IV.	参考.....	100
	ICSR メッセージにおける E2B (R3) データ項目構造.....	100

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 o:エンティ ティ	項目番号	職業名	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 (パツ チラッパー: BATCH WRAPPER)					
e	N.1.1	パツチ内のメッセージの種 類	11A	Character String with Code (SC)	code=Coded With Equivalents (CE)	値	/MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=um:hl7-org:v3 MCCL_IN200100UV01.xsd]/name/@codeSystem=2.16.840.1.113883.3.989.2.1.1.1[1]@code
e	N.1.2	パツチ番号	100AN	Instance Identifier (II)	extension=Character String (ST)	値	/MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=um:hl7-org:v3 MCCL_IN200100UV01.xsd]/id/@root=2.16.840.1.113883.3.989.2.1.3.22[1]@extension
e	N.1.3	パツチ送信者識別子	60AN	Instance Identifier (II)	extension=Character String (ST)	値	/MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=um:hl7-org:v3 MCCL_IN200100UV01.xsd]/sender/@typeCode=SEND[device]@classCode=DEV[terminerCo de=INSTANCE]/id/@root=2.16.840.1.113883.3.989.2.1.3.13[1]@extension
e	N.1.4	パツチ受信者識別子	60AN	Instance Identifier (II)	extension=Character String (ST)	値	/MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=um:hl7-org:v3 MCCL_IN200100UV01.xsd]/receiver/@typeCode=RCV[device]@classCode=DEV[terminerC ode=INSTANCE]/id/@root=2.16.840.1.113883.3.989.2.1.3.14[1]@extension
e	N.1.5	パツチ伝送の日付	日付/ 時間	Point in Time (TS)		値	/MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=um:hl7-org:v3 MCCL_IN200100UV01.xsd]/creationTime/@value
h	N.2.r	ICH ICSR メッセージヘッダ (メッセージラッパー) (必 要に応じて繰り返す)				繰り返し ノード	/MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=um:hl7-org:v3 MCCL_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	/MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=um:hl7-org:v3 MCCL_IN200100UV01.xsd]/PORR_IN049016UV[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	/MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=um:hl7-org:v3 MCCL_IN200100UV01.xsd]/PORR_IN049016UV[id]@root=2.16.840.1.113883.3.989.2.1.3.11[1]@extension 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	/MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=um:hl7-org:v3 MCCL_IN200100UV01.xsd]/PORR_IN049016UV[id]@root=2.16.840.1.113883.3.989.2.1.3.12[1]@extension 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	/MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=um:hl7-org:v3 MCCL_IN200100UV01.xsd]/PORR_IN049016UV[id]@root=2.16.840.1.113883.3.989.2.1.3.13[1]@extension
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	/MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=um:hl7-org:v3 MCCL_IN200100UV01.xsd]/PORR_IN049016UV[id]@root=2.16.840.1.113883.3.989.2.1.3.13[1]@extension dCode=EVN[subject]@typeCode=SUBJ[1]@investigationEvent[1]@classCode=INVSTG[1]@moodCo de=EVN[id]@root=2.16.840.1.113883.3.989.2.1.3.13[1]@extension

(別添3)

C.1.2	作成の日付	日付/時間	Point in Time (TS)	値
C.1.3	報告の種類	1N	Coded With Equivalents (CE)	code=Character String (ST)
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)
C.1.5	本報告の最新情報入手日	日付/時間	Point in Time (TS)	値
C.1.6	送信者が保有している利用可能なその他の資料			値
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
C.1.6.1.r	送信者が保有している資料 (必要に応じて繰り返し返す)			繰り返しノード
C.1.6.1.r.1	送信者が保有している資料	2000AN	Character String (ST)	値
C.1.6.1.r.2	含まれる資料	N/A	Encapsulated Data (ED)	値

(別添 3)

e	C.1.7	本症例は当該国の緊急報告の基準を満たすか?	ブール型	Boolean (BL)	値	/MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3/MCCL_IN200100UV01.xsd]/PORR_IN049016UVJ/controlActProcess[@classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUBJ][investigationEvent[@classCode=INVESTG][@moodCode=EVN]/component[@typeCode=COMP][observationEvent[@code=23][@codeSystem=2.16.840.1.113883.3.989.2.1.1.19][1]jobServationEvent[@classCode=OBS][@moodCode=EVN]/value[@xsi:type=BL]]@value
e					NullFlavor	/MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3/MCCL_IN200100UV01.xsd]/PORR_IN049016UVJ/controlActProcess[@classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUBJ][investigationEvent[@classCode=INVESTG][@moodCode=EVN]/component[@typeCode=COMP][observationEvent[@code=23][@codeSystem=2.16.840.1.113883.3.989.2.1.1.19][1]jobServationEvent[@classCode=OBS][@moodCode=EVN]/value[@xsi:type=BL]]@nullFlavor
h	C.1.8	世界的に固有の症例識別子				
e	C.1.8.1	世界的に固有の症例識別子	100AN	Instance Identifier (I)	extension=Character String (ST)	/MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3/MCCL_IN200100UV01.xsd]/PORR_IN049016UVJ/controlActProcess[@classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUBJ][1]investigationEvent[@classCode=INVESTG][@moodCode=EVN]/id[@root=2.16.840.1.113883.3.989.2.1.3.2][1]@extension
e	C.1.8.2	本症例の第一送信者	1N	Coded With Equivalents (CE)	code=Character String (ST)	/MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3/MCCL_IN200100UV01.xsd]/PORR_IN049016UVJ/controlActProcess[@classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUBJ][1]investigationEvent[@classCode=INVESTG][@moodCode=EVN]/outboundRelationship[@typeCode=SPRT][relatedInvestigationCode=1][@codeSystem=2.16.840.1.113883.3.989.2.1.1.22][1]relatedInvestigation[@classCode=INVESTG][@moodCode=EVN]/subjectOf2[@typeCode=SUBJ][1]relatedInvestigation[@classCode=CACT][@moodCode=EVN]/author[@typeCode=AU][assignedEntity[@classCode=ASSIGNED][code[@codeSystem=2.16.840.1.113883.3.989.2.1.1.3]@code
h	C.1.9	その他の症例識別子				
e	C.1.9.1	過去の伝送で記載されたその他の症例識別子はあるか?	ブール型	Boolean (BL)	値	/MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3/MCCL_IN200100UV01.xsd]/PORR_IN049016UVJ/controlActProcess[@classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUBJ][1]investigationEvent[@classCode=INVESTG][@moodCode=EVN]/subjectOf2[@typeCode=SUBJ][1]investigationCharacteristic[@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	/MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3/MCCL_IN200100UV01.xsd]/PORR_IN049016UVJ/controlActProcess[@classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUBJ][1]investigationEvent[@classCode=INVESTG][@moodCode=EVN]/subjectOf2[@typeCode=SUBJ][1]investigationCharacteristic[@code=2][@codeSystem=2.16.840.1.113883.3.989.2.1.1.23][1]investigationCharacteristic[@classCode=OBS][@moodCode=EVN]/value[@xsi:type=BL]]@nullFlavor
h	C.1.9.1.r	症例識別子の情報源 (必要に応じて繰り返す)			繰り返し ノード	/MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3/MCCL_IN200100UV01.xsd]/PORR_IN049016UVJ/controlActProcess[@classCode=CACT][@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 (I)	値	/MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3/MCCL_IN200100UV01.xsd]/PORR_IN049016UVJ/controlActProcess[@classCode=CACT][@moodCode=EVN]/subjectOf1[@typeCode=SUBJ][controlActEvent/id][controlActEvent/id@root=2.16.840.1.113883.3.989.2.1.3.3][1]@assigningAuthorityName

(別添 3)

e	C.2.r.1.2	報告者の名前	60AN	Person Name (PN)	given=Entity Name Part (ENXP)	値	<pre> /MCCL_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='um:h7-org:v3 MCCL_IN200100UV01.xsd']/PORR_IN049016UVJ/controlAct/process/@classCode='CACT'[@moo dCode='EVN']/subject/@typeCode='SUBJ'[@typeCode='SPRT']/relatedInvestigation/@code[@code='2'][@code System='2.16.840.1.113883.3.989.2.1.1.22']/relatedInvestigation/@classCode='INVTG'[@mood Code='EVN']/subjectO2/@typeCode='SUBJ'/controlActEvent/@classCode='CACT'[@moodCode=' EVN']/author/@typeCode='AUT'/assignedEntity/@classCode='ASSIGNED'/assignedPerson/@clas sCode='PSN'[@determinerCode='INSTANCE']/name/given[1]text() </pre>
e						NullFlavor	<pre> /MCCL_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='um:h7-org:v3 MCCL_IN200100UV01.xsd']/PORR_IN049016UVJ/controlAct/process/@classCode='CACT'[@moo dCode='EVN']/subject/@typeCode='SUBJ'[@typeCode='SPRT']/relatedInvestigation/@code[@code='2'][@code System='2.16.840.1.113883.3.989.2.1.1.22']/relatedInvestigation/@classCode='INVTG'[@mood Code='EVN']/author/@typeCode='AUT'/assignedEntity/@classCode='ASSIGNED'/assignedPerson/@clas sCode='PSN'[@determinerCode='INSTANCE']/name/given[1]@nullFlavor </pre>
e	C.2.r.1.3	報告者の中間名	60AN	Person Name (PN)	given=Entity Name Part (ENXP)	値	<pre> /MCCL_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='um:h7-org:v3 MCCL_IN200100UV01.xsd']/PORR_IN049016UVJ/controlAct/process/@classCode='CACT'[@moo dCode='EVN']/subject/@typeCode='SUBJ'[@typeCode='SPRT']/relatedInvestigation/@code[@code='2'][@code System='2.16.840.1.113883.3.989.2.1.1.22']/relatedInvestigation/@classCode='INVTG'[@mood Code='EVN']/subjectO2/@typeCode='SUBJ'/controlActEvent/@classCode='CACT'[@moodCode=' EVN']/author/@typeCode='AUT'/assignedEntity/@classCode='ASSIGNED'/assignedPerson/@clas sCode='PSN'[@determinerCode='INSTANCE']/name/given[2]text() </pre>
e						NullFlavor	<pre> /MCCL_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='um:h7-org:v3 MCCL_IN200100UV01.xsd']/PORR_IN049016UVJ/controlAct/process/@classCode='CACT'[@moo dCode='EVN']/subject/@typeCode='SUBJ'[@typeCode='SPRT']/relatedInvestigation/@code[@code='2'][@code System='2.16.840.1.113883.3.989.2.1.1.22']/relatedInvestigation/@classCode='INVTG'[@mood Code='EVN']/subjectO2/@typeCode='SUBJ'/controlActEvent/@classCode='CACT'[@moodCode=' EVN']/author/@typeCode='AUT'/assignedEntity/@classCode='ASSIGNED'/assignedPerson/@clas sCode='PSN'[@determinerCode='INSTANCE']/name/given[2]@nullFlavor </pre>
e	C.2.r.1.4	報告者の姓	60AN	Person Name (PN)	family=Entity Name Part (ENXP)	値	<pre> /MCCL_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='um:h7-org:v3 MCCL_IN200100UV01.xsd']/PORR_IN049016UVJ/controlAct/process/@classCode='CACT'[@moo dCode='EVN']/subject/@typeCode='SUBJ'[@typeCode='SPRT']/relatedInvestigation/@code[@code='2'][@code System='2.16.840.1.113883.3.989.2.1.1.22']/relatedInvestigation/@classCode='INVTG'[@mood Code='EVN']/subjectO2/@typeCode='SUBJ'/controlActEvent/@classCode='CACT'[@moodCode=' EVN']/author/@typeCode='AUT'/assignedEntity/@classCode='ASSIGNED'/assignedPerson/@clas sCode='PSN'[@determinerCode='INSTANCE']/name/family[1]text() </pre>
e						NullFlavor	<pre> /MCCL_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='um:h7-org:v3 MCCL_IN200100UV01.xsd']/PORR_IN049016UVJ/controlAct/process/@classCode='CACT'[@moo dCode='EVN']/subject/@typeCode='SUBJ'[@typeCode='SPRT']/relatedInvestigation/@code[@code='2'][@code System='2.16.840.1.113883.3.989.2.1.1.22']/relatedInvestigation/@classCode='INVTG'[@mood Code='EVN']/subjectO2/@typeCode='SUBJ'/controlActEvent/@classCode='CACT'[@moodCode=' EVN']/author/@typeCode='AUT'/assignedEntity/@classCode='ASSIGNED'/assignedPerson/@clas sCode='PSN'[@determinerCode='INSTANCE']/name/family[1]@nullFlavor </pre>
h	C.2.r.2	報告者の住所及び電話番号					

(別添 3)

e				Postal Address (AD)	city=Address Part (ADXP)	NullFlavor	/MCCI_IN200100UV01[ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]yPARR_IN049016UVfj/controlActProcess[classCode=CACT][moodCode=EVN]/subject[typeCode=SUBJ][relatedInvestigationEvent[classCode=INVESTG][moodCode=EVN]/outboundRelationship[typeCode=SPRT][relatedInvestigationCode=@code=2][@codeSystem=2,16.840.1.113883.3.989.2.1.1.22][relatedInvestigation[classCode=INVESTG][moodCode=EVN]/subjectOf2[typeCode=SUBJ]/controlActEvent[classCode=CACT][moodCode=EVN]/author[@typeCode=AUT]/assignedEntity[classCode=ASSIGNED][addrf1]/streetAddressLine1/@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]yPARR_IN049016UVfj/controlActProcess[classCode=CACT][moodCode=EVN]/subject[typeCode=SUBJ][relatedInvestigationEvent[classCode=INVESTG][moodCode=EVN]/outboundRelationship[typeCode=SPRT][relatedInvestigationCode=@code=2][@codeSystem=2,16.840.1.113883.3.989.2.1.1.22][relatedInvestigation[classCode=INVESTG][moodCode=EVN]/subjectOf2[typeCode=SUBJ]/controlActEvent[classCode=CACT][moodCode=EVN]/author[@typeCode=AUT]/assignedEntity[classCode=ASSIGNED][addrf1]/city/text()
e				Postal Address (AD)	state=Address Part (ADXP)	NullFlavor	/MCCI_IN200100UV01[ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]yPARR_IN049016UVfj/controlActProcess[classCode=CACT][moodCode=EVN]/subject[typeCode=SUBJ][relatedInvestigationEvent[classCode=INVESTG][moodCode=EVN]/outboundRelationship[typeCode=SPRT][relatedInvestigationCode=@code=2][@codeSystem=2,16.840.1.113883.3.989.2.1.1.22][relatedInvestigation[classCode=INVESTG][moodCode=EVN]/subjectOf2[typeCode=SUBJ]/controlActEvent[classCode=CACT][moodCode=EVN]/author[@typeCode=AUT]/assignedEntity[classCode=ASSIGNED][addrf1]/state/@nullFlavor
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]yPARR_IN049016UVfj/controlActProcess[classCode=CACT][moodCode=EVN]/subject[typeCode=SUBJ][relatedInvestigationEvent[classCode=INVESTG][moodCode=EVN]/outboundRelationship[typeCode=SPRT][relatedInvestigationCode=@code=2][@codeSystem=2,16.840.1.113883.3.989.2.1.1.22][relatedInvestigation[classCode=INVESTG][moodCode=EVN]/subjectOf2[typeCode=SUBJ]/controlActEvent[classCode=CACT][moodCode=EVN]/author[@typeCode=AUT]/assignedEntity[classCode=ASSIGNED][addrf1]/state/text()
e				Postal Address (AD)	postalCode=Address Part (ADXP)	NullFlavor	/MCCI_IN200100UV01[ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]yPARR_IN049016UVfj/controlActProcess[classCode=CACT][moodCode=EVN]/subject[typeCode=SUBJ][relatedInvestigationEvent[classCode=INVESTG][moodCode=EVN]/outboundRelationship[typeCode=SPRT][relatedInvestigationCode=@code=2][@codeSystem=2,16.840.1.113883.3.989.2.1.1.22][relatedInvestigation[classCode=INVESTG][moodCode=EVN]/subjectOf2[typeCode=SUBJ]/controlActEvent[classCode=CACT][moodCode=EVN]/author[@typeCode=AUT]/assignedEntity[classCode=ASSIGNED][addrf1]/state/@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]yPARR_IN049016UVfj/controlActProcess[classCode=CACT][moodCode=EVN]/subject[typeCode=SUBJ][relatedInvestigationEvent[classCode=INVESTG][moodCode=EVN]/outboundRelationship[typeCode=SPRT][relatedInvestigationCode=@code=2][@codeSystem=2,16.840.1.113883.3.989.2.1.1.22][relatedInvestigation[classCode=INVESTG][moodCode=EVN]/subjectOf2[typeCode=SUBJ]/controlActEvent[classCode=CACT][moodCode=EVN]/author[@typeCode=AUT]/assignedEntity[classCode=ASSIGNED][addrf1]/postalCode/text()

(別添 3)

e				NullFlavor	<pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0]@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]PORR_IN049016UVJ/controlActProcess[classCode=CACT]@moodCode=EVN/subject[@typeCode=SUBJ]1/investigationEvent[classCode=INVTG]@moodCode=EVN/youboundRelationship[@typeCode=SPRT]1/relatedInvestigation/code[@code=2]@codeSystem=2,16,840,1,113883,3,989,2,1,1,22]1/relatedInvestigation[classCode=INVTG]@moodCode=EVN/subjectO2[@typeCode=SUBJ]controlActEvent[classCode=CACT]@moodCode=EVN/author[@typeCode=AUT]1/assignedEntity[@classCode=ASSIGNED]1/act[1]postalCode[1]@nullFlavor </pre>
e	C.2.r.2.7	報告者の電話番号	33AN	Telecommunication Address (TEL)	<pre> substring(MCCL_IN200100UV01[@ITSVersion=XML_1.0]@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]PORR_IN049016UVJ/controlActProcess[classCode=CACT]@moodCode=EVN/subject[@typeCode=SUBJ]1/investigationEvent[classCode=INVTG]@moodCode=EVN/youboundRelationship[@typeCode=SPRT]1/relatedInvestigation/code[@code=2]@codeSystem=2,16,840,1,113883,3,989,2,1,1,22]1/relatedInvestigation[classCode=INVTG]@moodCode=EVN/subjectO2[@typeCode=SUBJ]controlActEvent[classCode=CACT]@moodCode=EVN/author[@typeCode=AUT]1/assignedEntity[@classCode=ASSIGNED]1/telecom1starts-with(@value, 'tel:'))[1]@nullFlavor </pre>
e				NullFlavor	<pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0]@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]PORR_IN049016UVJ/controlActProcess[classCode=CACT]@moodCode=EVN/subject[@typeCode=SUBJ]1/investigationEvent[classCode=INVTG]@moodCode=EVN/youboundRelationship[@typeCode=SPRT]1/relatedInvestigation/code[@code=2]@codeSystem=2,16,840,1,113883,3,989,2,1,1,22]1/relatedInvestigation[classCode=INVTG]@moodCode=EVN/subjectO2[@typeCode=SUBJ]controlActEvent[classCode=CACT]@moodCode=EVN/author[@typeCode=AUT]1/assignedEntity[@classCode=ASSIGNED]1/telecom1starts-with(@value, 'tel:'))[1]@nullFlavor </pre>
e	C.2.r.3	報告者の国コード	2A	Concept Descriptor (CD)	<pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0]@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]PORR_IN049016UVJ/controlActProcess[classCode=CACT]@moodCode=EVN/subject[@typeCode=SUBJ]1/investigationEvent[classCode=INVTG]@moodCode=EVN/youboundRelationship[@typeCode=SPRT]1/relatedInvestigation/code[@code=2]@codeSystem=2,16,840,1,113883,3,989,2,1,1,22]1/relatedInvestigation[classCode=INVTG]@moodCode=EVN/subjectO2[@typeCode=SUBJ]controlActEvent[classCode=CACT]@moodCode=EVN/author[@typeCode=AUT]1/assignedEntity[@classCode=ASSIGNED]1/assignedPerson[classCode=PSN]1/@determinerCode=INSTANCE]1/locatedEntity[@classCode=LOCE]1/location[@classCode=COUNTRY]1/@determinerCode=INSTANCE]1/code[@codeSystem=1,0,3166,1,2,2]@nullFlavor </pre>
e				NullFlavor	<pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0]@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]PORR_IN049016UVJ/controlActProcess[classCode=CACT]@moodCode=EVN/subject[@typeCode=SUBJ]1/investigationEvent[classCode=INVTG]@moodCode=EVN/youboundRelationship[@typeCode=SPRT]1/relatedInvestigation/code[@code=2]@codeSystem=2,16,840,1,113883,3,989,2,1,1,22]1/relatedInvestigation[classCode=INVTG]@moodCode=EVN/subjectO2[@typeCode=SUBJ]controlActEvent[classCode=CACT]@moodCode=EVN/author[@typeCode=AUT]1/assignedEntity[@classCode=ASSIGNED]1/assignedPerson[classCode=PSN]1/@determinerCode=INSTANCE]1/locatedEntity[@classCode=LOCE]1/location[@classCode=COUNTRY]1/@determinerCode=INSTANCE]1/code[@codeSystem=1,0,3166,1,2,2]@nullFlavor </pre>

(別添 3)

e	C.2.r.4	資格	1N	Coded With Equivalents (CE)	code=Character String (ST)	値	/MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xmlns:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PARR_IN049016UVJ/controlActProcess[@classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUBJ][investigationEvent[@classCode=INVTG][@moodCode=EVN]/outboundRelationship[@typeCode=SPRT][relatedInvestigation/@code=2][@codeSystem=2,16.840,1.113883,3.989,2,1.1,22][r/relatedInvestigation/@classCode=INVTG][@moodCode=EVN]/author[@typeCode=AUT]/assignedEntity[@classCode=ASSIGNED/assignedPerson/@classCode=PSN][@determinerCode=INSTANCE]/asQualifiedEntity[@classCode=QUAL][@code/@codeSystem=2,16.840,1.113883,3.989,2,1.1,6]/@code
e					NullFlavor	値	/MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xmlns:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PARR_IN049016UVJ/controlActProcess[@classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUBJ][investigationEvent[@classCode=INVTG][@moodCode=EVN]/outboundRelationship[@typeCode=SPRT][relatedInvestigation/@code=2][@codeSystem=2,16.840,1.113883,3.989,2,1.1,22][r/relatedInvestigation/@classCode=INVTG][@moodCode=EVN]/subjectO2[@typeCode=SUBJ]/controlActEvent[@classCode=CACT][@moodCode=EVN]/author[@typeCode=AUT]/assignedEntity[@classCode=ASSIGNED/assignedPerson/@classCode=PSN][@determinerCode=INSTANCE]/asQualifiedEntity[@classCode=QUAL][@code/@codeSystem=2,16.840,1.113883,3.989,2,1.1,6]/@nullFlavor
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][@xmlns:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PARR_IN049016UVJ/controlActProcess[@classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUBJ][investigationEvent[@classCode=INVTG][@moodCode=EVN]/outboundRelationship[@typeCode=SPRT][relatedInvestigation/@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][@xmlns:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PARR_IN049016UVJ/controlActProcess[@classCode=CACT][@moodCode=EVN]/subjectO1[@typeCode=SUBJ][controlActEvent/author/assignedEntity/@codeSystem=2,16.840,1.113883,3.989,2,1.1,7][@typeCode=CACT][@moodCode=EVN]/author[@typeCode=AUT]/assignedEntity[@classCode=ASSIGNED/@codeSystem=2,16.840,1.113883,3.989,2,1.1,7]/@code
e	C.3.2	送信者の組織	100AN	Organization Name (ON)	name=Entity Name Part (ENXP)	値	/MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xmlns:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PARR_IN049016UVJ/controlActProcess[@classCode=CACT][@moodCode=EVN]/subjectO1[@typeCode=SUBJ][controlActEvent/author/assignedEntity/@codeSystem=2,16.840,1.113883,3.989,2,1.1,7][@typeCode=CACT][@moodCode=EVN]/author[@typeCode=AUT]/assignedEntity[@classCode=ASSIGNED/representedOrganization/@determinerCode=ORG][@determinerCode=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][@xmlns:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PARR_IN049016UVJ/controlActProcess[@classCode=CACT][@moodCode=EVN]/subjectO1[@typeCode=SUBJ][investigationEvent[@classCode=INVTG][@moodCode=EVN]/subjectO1[@typeCode=SUBJ][controlActEvent/author/assignedEntity/@codeSystem=2,16.840,1.113883,3.989,2,1.1,7][@typeCode=CACT][@moodCode=EVN]/author[@typeCode=AUT]/assignedEntity[@classCode=ASSIGNED/representedOrganization/@determinerCode=ORG][@determinerCode=INSTANCE]/name/text()

(別添 3)

c	C.3.3.2	送信者の職名	50AN	Person Name (PN)	prefix=Entity Name Part (ENXP)	<pre> /MCCL_IN200100UV01[@ITSVersion='XML_1.0']/@xsi:schemaLocation='urn:hl7-org:v3 /MCCL_IN200100UV01.xsd' /PDRR_IN049016UVr/controlActProcess[@classCode='CACT']/@moodCo dCode='EVN']/subjectOf[@typeCode='SUBJ']/investigationEvent[@classCode='INVTG']/@moodCo de='EVN']/subjectOf1[@typeCode='SUBJ']/controlActEvent/assignedEntity/code/@codeSysteme m='2.16.840.1.113883.3.989.2.1.1.7' /controlActEvent/@classCode='CACT']/@moodCode='EVN'] /author[@typeCode='AUT']/assignedEntity[@classCode='ASSIGNED']/assignedPerson[@classCode ='PSN']/@determinerCode='INSTANCE'/name/prefix[1]/text() </pre>
c	C.3.3.3.	送信者の名前	60AN	Person Name (PN)	given=Entity Name Part (ENXP)	<pre> /MCCL_IN200100UV01[@ITSVersion='XML_1.0']/@xsi:schemaLocation='urn:hl7-org:v3 /MCCL_IN200100UV01.xsd' /PDRR_IN049016UVr/controlActProcess[@classCode='CACT']/@moodCo dCode='EVN']/subjectOf[@typeCode='SUBJ']/investigationEvent[@classCode='INVTG']/@moodCo de='EVN']/subjectOf1[@typeCode='SUBJ']/controlActEvent/assignedEntity/code/@codeSysteme m='2.16.840.1.113883.3.989.2.1.1.7' /controlActEvent/@classCode='CACT']/@moodCode='EVN'] /author[@typeCode='AUT']/assignedEntity[@classCode='ASSIGNED']/assignedPerson[@classCode ='PSN']/@determinerCode='INSTANCE'/name/given[1]/text() </pre>
c	C.3.3.4	送信者の中間名	60AN	Person Name (PN)	given=Entity Name Part (ENXP)	<pre> /MCCL_IN200100UV01[@ITSVersion='XML_1.0']/@xsi:schemaLocation='urn:hl7-org:v3 /MCCL_IN200100UV01.xsd' /PDRR_IN049016UVr/controlActProcess[@classCode='CACT']/@moodCo dCode='EVN']/subjectOf[@typeCode='SUBJ']/investigationEvent[@classCode='INVTG']/@moodCo de='EVN']/subjectOf1[@typeCode='SUBJ']/controlActEvent/assignedEntity/code/@codeSysteme m='2.16.840.1.113883.3.989.2.1.1.7' /controlActEvent/@classCode='CACT']/@moodCode='EVN'] /author[@typeCode='AUT']/assignedEntity[@classCode='ASSIGNED']/assignedPerson[@classCode ='PSN']/@determinerCode='INSTANCE'/name/given[2]/text() </pre>
c	C.3.3.5	送信者の姓	60AN	Person Name (PN)	family=Entity Name Part (ENXP)	<pre> /MCCL_IN200100UV01[@ITSVersion='XML_1.0']/@xsi:schemaLocation='urn:hl7-org:v3 /MCCL_IN200100UV01.xsd' /PDRR_IN049016UVr/controlActProcess[@classCode='CACT']/@moodCo dCode='EVN']/subjectOf[@typeCode='SUBJ']/investigationEvent[@classCode='INVTG']/@moodCo de='EVN']/subjectOf1[@typeCode='SUBJ']/controlActEvent/assignedEntity/code/@codeSysteme m='2.16.840.1.113883.3.989.2.1.1.7' /controlActEvent/@classCode='CACT']/@moodCode='EVN'] /author[@typeCode='AUT']/assignedEntity[@classCode='ASSIGNED']/assignedPerson[@classCode ='PSN']/@determinerCode='INSTANCE'/name/family[1]/text() </pre>
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)	<pre> /MCCL_IN200100UV01[@ITSVersion='XML_1.0']/@xsi:schemaLocation='urn:hl7-org:v3 /MCCL_IN200100UV01.xsd' /PDRR_IN049016UVr/controlActProcess[@classCode='CACT']/@moodCo dCode='EVN']/subjectOf[@typeCode='SUBJ']/investigationEvent[@classCode='INVTG']/@moodCo de='EVN']/subjectOf1[@typeCode='SUBJ']/controlActEvent/assignedEntity/code/@codeSysteme m='2.16.840.1.113883.3.989.2.1.1.7' /controlActEvent/@classCode='CACT']/@moodCode='EVN'] /author[@typeCode='AUT']/assignedEntity[@classCode='ASSIGNED']/address[1]/streetAddressLine[1]/t ext() </pre>
e	C.3.4.2	送信者の住所 (市町村等)	35AN	Postal Address (AD)	city=Address Part (ADXP)	<pre> /MCCL_IN200100UV01[@ITSVersion='XML_1.0']/@xsi:schemaLocation='urn:hl7-org:v3 /MCCL_IN200100UV01.xsd' /PDRR_IN049016UVr/controlActProcess[@classCode='CACT']/@moodCo dCode='EVN']/subjectOf[@typeCode='SUBJ']/investigationEvent[@classCode='INVTG']/@moodCo de='EVN']/subjectOf1[@typeCode='SUBJ']/controlActEvent/assignedEntity/code/@codeSysteme m='2.16.840.1.113883.3.989.2.1.1.7' /controlActEvent/@classCode='CACT']/@moodCode='EVN'] /author[@typeCode='AUT']/assignedEntity[@classCode='ASSIGNED']/address[1]/city[1]/next() </pre>

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e	C.3.4.3	送信者の住所 (都道府県等)	40AN	Postal Address (AD)	state=Address Part (ADXP)	値	<pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/PORR_IN049016UVJ/controlAcProcess[@classCode=CACT][@moo dCode=EVN]/subject[@typeCode=SUBJ][investigationEvent][@classCode=INVTGT][@moodCo de=EVN]/subjectOf[@typeCode=SUBJ][controlAcEvent/authorAssignedEntity/code/@codeSyste m=2.16.840.1.113883.3.989.2.1.1.7][1]/controlAcEvent[@classCode=CACT][@moodCode=EVN] /author[@typeCode=AUT]/assignedEntity[@classCode=ASSIGNED][addr1 y state y text] </pre>
e	C.3.4.4	送信者の住所 (郵便番号)	15AN	Postal Address (AD)	postalCode=Address Part (ADXP)	値	<pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/PORR_IN049016UVJ/controlAcProcess[@classCode=CACT][@moo dCode=EVN]/subject[@typeCode=SUBJ][investigationEvent][@classCode=INVTGT][@moodCo de=EVN]/subjectOf[@typeCode=SUBJ][controlAcEvent/authorAssignedEntity/code/@codeSyste m=2.16.840.1.113883.3.989.2.1.1.7][1]/controlAcEvent[@classCode=CACT][@moodCode=EVN] /author[@typeCode=AUT]/assignedEntity[@classCode=ASSIGNED][addr1 y postalCode y text] </pre>
e	C.3.4.5	送信者の住所 (国コード)	2A	Concept Descriptor (CD)	code=Character String (ST)	値	<pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/PORR_IN049016UVJ/controlAcProcess[@classCode=CACT][@moo dCode=EVN]/subjectOf[@typeCode=SUBJ][investigationEvent][@classCode=INVTGT][@moodCo de=EVN]/subjectOf1[@typeCode=SUBJ][controlAcEvent/authorAssignedEntity/code/@codeSyste m=2.16.840.1.113883.3.989.2.1.1.7][1]/controlAcEvent[@classCode=CACT][@moodCode=EVN] /author[@typeCode=AUT]/assignedEntity[@classCode=ASSIGNED][person/@classCode=EVN] =PSN][@determinerCode=INSTANCE][code/@codeSystem=1.0.3.156.1.2.2][@code ode=COUNTRY][@determinerCode=INSTANCE][code/@codeSystem=1.0.3.156.1.2.2][@code </pre>
e	C.3.4.6	送信者の電話番号	33AN	Telecommunication Address (TEL)		値	<pre> substring(MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/PORR_IN049016UVJ/controlAcProcess[@classCode=CACT][@moo dCode=EVN]/subjectOf[@typeCode=SUBJ][investigationEvent][@classCode=INVTGT][@moodCo de=EVN]/subjectOf1[@typeCode=SUBJ][controlAcEvent/authorAssignedEntity/code/@codeSyste m=2.16.840.1.113883.3.989.2.1.1.7][1]/controlAcEvent[@classCode=CACT][@moodCode=EVN] /author[@typeCode=AUT]/assignedEntity[@classCode=ASSIGNED][telecom starts-with @value, 'tel:'] y value, 5) </pre>
e	C.3.4.7	送信者の FAX 番号	33AN	Telecommunication Address (TEL)		値	<pre> substring(MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/PORR_IN049016UVJ/controlAcProcess[@classCode=CACT][@moo dCode=EVN]/subjectOf[@typeCode=SUBJ][investigationEvent][@classCode=INVTGT][@moodCo de=EVN]/subjectOf1[@typeCode=SUBJ][controlAcEvent/authorAssignedEntity/code/@codeSyste m=2.16.840.1.113883.3.989.2.1.1.7][1]/controlAcEvent[@classCode=CACT][@moodCode=EVN] /author[@typeCode=AUT]/assignedEntity[@classCode=ASSIGNED][telecom starts-with @value, 'fax:'] y value, 5) </pre>
e	C.3.4.8	送信者の電子メールアドレス	100AN	Telecommunication Address (TEL)		値	<pre> substring(MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/PORR_IN049016UVJ/controlAcProcess[@classCode=CACT][@moo dCode=EVN]/subjectOf[@typeCode=SUBJ][investigationEvent][@classCode=INVTGT][@moodCo de=EVN]/subjectOf1[@typeCode=SUBJ][controlAcEvent/authorAssignedEntity/code/@codeSyste m=2.16.840.1.113883.3.989.2.1.1.7][1]/controlAcEvent[@classCode=CACT][@moodCode=EVN] /author[@typeCode=AUT]/assignedEntity[@classCode=ASSIGNED][telecom starts-with @value, 'mailto:'] y value, 8) </pre>
h	C.4.r	引用文献 (必要に応じ繰り返し)				繰り返し ノード	<pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/PORR_IN049016UVJ/controlAcProcess[@classCode=CACT][@moo dCode=EVN]/subjectOf[@typeCode=SUBJ][investigationEvent][@classCode=INVTGT][@moodCo de=EVN]/reference[@typeCode=REFR][document/code/@code=2][@codeSystem=2.16.840.1.11 3883.3.989.2.1.1.2][1] </pre>

(別添 3)

<p>a</p> <p>C.4.r.1</p> <p>引用文献</p>	<p>500AN</p>	<p>Encapsulated Data (ED)</p>	<p>値</p>	<pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation='um:hi7-org:v3 MCC_IN200100UV01.xsd']/PARR_IN049016UV/r/controlAct/process/@classCode=CACT][@moo dCode=EVN]/subject/@typeCode=SUBJ/1/investigationEvent/@classCode=INVESTG][@moodCo de=EVN]/reference/@typeCode=REFR][document/code/@code=2][@codeSystem=2.16.840.1.11 3883.3.989.2.1.1.27]]/document/@classCode=DOC][@moodCode=EVN]/bibliographicDesignati on/Text/text() /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation='um:hi7-org:v3 MCC_IN200100UV01.xsd']/PARR_IN049016UV/r/controlAct/process/@classCode=CACT][@moo dCode=EVN]/subject/@typeCode=SUBJ/1/investigationEvent/@classCode=INVESTG][@moodCo de=EVN]/reference/@typeCode=REFR][document/code/@code=2][@codeSystem=2.16.840.1.11 3883.3.989.2.1.1.27]]/document/@classCode=DOC][@moodCode=EVN]/bibliographicDesignati on/Text/text() </pre>	<p>NullFlavor</p>
<p>b</p> <p>C.4.r.2</p> <p>含まれる資料</p>	<p>N/A</p>	<p>Encapsulated Data (ED)</p>	<p>値</p>	<pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation='um:hi7-org:v3 MCC_IN200100UV01.xsd']/PARR_IN049016UV/r/controlAct/process/@classCode=CACT][@moo dCode=EVN]/subject/@typeCode=SUBJ/1/investigationEvent/@classCode=INVESTG][@moodCo de=EVN]/reference/@typeCode=REFR][document/code/@code=2][@codeSystem=2.16.840.1.11 3883.3.989.2.1.1.27]]/document/@classCode=DOC][@moodCode=EVN]/bibliographicDesignati on/Text/text() </pre>	<p>NullFlavor</p>
<p>c</p> <p>C.5</p> <p>試験の識別</p>	<p>N/A</p>	<p>Encapsulated Data (ED)</p>	<p>値</p>	<pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation='um:hi7-org:v3 MCC_IN200100UV01.xsd']/PARR_IN049016UV/r/controlAct/process/@classCode=CACT][@moo dCode=EVN]/subject/@typeCode=SUBJ/1/investigationEvent/@classCode=INVESTG][@moodCo de=EVN]/reference/@typeCode=REFR][document/code/@code=2][@codeSystem=2.16.840.1.11 3883.3.989.2.1.1.27]]/document/@classCode=DOC][@moodCode=EVN]/text/text() </pre>	<p>NullFlavor</p>
<p>d</p> <p>C.5.1.r</p> <p>試験の登録情報 (必要に 応じ繰り返す)</p>	<p>N/A</p>	<p>Encapsulated Data (ED)</p>	<p>繰り返し ノード</p>	<pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation='um:hi7-org:v3 MCC_IN200100UV01.xsd']/PARR_IN049016UV/r/controlAct/process/@classCode=CACT][@moo dCode=EVN]/subject/@typeCode=SUBJ/1/investigationEvent/@classCode=INVESTG][@moodCo de=EVN]/component/@typeCode=COMP/1/adverseEventAssessment/1/1/adverseEventAssessment /@classCode=INVESTG][@moodCode=EVN]/subject/@typeCode=SUBJ/1/primaryRole/@classC ode=INVESTG/subjectOf1/@typeCode=SUBJ/1/researchStudy/@classCode=CLNTRL][@moodCo de=EVN]/authorization/@typeCode=AUTH/1/1/3.6.y/extension </pre>	<p>NullFlavor</p>
<p>e</p> <p>C.5.1.r.1</p> <p>試験の登録番号</p>	<p>.500AN</p>	<p>Instance Identifier (II)</p>	<p>extension=Character String (ST)</p>	<pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation='um:hi7-org:v3 MCC_IN200100UV01.xsd']/PARR_IN049016UV/r/controlAct/process/@classCode=CACT][@moo dCode=EVN]/subject/@typeCode=SUBJ/1/investigationEvent/@classCode=INVESTG][@moodCo de=EVN]/component/@typeCode=COMP/1/adverseEventAssessment/1/1/adverseEventAssessment /@classCode=INVESTG][@moodCode=EVN]/subject/@typeCode=SUBJ/1/primaryRole/@classC ode=INVESTG/subjectOf1/@typeCode=SUBJ/1/researchStudy/@classCode=CLNTRL][@moodCo de=EVN]/authorization/@typeCode=AUTH/1/1/3.6.y/extension </pre>	<p>NullFlavor</p>

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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]JPORR_IN049016UV1/controlActProcess[@classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUBJ]/investigationEvent[@classCode=INVESTG][@moodCode=EVN]/component[@typeCode=COMP]/adverseEventAssessment[1]/adverseEventAssessment[@classCode=INVESTG][@moodCode=EVN]/subject[@typeCode=SBJ]/primaryRole[@classCode=INVSBJ]/subjectOf[@typeCode=SBJ]/researchStudy[@classCode=CLNTRL][@moodCode=EVN]/code[@codeSystem=2.16.840.1.113883.3.989.2.1.1.8]/@code
D	患者特性					/MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]JPORR_IN049016UV1/controlActProcess[@classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUBJ]/investigationEvent[@classCode=INVESTG][@moodCode=EVN]/component[@typeCode=COMP]/adverseEventAssessment[1]/adverseEventAssessment[@classCode=INVESTG][@moodCode=EVN]/subject1[@typeCode=SBJ]/primaryRole[@classCode=INVSBJ]/player1[@classCode=PSN][@determinerCode=INSTANCE]/name[1]/text
D.1	患者 (名前又はイニシヤル)	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]JPORR_IN049016UV1/controlActProcess[@classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUBJ]/investigationEvent[@classCode=INVESTG][@moodCode=EVN]/component[@typeCode=COMP]/adverseEventAssessment[1]/adverseEventAssessment[@classCode=INVESTG][@moodCode=EVN]/subject1[@typeCode=SBJ]/primaryRole[@classCode=INVSBJ]/player1[@classCode=PSN][@determinerCode=INSTANCE]/name[1]/text
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)				NullFlavor	/MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]JPORR_IN049016UV1/controlActProcess[@classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUBJ]/investigationEvent[@classCode=INVESTG][@moodCode=EVN]/component[@typeCode=COMP]/adverseEventAssessment[1]/adverseEventAssessment[@classCode=INVESTG][@moodCode=EVN]/subject1[@typeCode=SBJ]/primaryRole[@classCode=INVSBJ]/player1[@classCode=PSN][@determinerCode=INSTANCE]/name[1]/@nullFlavor
D.1.1.1	患者の診療記録番号及びその情報源 (閉塞区診療記録番号)	20AN	Instance Identifier (I)	extension=Character String (ST)	値	/MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]JPORR_IN049016UV1/controlActProcess[@classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUBJ]/investigationEvent[@classCode=INVESTG][@moodCode=EVN]/component[@typeCode=COMP]/adverseEventAssessment[1]/adverseEventAssessment[@classCode=INVESTG][@moodCode=EVN]/subject1[@typeCode=SBJ]/primaryRole[@classCode=INVSBJ]/player1[@classCode=PSN][@determinerCode=INSTANCE]/assIdentifiedEntity[@classCode=IDENT][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"]/@extension
					NullFlavor	/MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]JPORR_IN049016UV1/controlActProcess[@classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUBJ]/investigationEvent[@classCode=INVESTG][@moodCode=EVN]/component[@typeCode=COMP]/adverseEventAssessment[1]/adverseEventAssessment[@classCode=INVESTG][@moodCode=EVN]/subject1[@typeCode=SBJ]/primaryRole[@classCode=INVSBJ]/player1[@classCode=PSN][@determinerCode=INSTANCE]/assIdentifiedEntity[@classCode=IDENT][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"]/@nullFlavor

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e	D.2.1	生年月日	日付/時間	Point In Time (TS)	値	/MCCI_IN200100UV01[ITSVersion=XML_1.0T][xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]PORR_IN049016UV[controlAciprocess][classCode=CACT][moodCode=EVN]/subject[typeCode=SUBJ]/investigationEvent[classCode=INVESTG][moodCode=EVN]/component[typeCode=COMP]/adverseEventAssessment[1]/adverseEventAssessment[classCode=INVESTG][moodCode=EVN]/subject[typeCode=SBJ]/primaryRole[classCode=INVSBJ]/player[1]/classCode=PSN][determinerCode=INSTANCE][birthTime/@value
e					NullFlavor	/MCCI_IN200100UV01[ITSVersion=XML_1.0T][xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]PORR_IN049016UV[controlAciprocess][classCode=CACT][moodCode=EVN]/subject[typeCode=SUBJ]/investigationEvent[classCode=INVESTG][moodCode=EVN]/component[typeCode=COMP]/adverseEventAssessment[1]/adverseEventAssessment[classCode=INVESTG][moodCode=EVN]/subject[typeCode=SBJ]/primaryRole[classCode=INVSBJ]/player[1]/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)	/MCCI_IN200100UV01[ITSVersion=XML_1.0T][xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]PORR_IN049016UV[controlAciprocess][classCode=CACT][moodCode=EVN]/subject[typeCode=SUBJ]/investigationEvent[classCode=INVESTG][moodCode=EVN]/component[typeCode=COMP]/adverseEventAssessment[1]/adverseEventAssessment[classCode=INVESTG][moodCode=EVN]/subject[typeCode=SBJ]/primaryRole[classCode=INVSBJ]/subjectOf2[typeCode=SBJ]/observation/code/@code=3][codeSystem=2.16.84.0.1.113883.3.989.2.1.1.19][1]/observation[classCode=OBS][moodCode=EVN]/value/@xsi: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)	/MCCI_IN200100UV01[ITSVersion=XML_1.0T][xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]PORR_IN049016UV[controlAciprocess][classCode=CACT][moodCode=EVN]/subject[typeCode=SUBJ]/investigationEvent[classCode=INVESTG][moodCode=EVN]/component[typeCode=COMP]/adverseEventAssessment[1]/adverseEventAssessment[classCode=INVESTG][moodCode=EVN]/subject[typeCode=SBJ]/primaryRole[classCode=INVSBJ]/subjectOf2[typeCode=SBJ]/observation/code/@code=3][codeSystem=2.16.84.0.1.113883.3.989.2.1.1.19][1]/observation[classCode=OBS][moodCode=EVN]/value/@xsi: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)	/MCCI_IN200100UV01[ITSVersion=XML_1.0T][xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]PORR_IN049016UV[controlAciprocess][classCode=CACT][moodCode=EVN]/subject[typeCode=SUBJ]/investigationEvent[classCode=INVESTG][moodCode=EVN]/component[typeCode=COMP]/adverseEventAssessment[1]/adverseEventAssessment[classCode=INVESTG][moodCode=EVN]/subject[typeCode=SBJ]/primaryRole[classCode=INVSBJ]/subjectOf2[typeCode=SBJ]/observation/code/@code=16][codeSystem=2.16.84.0.1.113883.3.989.2.1.1.19][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)	/MCCI_IN200100UV01[ITSVersion=XML_1.0T][xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]PORR_IN049016UV[controlAciprocess][classCode=CACT][moodCode=EVN]/subject[typeCode=SUBJ]/investigationEvent[classCode=INVESTG][moodCode=EVN]/component[typeCode=COMP]/adverseEventAssessment[1]/adverseEventAssessment[classCode=INVESTG][moodCode=EVN]/subject[typeCode=SBJ]/primaryRole[classCode=INVSBJ]/subjectOf2[typeCode=SBJ]/observation/code/@code=16][codeSystem=2.16.84.0.1.113883.3.989.2.1.1.19][1]/observation[classCode=OBS][moodCode=EVN]/value/@xsi:type=PQ][1]/@unit

(別添 3)

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]JPORR_IN049016UV[controlActProcess/@classCode=CACT][@moodCode=EVN]/subject/@typeCode=SUBJ[investigationEvent/@classCode=INVTG][@moodCode=EVN]/component/@typeCode=COMP[adverseEventAssessment[1]/adverseEventAssessment/@classCode=INVTG][@moodCode=EVN]/subject[1]/primaryRole/@classCode=INVSBJ[subjectOf/@typeCode=SBJ][observation/code/@code=4][@codeSystem=2.16.84 0.1.113883.3.989.2.1.1.19][1]observation[1]@code=EVN][value/@xsi:type=CE][@codeSystem=2.16.84 0.1.113883.3.989.2.1.1.19][1]@code
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]JPORR_IN049016UV[controlActProcess/@classCode=CACT][@moodCode=EVN]/subject/@typeCode=SUBJ[investigationEvent/@classCode=INVTG][@moodCode=EVN]/component/@typeCode=COMP[adverseEventAssessment[1]/adverseEventAssessment/@classCode=INVTG][@moodCode=EVN]/subject[1]/primaryRole/@classCode=INVSBJ[subjectOf/@typeCode=SBJ][observation/code/@code=7][@codeSystem=2.16.84 0.1.113883.3.989.2.1.1.19][1]observation[1]@code=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]JPORR_IN049016UV[controlActProcess/@classCode=CACT][@moodCode=EVN]/subject/@typeCode=SUBJ[investigationEvent/@classCode=INVTG][@moodCode=EVN]/component/@typeCode=COMP[adverseEventAssessment[1]/adverseEventAssessment/@classCode=INVTG][@moodCode=EVN]/subject[1]/primaryRole/@classCode=INVSBJ[subjectOf/@typeCode=SBJ][observation/code/@code=17][@codeSystem=2.16.84 0.1.113883.3.989.2.1.1.19][1]observation[1]@code=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]JPORR_IN049016UV[controlActProcess/@classCode=CACT][@moodCode=EVN]/subject/@typeCode=SUBJ[investigationEvent/@classCode=INVTG][@moodCode=EVN]/component/@typeCode=COMP[adverseEventAssessment[1]/adverseEventAssessment/@classCode=INVTG][@moodCode=EVN]/subject[1]/primaryRole/@classCode=INVSBJ[subjectOf/@typeCode=SBJ][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]JPORR_IN049016UV[controlActProcess/@classCode=CACT][@moodCode=EVN]/subject/@typeCode=SUBJ[investigationEvent/@classCode=INVTG][@moodCode=EVN]/component/@typeCode=COMP[adverseEventAssessment[1]/adverseEventAssessment/@classCode=INVTG][@moodCode=EVN]/subject[1]/primaryRole/@classCode=INVSBJ[subjectOf/@typeCode=SBJ][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]JPORR_IN049016UV[controlActProcess/@classCode=CACT][@moodCode=EVN]/subject/@typeCode=SUBJ[investigationEvent/@classCode=INVTG][@moodCode=EVN]/component/@typeCode=COMP[adverseEventAssessment[1]/adverseEventAssessment/@classCode=INVTG][@moodCode=EVN]/subject[1]/primaryRole/@classCode=INVSBJ[subjectOf/@typeCode=SBJ][observation/code/@code=22][@codeSystem=2.16.84 0.1.113883.3.989.2.1.1.19][1]observation[1]@code=OBS][@moodCode=EVN][value/@xsi:type=TS][1]@value

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e				NullFlavor		<pre> /MCCI_IN200100UV01/@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/P/RR_IN049016UV/r/controlActProcess/@classCode=CACT][@moodCode=EVN]/subject/@typeCode=SUBJ][/investigationEvent/@classCode=INVTG][@moodCode=EVN]/component/@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment/@classCode=INVTG][@moodCode=EVN]/subject1/@typeCode=SBJ][/primaryRole/@classCode=INVTG][@moodCode=EVN]/subject/@code=22][@codeSystem=2.16.840.1.113883.3.989.2.1.1.19][/observation/@classCode=OBS][@moodCode=EVN]/value/@xsi:type=TS][/@nullFlavor </pre>
h	D.7	関連する治療歴及び随伴症状 (副作用/有害事象を除く)				<pre> /MCCI_IN200100UV01/@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/P/RR_IN049016UV/r/controlActProcess/@classCode=CACT][@moodCode=EVN]/subject/@typeCode=SUBJ][/investigationEvent/@classCode=INVTG][@moodCode=EVN]/component/@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment/@classCode=INVTG][@moodCode=EVN]/subject1/@typeCode=SBJ][/primaryRole/@classCode=INVTG][@moodCode=EVN]/subject/@code=22][@codeSystem=2.16.840.1.113883.3.989.2.1.1.20][/organizer/@classCode=CATEGORY][@moodCode=EVN]/component/@typeCode=COMP][observation/@code/@codeSystem=2.16.840.1.113883.6.163] </pre>
h	D.7.1.r	関連する治療歴及び随伴症状の精選化された情報 (必要に応じて繰り返す)		繰り返しノード		<pre> /MCCI_IN200100UV01/@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/P/RR_IN049016UV/r/controlActProcess/@classCode=CACT][@moodCode=EVN]/subject/@typeCode=SUBJ][/investigationEvent/@classCode=INVTG][@moodCode=EVN]/component/@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment/@classCode=INVTG][@moodCode=EVN]/subject1/@typeCode=SBJ][/primaryRole/@classCode=INVTG][@moodCode=EVN]/subject/@code=22][@codeSystem=2.16.840.1.113883.3.989.2.1.1.20][/organizer/@classCode=CATEGORY][@moodCode=EVN]/component/@typeCode=COMP][observation/@code/@codeSystem=2.16.840.1.113883.6.163] </pre>
e	D.7.1.r.1a	関連する治療歴及び随伴症状の MedDRA パージョン	4AN	Concept Descriptor (CD)	codeSystemVersion=Character String (ST)	<pre> /MCCI_IN200100UV01/@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/P/RR_IN049016UV/r/controlActProcess/@classCode=CACT][@moodCode=EVN]/subject/@typeCode=SUBJ][/investigationEvent/@classCode=INVTG][@moodCode=EVN]/component/@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment/@classCode=INVTG][@moodCode=EVN]/subject1/@typeCode=SBJ][/primaryRole/@classCode=INVTG][@moodCode=EVN]/subject/@code=22][@codeSystem=2.16.840.1.113883.3.989.2.1.1.20][/organizer/@classCode=CATEGORY][@moodCode=EVN]/component/@typeCode=OBS][@moodCode=EVN]/code/@code </pre>
e	D.7.1.r.1b	関連する治療歴及び随伴症状 (疾病/手術処置/その他) (MedDRA コード)	8N	Concept Descriptor (CD)	code=Character String (ST)	<pre> /MCCI_IN200100UV01/@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/P/RR_IN049016UV/r/controlActProcess/@classCode=CACT][@moodCode=EVN]/subject/@typeCode=SUBJ][/investigationEvent/@classCode=INVTG][@moodCode=EVN]/component/@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment/@classCode=INVTG][@moodCode=EVN]/subject1/@typeCode=SBJ][/primaryRole/@classCode=INVTG][@moodCode=EVN]/subject/@code=22][@codeSystem=2.16.840.1.113883.3.989.2.1.1.20][/organizer/@classCode=CATEGORY][@moodCode=EVN]/component/@typeCode=OBS][@moodCode=EVN]/code/@code </pre>
e	D.7.1.r.2	開始日	日付/時間	Interval of Point in Time (IVL<TS>)	low=Interval Boundary (IVXB)	<pre> /MCCI_IN200100UV01/@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/P/RR_IN049016UV/r/controlActProcess/@classCode=CACT][@moodCode=EVN]/subject/@typeCode=SUBJ][/investigationEvent/@classCode=INVTG][@moodCode=EVN]/component/@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment/@classCode=INVTG][@moodCode=EVN]/subject1/@typeCode=SBJ][/primaryRole/@classCode=INVTG][@moodCode=EVN]/subject/@code=22][@codeSystem=2.16.840.1.113883.3.989.2.1.1.20][/organizer/@classCode=CATEGORY][@moodCode=EVN]/component/@typeCode=OBS][@moodCode=EVN]/effectiveTime/@xsi:type=IVL_TS][low/@value </pre>

(別添 3)

<p>e</p>	<p>D.7.1.r.3</p>	<p>継続</p>	<p>ルール型</p>	<p>Boolean (BL)</p>	<p>NullFlavor</p>	<pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/PARR_IN049016UVI/control/ActProcess[@classCode=CACT][@moodCo dCode=EVN]/subject/@typeCode=SUBJ][investigationEvent/@classCode=INVS][@moodCo dCode=EVN]/component/@typeCode=COMP][adverseEventAssessment][adverseEventAssessment /@classCode=INVS][@moodCode=EVN]/subject/@typeCode=SBJ][primaryRole/@classC ode=INVS][subjectOr2/@typeCode=SBJ][organizer/@code=1][@codeSystem=2.16.840.1 .113883.3.989.2.1.1.20][organizer/@classCode=CATEGORY][@moodCode=EVN]/component[@typeCode=COMP][observation/@code/@codeSystem=2.16.840.1.113883.6.163][observation/@ classCode=OBS][@moodCode=EVN]/effectiveTime[@xsi:type=IVL_TS]/low/@nullFlavor </pre>
<p>e</p>	<p>D.7.1.r.4</p>	<p>終了日</p>	<p>日付/時間</p>	<p>Interval of Point In Time (IVL<TS>)</p>	<p>NullFlavor</p>	<pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/PARR_IN049016UVI/control/ActProcess[@classCode=CACT][@moodCo dCode=EVN]/subject/@typeCode=SUBJ][investigationEvent/@classCode=INVS][@moodCo dCode=EVN]/component/@typeCode=COMP][adverseEventAssessment][adverseEventAssessment /@classCode=INVS][@moodCode=EVN]/subject/@typeCode=SBJ][primaryRole/@classC ode=INVS][subjectOr2/@typeCode=SBJ][organizer/@code=1][@codeSystem=2.16.840.1 .113883.3.989.2.1.1.20][organizer/@classCode=CATEGORY][@moodCode=EVN]/component[@typeCode=COMP][observation/@code/@codeSystem=2.16.840.1.113883.6.163][observation/@ classCode=OBS][@moodCode=EVN]/inboundRelationship[@typeCode=REFR][observation/@code[@code=13][@codeSystem=2.16.840.1.113883.3.989.2.1.1.19][observation/@classCode=OBS']/@moodCode=EVN]/value/@xsi:type=BL][1]@value </pre>
<p>e</p>	<p>D.7.1.r.4</p>	<p>終了日</p>	<p>日付/時間</p>	<p>Interval of Point In Time (IVL<TS>)</p>	<p>NullFlavor</p>	<pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/PARR_IN049016UVI/control/ActProcess[@classCode=CACT][@moodCo dCode=EVN]/subject/@typeCode=SUBJ][investigationEvent/@classCode=INVS][@moodCo dCode=EVN]/component/@typeCode=COMP][adverseEventAssessment][adverseEventAssessment /@classCode=INVS][@moodCode=EVN]/subject/@typeCode=SBJ][primaryRole/@classC ode=INVS][subjectOr2/@typeCode=SBJ][organizer/@code=1][@codeSystem=2.16.840.1 .113883.3.989.2.1.1.20][organizer/@classCode=CATEGORY][@moodCode=EVN]/component[@typeCode=COMP][observation/@code/@codeSystem=2.16.840.1.113883.6.163][observation/@ classCode=OBS][@moodCode=EVN]/inboundRelationship[@typeCode=REFR][observation/@code[@code=13][@codeSystem=2.16.840.1.113883.3.989.2.1.1.19][observation/@classCode=OBS']/@moodCode=EVN]/value/@xsi:type=BL][1]@value </pre>
<p>e</p>	<p>D.7.1.r.4</p>	<p>終了日</p>	<p>日付/時間</p>	<p>Interval of Point In Time (IVL<TS>)</p>	<p>NullFlavor</p>	<pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/PARR_IN049016UVI/control/ActProcess[@classCode=CACT][@moodCo dCode=EVN]/subject/@typeCode=SUBJ][investigationEvent/@classCode=INVS][@moodCo dCode=EVN]/component/@typeCode=COMP][adverseEventAssessment][adverseEventAssessment /@classCode=INVS][@moodCode=EVN]/subject/@typeCode=SBJ][primaryRole/@classC ode=INVS][subjectOr2/@typeCode=SBJ][organizer/@code=1][@codeSystem=2.16.840.1 .113883.3.989.2.1.1.20][organizer/@classCode=CATEGORY][@moodCode=EVN]/component[@typeCode=COMP][observation/@code/@codeSystem=2.16.840.1.113883.6.163][observation/@ classCode=OBS][@moodCode=EVN]/effectiveTime[@xsi:type=IVL_TS]/high/@value </pre>
<p>e</p>	<p>D.7.1.r.4</p>	<p>終了日</p>	<p>日付/時間</p>	<p>Interval of Point In Time (IVL<TS>)</p>	<p>NullFlavor</p>	<pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/PARR_IN049016UVI/control/ActProcess[@classCode=CACT][@moodCo dCode=EVN]/subject/@typeCode=SUBJ][investigationEvent/@classCode=INVS][@moodCo dCode=EVN]/component/@typeCode=COMP][adverseEventAssessment][adverseEventAssessment /@classCode=INVS][@moodCode=EVN]/subject/@typeCode=SBJ][primaryRole/@classC ode=INVS][subjectOr2/@typeCode=SBJ][organizer/@code=1][@codeSystem=2.16.840.1 .113883.3.989.2.1.1.20][organizer/@classCode=CATEGORY][@moodCode=EVN]/component[@typeCode=COMP][observation/@code/@codeSystem=2.16.840.1.113883.6.163][observation/@ classCode=OBS][@moodCode=EVN]/effectiveTime[@xsi:type=IVL_TS]/high/@value </pre>

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<p>D.7.1.r.5</p>	<p>備考</p>	<p>2000AN</p>	<p>Encapsulated Data (ED)</p>	<p>値</p>	<pre> /MCCI_IN200100UV01[@ITSVersion='XML_1.0']/@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd'JPORR_IN049016UV1/controlActProcess[@classCode='CACT']@moodCode='EVN']/subject[@typeCode='SUBJ']/investigationEvent[@classCode='INVTG']@moodCode='EVN']/component[@typeCode='COMP']/adverseEventAssessment[1]/adverseEventAssessment[@classCode='INVTG']@moodCode='EVN']/subject1[@typeCode='SBJ']/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ']/organizer/code[@code='1']/@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']/organizer/@classCode='CATEGORY']@moodCode='EVN']/component[1]/typeCode='COMP']/observation/code/@codeSystem='2.16.840.1.113883.6.163']/observation/@classCode='OBS']@moodCode='EVN']/value[@xsi:type='ED']/text() </pre>
<p>D.7.1.r.6</p>	<p>家族歴</p>	<p>ブール型</p>	<p>Boolean (BL)</p>	<p>値</p>	<pre> /MCCI_IN200100UV01[@ITSVersion='XML_1.0']/@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd'JPORR_IN049016UV1/controlActProcess[@classCode='CACT']@moodCode='EVN']/subject[@typeCode='SUBJ']/investigationEvent[@classCode='INVTG']@moodCode='EVN']/component[@typeCode='COMP']/adverseEventAssessment[1]/adverseEventAssessment[@classCode='INVTG']@moodCode='EVN']/subject1[@typeCode='SBJ']/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ']/organizer/code[@code='1']/@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']/organizer/@classCode='CATEGORY']@moodCode='EVN']/component[1]/typeCode='OBS']@moodCode='EVN']/outboundRelationship2/@typeCode='EXPL']/observation/code/@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']/@value </pre>
<p>D.7.2</p>	<p>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</p>	<p>10000AN</p>	<p>Encapsulated Data (ED)</p>	<p>値</p>	<pre> /MCCI_IN200100UV01[@ITSVersion='XML_1.0']/@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd'JPORR_IN049016UV1/controlActProcess[@classCode='CACT']@moodCode='EVN']/subject[@typeCode='SUBJ']/investigationEvent[@classCode='INVTG']@moodCode='EVN']/component[@typeCode='COMP']/adverseEventAssessment[1]/adverseEventAssessment[@classCode='INVTG']@moodCode='EVN']/subject1[@typeCode='SBJ']/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ']/organizer/code[@code='1']/@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']/organizer/@classCode='CATEGORY']@moodCode='EVN']/component[1]/typeCode='COMP']/observation/code/@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']/observation/@classCode='OBS']@moodCode='EVN']/value[@xsi:type='ED']/text() </pre>
<p>e</p>			<p>Null Flavor</p>		<pre> /MCCI_IN200100UV01[@ITSVersion='XML_1.0']/@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd'JPORR_IN049016UV1/controlActProcess[@classCode='CACT']@moodCode='EVN']/subject[@typeCode='SUBJ']/investigationEvent[@classCode='INVTG']@moodCode='EVN']/component[@typeCode='COMP']/adverseEventAssessment[1]/adverseEventAssessment[@classCode='INVTG']@moodCode='EVN']/subject1[@typeCode='SBJ']/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ']/organizer/code[@code='1']/@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']/organizer/@classCode='CATEGORY']@moodCode='EVN']/component[1]/typeCode='COMP']/observation/code/@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']/observation/@classCode='OBS']@moodCode='EVN']/value[@xsi:type='ED']/text() </pre>
<p>e</p>	<p>併用療法</p>	<p>ブール型</p>	<p>Boolean (BL)</p>	<p>値</p>	<pre> /MCCI_IN200100UV01[@ITSVersion='XML_1.0']/@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd'JPORR_IN049016UV1/controlActProcess[@classCode='CACT']@moodCode='EVN']/subject[@typeCode='SUBJ']/investigationEvent[@classCode='INVTG']@moodCode='EVN']/component[@typeCode='COMP']/adverseEventAssessment[1]/adverseEventAssessment[@classCode='INVTG']@moodCode='EVN']/subject1[@typeCode='SBJ']/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ']/organizer/code[@code='1']/@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']/organizer/@classCode='CATEGORY']@moodCode='EVN']/component[1]/typeCode='COMP']/observation/code/@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']/observation/@classCode='OBS']@moodCode='EVN']/value[@xsi:type='BL']/value </pre>

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h	D.8.r	関連する過去の医薬品使用歴 (必要に応じて繰り返し返す)			繰り返し ノード	<pre> /MCCL_IN200100UV01/@ITSVersion=XML_1.0][@xsi:schemaLocation=um:h7-org:v3 dCode=EVN]/subject/@typeCode=SUBJ][investigationEvent/@classCode=CACT][@moodCo de=EVN]/component/@typeCode=COMP][adverseEventAssessment][adverseEventAssessment /@classCode=INVTG][@moodCode=EVN]/subject/@typeCode=SBJ][primaryRole/@classC ode=INVSBJ]/subjectOrZ/@typeCode=SBJ][organizerCode=@code=2][@codeSystem=2.16.840.1 .113883.3.989.2.1.1.20][organizer/@classCode=CATEGORY][@moodCode=EVN]/component[@typeCode=COMP][substanceAdministration] </pre>
e	D.8.r.1	医薬品名 (報告された薬項)	250AN	Entity Name (EN) name=Entity Name Part (ENXP)	値	<pre> /MCCL_IN200100UV01/@ITSVersion=XML_1.0][@xsi:schemaLocation=um:h7-org:v3 dCode=EVN]/subject/@typeCode=SUBJ][investigationEvent/@classCode=CACT][@moodCo de=EVN]/component/@typeCode=COMP][adverseEventAssessment][adverseEventAssessment /@classCode=INVTG][@moodCode=EVN]/subject/@typeCode=SBJ][primaryRole/@classC ode=INVSBJ]/subjectOrZ/@typeCode=SBJ][organizerCode=@code=2][@codeSystem=2.16.840.1 .113883.3.989.2.1.1.20][organizer/@classCode=CATEGORY][@moodCode=EVN]/component[@typeCode=COMP][substanceAdministration]/substanceAdministration/@classCode=SBADM][@typeCode=EVN]/consumable/@typeCode=CSM][instanceOfKind/@classCode=INST]/kindO fProduct/@classCode=MMA][@determinerCode=KIND]/name[1]text() </pre>
e	D.8.r.2a	MPID パージョン日付/番号	M5 ガイド を参照	Coded With Equivalents (CE) codeSystemVersion= Character String (ST)	Null Flavor	<pre> /MCCL_IN200100UV01/@ITSVersion=XML_1.0][@xsi:schemaLocation=um:h7-org:v3 dCode=EVN]/subject/@typeCode=SUBJ][investigationEvent/@classCode=CACT][@moodCo de=EVN]/component/@typeCode=COMP][adverseEventAssessment][adverseEventAssessment /@classCode=INVTG][@moodCode=EVN]/subject/@typeCode=SBJ][primaryRole/@classC ode=INVSBJ]/subjectOrZ/@typeCode=SBJ][organizerCode=@code=2][@codeSystem=2.16.840.1 .113883.3.989.2.1.1.20][organizer/@classCode=CATEGORY][@moodCode=EVN]/component[@typeCode=COMP][substanceAdministration]/substanceAdministration/@classCode=SBADM][@typeCode=EVN]/consumable/@typeCode=CSM][instanceOfKind/@classCode=INST]/kindO fProduct/@classCode=MMA][@determinerCode=KIND]/name[1]nullFlavor </pre>
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	<pre> /MCCL_IN200100UV01/@ITSVersion=XML_1.0][@xsi:schemaLocation=um:h7-org:v3 dCode=EVN]/subject/@typeCode=SUBJ][investigationEvent/@classCode=CACT][@moodCo de=EVN]/component/@typeCode=COMP][adverseEventAssessment][adverseEventAssessment /@classCode=INVTG][@moodCode=EVN]/subject/@typeCode=SBJ][primaryRole/@classC ode=INVSBJ]/subjectOrZ/@typeCode=SBJ][organizerCode=@code=2][@codeSystem=2.16.840.1 .113883.3.989.2.1.1.20][organizer/@classCode=CATEGORY][@moodCode=EVN]/component[@typeCode=COMP][substanceAdministration]/substanceAdministration/@classCode=SBADM][@typeCode=EVN]/consumable/@typeCode=CSM][instanceOfKind/@classCode=INST]/kindO fProduct/@classCode=MMA][@determinerCode=KIND]/code/@codeSystem=TBD-MPID]/@cod eSystemVersion </pre>

(別添 3)

<p>D.8.r.3a</p>	<p>PhPID パージョン日付／番 号</p>	<p>M5 ガイド を参照</p>	<p>Coded With Equivalents (CE)</p>	<p>codeSystemVersion= Character String (ST)</p>	<p>値</p>	<pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0T][@xsi:schemaLocation=urn:hl7-org:v3 /MCCL_IN200100UV01.xsd]/PDRR_IN049016UVJ/controlAcIProcess[@classCode=CACT][@moo dCode=EVN]/subject/@typeCode=SUBJ[1]/investigationEvent[@classCode=INVESTG][@moodCo de=EVN]/component/@typeCode=COMP[1]/adverseEventAssessment[1]/adverseEventAssessment [@classCode=INVESTG][@moodCode=EVN]/subject/@typeCode=SBJ[1]/primaryRole/@classC ode=INVSBJ/subjectO2/@typeCode=SBJ[1]/organizer/@code=2][@codeSystem=2.16.840.1 .113883.3.989.2.1.1.20][1]/organizer/@classCode=CATEGORY][@moodCode=EVN]/component[@typeCode=COMP][substanceAdministration]/substanceAdministration/@classCode=SBADM][@moodCode=EVN]/consumable/@typeCode=CSM[1]/instanceOfKind/@classCode=INSTJ/kinD P/product/@classCode=MMA[1][@determinerCode=KIND]/code/@codeSystem=TBD-PhPID]/@cod eSystemVersion </pre>
<p>D.8.r.3b</p>	<p>製剤識別子 (PhPID)</p>	<p>M5 ガイド を参照</p>	<p>Coded With Equivalents (CE)</p>	<p>code=Character String (ST)</p>	<p>値</p>	<pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0T][@xsi:schemaLocation=urn:hl7-org:v3 /MCCL_IN200100UV01.xsd]/PDRR_IN049016UVJ/controlAcIProcess[@classCode=CACT][@moo dCode=EVN]/subject/@typeCode=SUBJ[1]/investigationEvent[@classCode=INVESTG][@moodCo de=EVN]/component/@typeCode=COMP[1]/adverseEventAssessment[1]/adverseEventAssessment [@classCode=INVESTG][@moodCode=EVN]/subject/@typeCode=SBJ[1]/primaryRole/@classC ode=INVSBJ/subjectO2/@typeCode=SBJ[1]/organizer/@code=2][@codeSystem=2.16.840.1 .113883.3.989.2.1.1.20][1]/organizer/@classCode=CATEGORY][@moodCode=EVN]/component[@typeCode=COMP][substanceAdministration]/substanceAdministration/@classCode=SBADM][@moodCode=EVN]/consumable/@typeCode=CSM[1]/instanceOfKind/@classCode=INSTJ/kinD P/product/@classCode=MMA[1][@determinerCode=KIND]/code/@codeSystem=TBD-PhPID]/@cod eSystemVersion </pre>
<p>D.8.r.4</p>	<p>開始日</p>	<p>日付／時間</p>	<p>Interval of Point In Time (VL<TS>)</p>	<p>low=Interval Boundary (VXB)</p>	<p>値</p>	<pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0T][@xsi:schemaLocation=urn:hl7-org:v3 /MCCL_IN200100UV01.xsd]/PDRR_IN049016UVJ/controlAcIProcess[@classCode=CACT][@moo dCode=EVN]/subject/@typeCode=SUBJ[1]/investigationEvent[@classCode=INVESTG][@moodCo de=EVN]/component/@typeCode=COMP[1]/adverseEventAssessment[1]/adverseEventAssessment [@classCode=INVESTG][@moodCode=EVN]/subject/@typeCode=SBJ[1]/primaryRole/@classC ode=INVSBJ/subjectO2/@typeCode=SBJ[1]/organizer/@code=2][@codeSystem=2.16.840.1 .113883.3.989.2.1.1.20][1]/organizer/@classCode=CATEGORY][@moodCode=EVN]/component[@typeCode=COMP][substanceAdministration]/substanceAdministration/@classCode=SBADM][@moodCode=EVN]/effectiveTime/@xsi:type=IVL_TS/low/@value </pre>
<p>e</p>				<p>NullFlavor</p>		<pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0T][@xsi:schemaLocation=urn:hl7-org:v3 /MCCL_IN200100UV01.xsd]/PDRR_IN049016UVJ/controlAcIProcess[@classCode=CACT][@moo dCode=EVN]/subject/@typeCode=SUBJ[1]/investigationEvent[@classCode=INVESTG][@moodCo de=EVN]/component/@typeCode=COMP[1]/adverseEventAssessment[1]/adverseEventAssessment [@classCode=INVESTG][@moodCode=EVN]/subject/@typeCode=SBJ[1]/primaryRole/@classC ode=INVSBJ/subjectO2/@typeCode=SBJ[1]/organizer/@code=2][@codeSystem=2.16.840.1 .113883.3.989.2.1.1.20][1]/organizer/@classCode=CATEGORY][@moodCode=EVN]/component[@typeCode=COMP][substanceAdministration]/substanceAdministration/@classCode=SBADM][@moodCode=EVN]/effectiveTime/@xsi:type=IVL_TS/low/@value </pre>
<p>D.8.r.5</p>	<p>終了日</p>	<p>日付／時間</p>	<p>Interval of Point In Time (VL<TS>)</p>	<p>high=Interval Boundary (VXB)</p>	<p>値</p>	<pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0T][@xsi:schemaLocation=urn:hl7-org:v3 /MCCL_IN200100UV01.xsd]/PDRR_IN049016UVJ/controlAcIProcess[@classCode=CACT][@moo dCode=EVN]/subject/@typeCode=SUBJ[1]/investigationEvent[@classCode=INVESTG][@moodCo de=EVN]/component/@typeCode=COMP[1]/adverseEventAssessment[1]/adverseEventAssessment [@classCode=INVESTG][@moodCode=EVN]/subject/@typeCode=SBJ[1]/primaryRole/@classC ode=INVSBJ/subjectO2/@typeCode=SBJ[1]/organizer/@code=2][@codeSystem=2.16.840.1 .113883.3.989.2.1.1.20][1]/organizer/@classCode=CATEGORY][@moodCode=EVN]/component[@typeCode=COMP][substanceAdministration]/substanceAdministration/@classCode=SBADM][@moodCode=EVN]/effectiveTime/@xsi:type=IVL_TS/high/@value </pre>

(別添 3)

e			NullFlavor		<pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation='urn:hl7-org:v3 MCCL_IN200100UV01.xsd']/PDRR_IN049016UV1/control/ActProcess[@classCode=CACT][@mo dCode=EVN]/subject/@typeCode=SUBJ][1]/investigationEvent[@classCode=INVESTG][@moodCo de=EVN]/component/@typeCode=COMP][1]/adverseEventAssessment[1]/adverseEventAssessment [classCode=INVESTG][@moodCode=EVN]/subject[1]/typeCode=SBJ][1]/primaryRole[@classC ode=INVSBJ]/subjectOr2/@typeCode=SBJ][organizer/codet/@code=2][@codeSystem=2.16.840.1 13883.3.989.2.1.1.20][1]/organizer/@classCode=CATEGORY][@moodCode=EVN]/component[@typeCode=COMP][substanceAdministration[1]/substanceAdministration[@classCode=SBADM][@moodCode=EVN]/effectiveTime[@xsi:type=IVL_TS]/high/@nullFlavor </pre>
e	D.8.r.6a	使用理由の MedDRA パー ション	4AN	Coded With Equivalents (CE)	<pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation='urn:hl7-org:v3 MCCL_IN200100UV01.xsd']/PDRR_IN049016UV1/control/ActProcess[@classCode=CACT][@mo dCode=EVN]/subject/@typeCode=SUBJ][1]/investigationEvent[@classCode=INVESTG][@moodCo de=EVN]/component/@typeCode=COMP][1]/adverseEventAssessment[1]/adverseEventAssessment [classCode=INVESTG][@moodCode=EVN]/subject[1]/typeCode=SBJ][1]/primaryRole[@classC ode=INVSBJ]/subjectOr2/@typeCode=SBJ][organizer/codet/@code=2][@codeSystem=2.16.840.1 13883.3.989.2.1.1.20][1]/organizer/@classCode=CATEGORY][@moodCode=EVN]/component[@typeCode=COMP][substanceAdministration[1]/substanceAdministration[@classCode=SBADM][@moodCode=EVN]/outboundRelationship2/@typeCode=RSON][observation/codet/@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 </pre>
e	D.8.r.6b	使用理由 (MedDRA コード)	8N	Coded With Equivalents (CE)	<pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation='urn:hl7-org:v3 MCCL_IN200100UV01.xsd']/PDRR_IN049016UV1/control/ActProcess[@classCode=CACT][@mo dCode=EVN]/subject/@typeCode=SUBJ][1]/investigationEvent[@classCode=INVESTG][@moodCo de=EVN]/component/@typeCode=COMP][1]/adverseEventAssessment[1]/adverseEventAssessment [classCode=INVESTG][@moodCode=EVN]/subject[1]/typeCode=SBJ][1]/primaryRole[@classC ode=INVSBJ]/subjectOr2/@typeCode=SBJ][organizer/codet/@code=2][@codeSystem=2.16.840.1 13883.3.989.2.1.1.20][1]/organizer/@classCode=CATEGORY][@moodCode=EVN]/component[@typeCode=COMP][substanceAdministration[1]/substanceAdministration[@classCode=SBADM][@moodCode=EVN]/outboundRelationship2/@typeCode=RSON][observation/codet/@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 </pre>
e	D.8.r.7a	副作用の MedDRA パーショ ン	4AN	Coded With Equivalents (CE)	<pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation='urn:hl7-org:v3 MCCL_IN200100UV01.xsd']/PDRR_IN049016UV1/control/ActProcess[@classCode=CACT][@mo dCode=EVN]/subject/@typeCode=SUBJ][1]/investigationEvent[@classCode=INVESTG][@moodCo de=EVN]/component/@typeCode=COMP][1]/adverseEventAssessment[1]/adverseEventAssessment [classCode=INVESTG][@moodCode=EVN]/subject[1]/typeCode=SBJ][1]/primaryRole[@classC ode=INVSBJ]/subjectOr2/@typeCode=SBJ][organizer/codet/@code=2][@codeSystem=2.16.840.1 13883.3.989.2.1.1.20][1]/organizer/@classCode=CATEGORY][@moodCode=EVN]/component[@typeCode=COMP][substanceAdministration[1]/substanceAdministration[@classCode=SBADM][@moodCode=EVN]/outboundRelationship2/@typeCode=CAUS][observation/codet/@code=23][@ 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 </pre>

(別添 3)

e				NullFlavor	<pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/PORR_IN049016UV1/controlActProcess[@classCode=CACT][@moo dCode=EVN]/subject[@typeCode=SUBJ1]/investigationEvent[@classCode=INVSTG1][@moodCo de=EVN]/component[@typeCode=COMP1]/adverseEventAssessment[1]/adverseEventAssessment [classCode=INVSTG1][@moodCode=EVN]/subject[1]/typeCode=SBJ1/primaryRole[@classC ode=INVSBJ1/player1][@classCode=PSN1][@determinerCode=INSTANCE]/role[@classCode=PR S11]/associatedPerson[@classCode=PSN1][@determinerCode=INSTANCE]/birthTime/@nullFlavor </pre>
e	D.10.2.2a	親の年齢 (数)	3N	Physical Quantity (PQ)	<pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/PORR_IN049016UV1/controlActProcess[@classCode=CACT][@moo dCode=EVN]/subject[@typeCode=SUBJ1]/investigationEvent[@classCode=INVSTG1][@moodCo de=EVN]/component[@typeCode=COMP1]/adverseEventAssessment[1]/adverseEventAssessment [classCode=INVSTG1][@moodCode=EVN]/subject[1]/typeCode=SBJ1/primaryRole[@classC ode=INVSBJ1/player1][@classCode=PSN1][@determinerCode=INSTANCE]/role[@classCode=PR S11]/subjectO2[1]/typeCode=SBJ1/observation/code[@code=3][@codeSystem=2.16.840.1.11388 3.3.989.2.1.1.19][1]/observation[@classCode=OBS1][@moodCode=EVN]/value[@xsi:type=PQ][1] /@value </pre>
e	D.10.2.2b	親の年齢 (単位)	50AN	Physical Quantity (PQ)	<pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/PORR_IN049016UV1/controlActProcess[@classCode=CACT][@moo dCode=EVN]/subject[@typeCode=SUBJ1]/investigationEvent[@classCode=INVSTG1][@moodCo de=EVN]/component[@typeCode=COMP1]/adverseEventAssessment[1]/adverseEventAssessment [classCode=INVSTG1][@moodCode=EVN]/subject[1]/typeCode=SBJ1/primaryRole[@classC ode=INVSBJ1/player1][@classCode=PSN1][@determinerCode=INSTANCE]/role[@classCode=PR S11]/subjectO2[1]/typeCode=SBJ1/observation/code[@code=3][@codeSystem=2.16.840.1.11388 3.3.989.2.1.1.19][1]/observation[@classCode=OBS1][@moodCode=EVN]/value[@xsi:type=PQ][1] /@unit </pre>
e	D.10.3	親の最終月経日	日付/時間	Point in Time (TS)	<pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/PORR_IN049016UV1/controlActProcess[@classCode=CACT][@moo dCode=EVN]/subject[@typeCode=SUBJ1]/investigationEvent[@classCode=INVSTG1][@moodCo de=EVN]/component[@typeCode=COMP1]/adverseEventAssessment[1]/adverseEventAssessment [classCode=INVSTG1][@moodCode=EVN]/subject[1]/typeCode=SBJ1/primaryRole[@classC ode=INVSBJ1/player1][@classCode=PSN1][@determinerCode=INSTANCE]/role[@classCode=PR S11]/subjectO2[1]/typeCode=SBJ1/observation/code[@code=22][@codeSystem=2.16.840.1.11388 3.3.989.2.1.1.19][1]/observation[@classCode=OBS1][@moodCode=EVN]/value[@xsi:type=TS][1] /@value </pre>
e				NullFlavor	<pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/PORR_IN049016UV1/controlActProcess[@classCode=CACT][@moo dCode=EVN]/subject[@typeCode=SUBJ1]/investigationEvent[@classCode=INVSTG1][@moodCo de=EVN]/component[@typeCode=COMP1]/adverseEventAssessment[1]/adverseEventAssessment [classCode=INVSTG1][@moodCode=EVN]/subject[1]/typeCode=SBJ1/primaryRole[@classC ode=INVSBJ1/player1][@classCode=PSN1][@determinerCode=INSTANCE]/role[@classCode=PR S11]/subjectO2[1]/typeCode=SBJ1/observation/code[@code=22][@codeSystem=2.16.840.1.11388 3.3.989.2.1.1.19][1]/observation[@classCode=OBS1][@moodCode=EVN]/value[@xsi:type=TS][1] /@nullFlavor </pre>

(別添 3)

D.10.4	親の体重 (kg)	6N	Physical Quantity (PQ)	value=Real Number (REAL)	値	<pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0T][@xsi:schemaLocation=urn:hl7-org:v3 MCC_IN200100UV01.xsd]/PORR_IN049016UVJ/controlActProcess[@classCode=CACT][@moo dCode=EYN]/subject/@typeCode=SUBJ][investigationEvent][@classCode=INVESTG][@moodCo de=EYN]/component/@typeCode=COMP][adverseEventAssessment][adverseEventAssessment [@classCode=INVESTG][@moodCode=EYN]/subject/@typeCode=SBJ][primaryRole/@classC ode=INVSBJ/player1][@classCode=PSN][@determinerCode=INSTANCE]/role/@classCode=PR ST][subjectO2/@typeCode=SBJ][observation/code/@code=7][@codeSystem=2.16.840.1.11388 3.3.989.2.1.1.19][observation/@classCode=OBS][@moodCode=EYN]/value/@xsi:type=PQ]] @unit=kg]]/@value </pre>
D.10.5	親の身長 (cm)	3N	Physical Quantity (PQ)	value=Real Number (REAL)	値	<pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0T][@xsi:schemaLocation=urn:hl7-org:v3 MCC_IN200100UV01.xsd]/PORR_IN049016UVJ/controlActProcess[@classCode=CACT][@moo dCode=EYN]/subject/@typeCode=SUBJ][investigationEvent][@classCode=INVESTG][@moodCo de=EYN]/component/@typeCode=COMP][adverseEventAssessment][adverseEventAssessment [@classCode=INVESTG][@moodCode=EYN]/subject/@typeCode=SBJ][primaryRole/@classC ode=INVSBJ/player1][@classCode=PSN][@determinerCode=INSTANCE]/role/@classCode=PR ST][subjectO2/@typeCode=SBJ][observation/code/@code=17][@codeSystem=2.16.840.1.11388 3.3.989.2.1.1.19][observation/@classCode=OBS][@moodCode=EYN]/value/@xsi:type=PQ]] @unit=cm]]/@value </pre>
D.10.6	親の性別	1N	Coded With Equivalents (CE)	code=Character String (ST)	値	<pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0T][@xsi:schemaLocation=urn:hl7-org:v3 MCC_IN200100UV01.xsd]/PORR_IN049016UVJ/controlActProcess[@classCode=CACT][@moo dCode=EYN]/subject/@typeCode=SUBJ][investigationEvent][@classCode=INVESTG][@moodCo de=EYN]/component/@typeCode=COMP][adverseEventAssessment][adverseEventAssessment [@classCode=INVESTG][@moodCode=EYN]/subject/@typeCode=SBJ][primaryRole/@classC ode=INVSBJ/player1][@classCode=PSN][@determinerCode=INSTANCE]/role/@classCode=PR ST][associatedPerson/@classCode=PSN][@determinerCode=INSTANCE]/administrativeGender Code[@codeSystem=1.0.5218]]/@code </pre>
D.10.7	親に関連する治療歴及び随 伴症状			Null Flavor	Null Flavor	<pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0T][@xsi:schemaLocation=urn:hl7-org:v3 MCC_IN200100UV01.xsd]/PORR_IN049016UVJ/controlActProcess[@classCode=CACT][@moo dCode=EYN]/subject/@typeCode=SUBJ][investigationEvent][@classCode=INVESTG][@moodCo de=EYN]/component/@typeCode=COMP][adverseEventAssessment][adverseEventAssessment [@classCode=INVESTG][@moodCode=EYN]/subject/@typeCode=SBJ][primaryRole/@classC ode=INVSBJ/player1][@classCode=PSN][@determinerCode=INSTANCE]/role/@classCode=PR ST][associatedPerson/@classCode=PSN][@determinerCode=INSTANCE]/administrativeGender Code[@codeSystem=1.0.5218]]/@nullFlavor </pre>
D.10.7.1.r	親の構造化された情報 (必要 に応じて繰り返す)			繰り返し ノード	繰り返し ノード	<pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0T][@xsi:schemaLocation=urn:hl7-org:v3 MCC_IN200100UV01.xsd]/PORR_IN049016UVJ/controlActProcess[@classCode=CACT][@moo dCode=EYN]/subject/@typeCode=SUBJ][investigationEvent][@classCode=INVESTG][@moodCo de=EYN]/component/@typeCode=COMP][adverseEventAssessment][adverseEventAssessment [@classCode=INVESTG][@moodCode=EYN]/subject/@typeCode=SBJ][primaryRole/@classC ode=INVSBJ/player1][@classCode=PSN][@determinerCode=INSTANCE]/role/@classCode=PR ST][subjectO2/@typeCode=SBJ][organizer/@code=1][@codeSystem=2.16.840.1.113883. 3.989.2.1.1.20][organizer/@classCode=CATEGORY][@moodCode=EYN]/component/@typeC ode=COMP][observation/code/@codeSystem=2.16.840.1.113883.6.163]] </pre>

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e	D.10.7.1.r.1a	親の関連する治療歴及び随伴症状の MedDRA パージョン	4AN	Concept Descriptor (CD)	codeSystemVersion=Character String (ST)	/MCCLI_N200100UV01[@ITSVersion=XML_1.0][@xmlns:schemaLocation=urn:hl7-org:v3MCCLI_N200100UV01.xsd]/PORR_IN049016UVJ/controlActProcess[@classCode=CACT][@moodCode=EVN]/component[@typeCode=COMP]/adverseEventAssessment[1]/adverseEventAssessment[@classCode=INVSBJ][@moodCode=EVN]/subject[1][@typeCode=SBJ][1]primaryRole[@classCode=INVSBJ][@moodCode=PSN][@determinerCode=INSTANCE][@classCode=PR][1]subjectCZ[1][@typeCode=SBJ][@moodCode=EVN]/component[@typeCode=COMP][observation/code[@codeSystem=2.16.840.1.113883.6.163]]/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)	/MCCLI_N200100UV01[@ITSVersion=XML_1.0][@xmlns:schemaLocation=urn:hl7-org:v3MCCLI_N200100UV01.xsd]/PORR_IN049016UVJ/controlActProcess[@classCode=CACT][@moodCode=EVN]/subject[1][@typeCode=SUBJ][1]investigationEvent[1]/adverseEventAssessment[1]/adverseEventAssessment[@classCode=INVSBJ][@moodCode=EVN]/subject[1][@typeCode=SBJ][1]primaryRole[@classCode=INVSBJ][@moodCode=PSN][@determinerCode=INSTANCE][@classCode=PR][1]subjectCZ[1][@typeCode=SBJ][@moodCode=EVN]/component[@typeCode=COMP][observation/code[@codeSystem=2.16.840.1.113883.6.163]]/observation[@classCode=OBS][@moodCode=EVN]/code/@code
e	D.10.7.1.r.2	開始日	日付/時間	Interval of Point in Time (IVL<TS>)	low=Interval Boundary (VXB)	/MCCLI_N200100UV01[@ITSVersion=XML_1.0][@xmlns:schemaLocation=urn:hl7-org:v3MCCLI_N200100UV01.xsd]/PORR_IN049016UVJ/controlActProcess[@classCode=CACT][@moodCode=EVN]/subject[1][@typeCode=SUBJ][1]investigationEvent[1]/adverseEventAssessment[1]/adverseEventAssessment[@classCode=INVSBJ][@moodCode=EVN]/subject[1][@typeCode=SBJ][1]primaryRole[@classCode=INVSBJ][@moodCode=PSN][@determinerCode=INSTANCE][@classCode=PR][1]subjectCZ[1][@typeCode=SBJ][@moodCode=EVN]/component[@typeCode=COMP][observation/code[@codeSystem=2.16.840.1.113883.6.163]]/observation[@classCode=OBS][@moodCode=EVN]/effectiveTime[IVL_TS]/low/@value
e					NullFlavor	/MCCLI_N200100UV01[@ITSVersion=XML_1.0][@xmlns:schemaLocation=urn:hl7-org:v3MCCLI_N200100UV01.xsd]/PORR_IN049016UVJ/controlActProcess[@classCode=CACT][@moodCode=EVN]/component[@typeCode=COMP]/adverseEventAssessment[1]/adverseEventAssessment[@classCode=INVSBJ][@moodCode=EVN]/subject[1][@typeCode=SBJ][1]primaryRole[@classCode=INVSBJ][@moodCode=PSN][@determinerCode=INSTANCE][@classCode=PR][1]subjectCZ[1][@typeCode=SBJ][@moodCode=EVN]/component[@typeCode=COMP][observation/code[@codeSystem=2.16.840.1.113883.6.163]]/observation[@classCode=OBS][@moodCode=EVN]/effectiveTime[IVL_TS]/low/@nullFlavor

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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]/PARR_IN049016UV[controlActProcess/@classCode=CACT][@moodCode=EVN]/subject/@typeCode=SUBJ[1]/investigationEvent/@classCode=INVESTG[1]/moodCode=EVN/component/@typeCode=COMP[1]/adverseEventAssessment[1]/adverseEventAssessment/@classCode=INVESTG[1]/moodCode=EVN/subject1/@typeCode=SBJ[1]/primaryRole/@classCode=INVSBJ[1]/player1/@classCode=PSN[1]/determinerCode=INSTANCE/role/@classCode=PR 3.989.2.1.1.20[1]/organizer/@classCode=CATEGORY[1]/moodCode=EVN/component/@typeCode=COMP[1]/observation/code/@codeSystem=2.16.840.1.113883.3.989.2.1.1.19[1]/observation/@classCode=OBS[1]/moodCode=EVN/value/@xsi:type=BL[1]/@value
D.10.7.1.r.4	終了日	日付/時間	Interval of Point in Time (VL<TS>)	値 high=Interval Boundary (IVXB)	/MCCI_IN200100UV01[ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PARR_IN049016UV[controlActProcess/@classCode=CACT][@moodCode=EVN]/subject/@typeCode=SUBJ[1]/investigationEvent/@classCode=INVESTG[1]/moodCode=EVN/component/@typeCode=COMP[1]/adverseEventAssessment[1]/adverseEventAssessment/@classCode=INVESTG[1]/moodCode=EVN/subject1/@typeCode=SBJ[1]/primaryRole/@classCode=INVSBJ[1]/player1/@classCode=PSN[1]/determinerCode=INSTANCE/role/@classCode=PR 3.989.2.1.1.20[1]/organizer/@classCode=CATEGORY[1]/moodCode=EVN/component/@typeCode=COMP[1]/observation/code/@codeSystem=2.16.840.1.113883.3.989.2.1.1.19[1]/observation/@classCode=OBS[1]/moodCode=EVN/effectiveTime/@xsi:type=IVL_TS[1]/high/@value
				NullFlavor	/MCCI_IN200100UV01[ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PARR_IN049016UV[controlActProcess/@classCode=CACT][@moodCode=EVN]/subject/@typeCode=SUBJ[1]/investigationEvent/@classCode=INVESTG[1]/moodCode=EVN/component/@typeCode=COMP[1]/adverseEventAssessment[1]/adverseEventAssessment/@classCode=INVESTG[1]/moodCode=EVN/subject1/@typeCode=SBJ[1]/primaryRole/@classCode=INVSBJ[1]/player1/@classCode=PSN[1]/determinerCode=INSTANCE/role/@classCode=PR 3.989.2.1.1.20[1]/organizer/@classCode=CATEGORY[1]/moodCode=EVN/component/@typeCode=COMP[1]/observation/code/@codeSystem=2.16.840.1.113883.3.989.2.1.1.19[1]/observation/@classCode=OBS[1]/moodCode=EVN/effectiveTime/@xsi:type=IVL_TS[1]/high/@value
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]/PARR_IN049016UV[controlActProcess/@classCode=CACT][@moodCode=EVN]/subject/@typeCode=SUBJ[1]/investigationEvent/@classCode=INVESTG[1]/moodCode=EVN/component/@typeCode=COMP[1]/adverseEventAssessment[1]/adverseEventAssessment/@classCode=INVESTG[1]/moodCode=EVN/subject1/@typeCode=SBJ[1]/primaryRole/@classCode=INVSBJ[1]/player1/@classCode=PSN[1]/determinerCode=INSTANCE/role/@classCode=PR 3.989.2.1.1.20[1]/organizer/@classCode=CATEGORY[1]/moodCode=EVN/component/@typeCode=COMP[1]/observation/code/@codeSystem=2.16.840.1.113883.3.989.2.1.1.19[1]/observation/@classCode=OBS[1]/moodCode=EVN/value/@xsi:type=ED[1]/text()

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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	/MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/PARR_IN049016UV[controlActProcess/@classCode=CACT][@moodCode=EVN]/subject/@typeCode=SUBJ[1]/investigationEvent/@classCode=INVTG[1]/moodCode=EVN/component/@typeCode=COMP[1]adverseEventAssessment[1]adverseEventAssessment/@classCode=INVTG[1]/moodCode=EVN/subject/@typeCode=SBJ[1]primaryRole/@classCode=PR[S1]/subjectC1Z/@typeCode=PSN[1]determinerCode=INSTANCE[role]/@classCode=PR[3.989.2.1.1.20][1]organizer/@classCode=CATEGORY[1]moodCode=EVN/component/@typeCode=COMP[1]observation/code/@code=18[1]codeSystem=2.16.840.1.113883.3.989.2.1.1.19[1]observation/@classCode=OBS[1]@xsi:valueOf[1]text[1]
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	/MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/PARR_IN049016UV[controlActProcess/@classCode=CACT][@moodCode=EVN]/subject/@typeCode=SUBJ[1]/investigationEvent/@classCode=INVTG[1]/moodCode=EVN/component/@typeCode=COMP[1]adverseEventAssessment[1]adverseEventAssessment/@classCode=INVTG[1]/moodCode=EVN/subject/@typeCode=SBJ[1]primaryRole/@classCode=PR[S1]/subjectC1Z/@typeCode=PSN[1]determinerCode=INSTANCE[role]/@classCode=PR[3.989.2.1.1.20][1]organizer/@classCode=CATEGORY[1]moodCode=EVN/component/@typeCode=COMP[1]substanceAdministration
e	D.10.8.r.1	医薬品名 (報告された薬項)	250AN	Entity Name (EN) name=Entity Name Part (ENXP)	値	/MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/PARR_IN049016UV[controlActProcess/@classCode=CACT][@moodCode=EVN]/subject/@typeCode=SUBJ[1]/investigationEvent/@classCode=INVTG[1]/moodCode=EVN/component/@typeCode=COMP[1]adverseEventAssessment[1]adverseEventAssessment/@classCode=INVTG[1]/moodCode=EVN/subject/@typeCode=SBJ[1]primaryRole/@classCode=PR[S1]/subjectC1Z/@typeCode=PSN[1]determinerCode=INSTANCE[role]/@classCode=PR[3.989.2.1.1.20][1]organizer/@classCode=CATEGORY[1]moodCode=EVN/component/@typeCode=COMP[1]substanceAdministration/@classCode=SBADM[1]moodCode=EVN/consumable/@typeCode=CSM[1]instanceOfKind/@classCode=INST[1]kindOfProduct/@classCode=MMAT[1]determinerCode=KIND[1]name[1]text[1]
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	/MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/PARR_IN049016UV[controlActProcess/@classCode=CACT][@moodCode=EVN]/subject/@typeCode=SUBJ[1]/investigationEvent/@classCode=INVTG[1]/moodCode=EVN/component/@typeCode=COMP[1]adverseEventAssessment[1]adverseEventAssessment/@classCode=INVTG[1]/moodCode=EVN/subject/@typeCode=SBJ[1]primaryRole/@classCode=PR[S1]/subjectC1Z/@typeCode=PSN[1]determinerCode=INSTANCE[role]/@classCode=PR[3.989.2.1.1.20][1]organizer/@classCode=CATEGORY[1]moodCode=EVN/component/@typeCode=COMP[1]substanceAdministration/@classCode=SBADM[1]moodCode=EVN/consumable/@typeCode=CSM[1]instanceOfKind/@classCode=INST[1]kindOfProduct/@classCode=MMAT[1]determinerCode=KIND[1]name[1]text[1]

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<p>D.10.8.r.2b</p> <p>医薬品製品識別子 (MPID)</p> <p>M5 ガイド ラインを参 照</p> <p>Coded With Equivalents (CE)</p> <p>code=Character String (ST)</p> <p>値</p>	<pre> /MCCI_IN200100UV01[@ITSVersion=XML_1.0]@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/P/RR_IN049016UV/ControlActProcess/@classCode=CACTI/@mood dCode=EVN/subject/@typeCode=SUBJ/1/InvestigationEvent/@classCode=INVESTG/@moodCo de=EVN/Component/@typeCode=COMP/1/AdverseEventAssessment/1/AdverseEventAssessment /@classCode=INVESTG/@moodCode=EVN/subject/1/@typeCode=SB/1/1/primaryRole/@classC ode=INVSBJ/1/primaryRole/@classCode=PR S/1/1/subjectOf/2/@typeCode=SB/1/1/organizer/code/@code=2/1/@codeSystem=2.16.840.1.113883. 3.989.2.1.1.20/1/1/organizer/@classCode=CATEGORY/@moodCode=EVN/Component/@typeC ode=COMP/1/subjectAdministration/1/1/subjectAdministration/@classCode=SBADM/@mood Code=EVN/Consumable/@typeCode=CSM/1/1/instanceOfKind/@classCode=INST/1/KindOfProduc t/@classCode=MMA/1/1/@determinerCode=KIND/1/1/@codeSystem=TBD-MPID/1/@code </pre>
<p>D.10.8.r.3a</p> <p>PHPID パージョン日付/番 号</p> <p>M5 ガイド ラインを参 照</p> <p>Coded With Equivalents (CE)</p> <p>codeSystemVersion= Character String (ST)</p> <p>値</p>	<pre> /MCCI_IN200100UV01[@ITSVersion=XML_1.0]@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/P/RR_IN049016UV/ControlActProcess/@classCode=CACTI/@mood dCode=EVN/subject/@typeCode=SUBJ/1/InvestigationEvent/@classCode=INVESTG/@moodCo de=EVN/Component/@typeCode=COMP/1/AdverseEventAssessment/1/AdverseEventAssessment /@classCode=INVESTG/@moodCode=EVN/subject/1/@typeCode=SB/1/1/primaryRole/@classC ode=INVSBJ/1/primaryRole/@classCode=PR S/1/1/subjectOf/2/@typeCode=SB/1/1/organizer/code/@code=2/1/@codeSystem=2.16.840.1.113883. 3.989.2.1.1.20/1/1/organizer/@classCode=CATEGORY/@moodCode=EVN/Component/@typeC ode=COMP/1/subjectAdministration/1/1/subjectAdministration/@classCode=SBADM/@mood Code=EVN/Consumable/@typeCode=CSM/1/1/instanceOfKind/@classCode=INST/1/KindOfProduc t/@classCode=MMA/1/1/@determinerCode=KIND/1/1/@codeSystem=TBD-MPID/1/@codeSyste mVersion </pre>
<p>D.10.8.r.3b</p> <p>製剤識別子 (PhPID)</p> <p>M5 ガイド ラインを参 照</p> <p>Coded With Equivalents (CE)</p> <p>code=Character String (ST)</p> <p>値</p>	<pre> /MCCI_IN200100UV01[@ITSVersion=XML_1.0]@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/P/RR_IN049016UV/ControlActProcess/@classCode=CACTI/@mood dCode=EVN/subject/@typeCode=SUBJ/1/InvestigationEvent/@classCode=INVESTG/@moodCo de=EVN/Component/@typeCode=COMP/1/AdverseEventAssessment/1/AdverseEventAssessment /@classCode=INVESTG/@moodCode=EVN/subject/1/@typeCode=SB/1/1/primaryRole/@classC ode=INVSBJ/1/primaryRole/@classCode=PR S/1/1/subjectOf/2/@typeCode=SB/1/1/organizer/code/@code=2/1/@codeSystem=2.16.840.1.113883. 3.989.2.1.1.20/1/1/organizer/@classCode=CATEGORY/@moodCode=EVN/Component/@typeC ode=COMP/1/subjectAdministration/1/1/subjectAdministration/@classCode=SBADM/@mood Code=EVN/Consumable/@typeCode=CSM/1/1/instanceOfKind/@classCode=INST/1/KindOfProduc t/@classCode=MMA/1/1/@determinerCode=KIND/1/1/@codeSystem=TBD-MPID/1/@code </pre>
<p>D.10.8.r.4</p> <p>開始日</p> <p>日付/時間</p> <p>Interval of Point in Time (IVL<TS>)</p> <p>low=Interval Boundary (IVXB)</p> <p>値</p>	<pre> /MCCI_IN200100UV01[@ITSVersion=XML_1.0]@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/P/RR_IN049016UV/ControlActProcess/@classCode=CACTI/@mood dCode=EVN/subject/@typeCode=SUBJ/1/InvestigationEvent/@classCode=INVESTG/@moodCo de=EVN/Component/@typeCode=COMP/1/AdverseEventAssessment/1/AdverseEventAssessment /@classCode=INVESTG/@moodCode=EVN/subject/1/@typeCode=SB/1/1/primaryRole/@classC ode=INVSBJ/1/primaryRole/@classCode=PR S/1/1/subjectOf/2/@typeCode=SB/1/1/organizer/code/@code=2/1/@codeSystem=2.16.840.1.113883. 3.989.2.1.1.20/1/1/organizer/@classCode=CATEGORY/@moodCode=EVN/Component/@typeC ode=COMP/1/subjectAdministration/1/1/subjectAdministration/@classCode=SBADM/@mood Code=EVN/EffectiveTime/@xsi:type=IVL_TS/low/@value </pre>

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e	D.10.8.r.6b	使用理由 (MedDRA コード)	8N	Coded With Equivalents (CE)	code=Character String (ST)	値 /MCC1_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCC1_IN200100UV01.xsd]/PORR_IN049016UVr/controlActProcess[@classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUBJ]/investigationEvent[@classCode=INVTG][@moodCode=EVN]/component[@typeCode=COMP]/adverseEventAssessment[1]/adverseEventAssessment[@classCode=INVTG][@moodCode=EVN]/subject1[@typeCode=SBJ]/primaryRole[@classCode=INVSBJ]/player1[@classCode=PSN]/determinerCode=INSTANCE/role[@classCode=PRST]/subjectOr2[@typeCode=SBJ]/organizer/code=@code=2][@codeSystem=2.16.840.1.113883.3.989.2.1.1.20][/organizer/@classCode=CATEGORY][@moodCode=EVN]/component[@typeCode=COMP]/substanceAdministration[r]/substanceAdministration[@classCode=SBADM][@moodCode=EVN]/outboundRelationship2[@typeCode=RSON][observation/code/@code=19][@codeSystem=2.16.840.1.113883.3.989.2.1.1.19][/observation/@classCode=OBS][@moodCode=EVN]/value[@xsi:type=CE][@codeSystem=2.16.840.1.113883.6.163][1]/@code
e	D.10.8.r.7a	副作用の MedDRA パージョン	4AN	Coded With Equivalents (CE)	code=SystemVersion=Character String (ST)	値 /MCC1_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCC1_IN200100UV01.xsd]/PORR_IN049016UVr/controlActProcess[@classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUBJ]/investigationEvent[@classCode=INVTG][@moodCode=EVN]/component[@typeCode=COMP]/adverseEventAssessment[1]/adverseEventAssessment[@classCode=INVTG][@moodCode=EVN]/subject1[@typeCode=SBJ]/primaryRole[@classCode=INVSBJ]/player1[@classCode=PSN]/determinerCode=INSTANCE/role[@classCode=PRST]/subjectOr2[@typeCode=SBJ]/organizer/code=@code=2][@codeSystem=2.16.840.1.113883.3.989.2.1.1.20][/organizer/@classCode=CATEGORY][@moodCode=EVN]/component[@typeCode=COMP]/substanceAdministration[r]/substanceAdministration[@classCode=SBADM][@moodCode=EVN]/outboundRelationship2[@typeCode=CAUS][observation/code/@code=29][@codeSystem=2.16.840.1.113883.3.989.2.1.1.19][/observation/@classCode=OBS][@moodCode=EVN]/value[@xsi:type=CE][@codeSystem=2.16.840.1.113883.6.163][1]/@codeSystem/Version
e	D.10.8.r.7b	副作用 (MedDRA コード)	8N	Coded With Equivalents (CE)	code=Character String (ST)	値 /MCC1_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCC1_IN200100UV01.xsd]/PORR_IN049016UVr/controlActProcess[@classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUBJ]/investigationEvent[@classCode=INVTG][@moodCode=EVN]/component[@typeCode=COMP]/adverseEventAssessment[1]/adverseEventAssessment[@classCode=INVTG][@moodCode=EVN]/subject1[@typeCode=SBJ]/primaryRole[@classCode=INVSBJ]/player1[@classCode=PSN]/determinerCode=INSTANCE/role[@classCode=PRST]/subjectOr2[@typeCode=SBJ]/organizer/code=@code=2][@codeSystem=2.16.840.1.113883.3.989.2.1.1.20][/organizer/@classCode=CATEGORY][@moodCode=EVN]/component[@typeCode=COMP]/substanceAdministration[r]/substanceAdministration[@classCode=SBADM][@moodCode=EVN]/outboundRelationship2[@typeCode=CAUS][observation/code/@code=29][@codeSystem=2.16.840.1.113883.3.989.2.1.1.19][/observation/@classCode=OBS][@moodCode=EVN]/value[@xsi:type=CE][@codeSystem=2.16.840.1.113883.6.163][1]/@code
h	E.i	副作用/有害事象 (必要に応じて繰り返す)			繰り返し ノード	値 /MCC1_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCC1_IN200100UV01.xsd]/PORR_IN049016UVr/controlActProcess[@classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUBJ]/investigationEvent[@classCode=INVTG][@moodCode=EVN]/component[@typeCode=COMP]/adverseEventAssessment[1]/adverseEventAssessment[@classCode=INVTG][@moodCode=EVN]/subject1[@typeCode=SBJ]/primaryRole[@classCode=INVSBJ]/subjectOr2[@typeCode=SBJ]/organizer/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				

(別添 3)

e	E.1.1.1a	母国語で記載された、第一次情報源により報告された副作用/有害事象	250AN	Coded With Equivalents (CE)	originalText = Encapsulated Data (ED)	値	/MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3:MCCL_IN200100UV01.xsd]/PDRR_IN049016UVJ/controlActProcess[@classCode=CACT][@moodCode=EVN]/subject/@typeCode=SUBJ[1]/investigationEvent[@classCode=INVESTG][@moodCode=EVN]/component/@typeCode=COMP[1]adverseEventAssessment[1]adverseEventAssessment[@classCode=INVESTG][@moodCode=EVN]/subject/@typeCode=SBJ[1]primaryRole[classCode=INVSBJ][subjectO2/@typeCode=SBJ][observation[id]code=29][@codeSystem=2.16.840.1.113883.3.989.2.1.1.19][observation/@classCode=OBS][@moodCode=EVN]value[xsi:type=CE][@codeSystem=2.16.840.1.113883.6.163][1]originalText/text()
e	E.1.1.1b	第一次情報源により報告された副作用/有害事象の重 語	3A	Coded With Equivalents (CE)	originalText/language =Coded Simple Value (CS)	値	/MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3:MCCL_IN200100UV01.xsd]/PDRR_IN049016UVJ/controlActProcess[@classCode=CACT][@moodCode=EVN]/subject/@typeCode=SUBJ[1]/investigationEvent[@classCode=INVESTG][@moodCode=EVN]/component/@typeCode=COMP[1]adverseEventAssessment[1]adverseEventAssessment[@classCode=INVESTG][@moodCode=EVN]/subject/@typeCode=SBJ[1]primaryRole[classCode=INVSBJ][subjectO2/@typeCode=SBJ][observation[id]code=29][@codeSystem=2.16.840.1.113883.3.989.2.1.1.19][observation/@classCode=OBS][@moodCode=EVN]value[xsi:type=CE][@codeSystem=2.16.840.1.113883.6.163][1]originalText/language
e	E.1.1.2	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	値	/MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3:MCCL_IN200100UV01.xsd]/PDRR_IN049016UVJ/controlActProcess[@classCode=CACT][@moodCode=EVN]/component/@typeCode=COMP[1]adverseEventAssessment[1]adverseEventAssessment[@classCode=INVESTG][@moodCode=EVN]/subject/@typeCode=SBJ[1]primaryRole[classCode=INVSBJ][subjectO2/@typeCode=SBJ][observation[id]code=29][@codeSystem=2.16.840.1.113883.3.989.2.1.1.19][observation/@classCode=OBS][@moodCode=EVN]outbound Relationship2[@typeCode=PERT][observation/code/@code=30][@codeSystem=2.16.840.1.11388 3.3.989.2.1.1.19][1]observation[@classCode=OBS][@moodCode=EVN]value[xsi:type=ED][1] /text()
e	E.1.2.1a	副作用 / 有害事象の MedDRAバージョン	4AN	Coded With Equivalents (CE)	codeSystemVersion= Character String (ST)	値	/MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3:MCCL_IN200100UV01.xsd]/PDRR_IN049016UVJ/controlActProcess[@classCode=CACT][@moodCode=EVN]/component/@typeCode=COMP[1]adverseEventAssessment[1]adverseEventAssessment[@classCode=INVESTG][@moodCode=EVN]/subject/@typeCode=SBJ[1]primaryRole[classCode=INVSBJ][subjectO2/@typeCode=SBJ][observation[id]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	E.1.2.1b	副作用 / 有害事象 (MedDRA コード)	8N	Coded With Equivalents (CE)	code=Character String (ST)	値	/MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3:MCCL_IN200100UV01.xsd]/PDRR_IN049016UVJ/controlActProcess[@classCode=CACT][@moodCode=EVN]/component/@typeCode=COMP[1]adverseEventAssessment[1]adverseEventAssessment[@classCode=INVESTG][@moodCode=EVN]/subject/@typeCode=SBJ[1]primaryRole[classCode=INVSBJ][subjectO2/@typeCode=SBJ][observation[id]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

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e	E.1.3.1 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_IN049016UV1/controlActProcess[@classCode='CACT'] /moodCode='EVN' /subject[@typeCode='SUBJ'] /investigationEvent[@classCode='INVESTG'] /moodCode='EVN' /component[@typeCode='COMP'] /adverseEventAssessment[1] /adverseEventAssessment[@classCode='INVESTG'] /moodCode='EVN' /subject1[@typeCode='SBJ'] /primaryRole[@classCode='INVSBJ'] /subjectOf2[@typeCode='SBJ'] /observation[id][code='29'] /codeSystem='2.16.840.1.113883.3.989.2.1.1.19' /observation[id][code='29'] /codeSystem='2.16.840.1.113883.3.989.2.1.1.19' /observation[id][code='37'] /codeSystem='2.16.840.1.113883.3.989.2.1.1.19' /observation[id][code='OBS'] /moodCode='OBS' /value
h	E.1.3.2 有害事象ごとの重篤性の基準				値 /MCCI_IN200100UV01[@ITSVersion='XML_1.0']/@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd' /PORR_IN049016UV1/controlActProcess[@classCode='CACT'] /moodCode='EVN' /subject[@typeCode='SUBJ'] /investigationEvent[@classCode='INVESTG'] /moodCode='EVN' /component[@typeCode='COMP'] /adverseEventAssessment[1] /adverseEventAssessment[@classCode='INVESTG'] /moodCode='EVN' /subject1[@typeCode='SBJ'] /primaryRole[@classCode='INVSBJ'] /subjectOf2[@typeCode='SBJ'] /observation[id][code='29'] /codeSystem='2.16.840.1.113883.3.989.2.1.1.19' /observation[id][code='29'] /codeSystem='2.16.840.1.113883.3.989.2.1.1.19' /observation[id][code='34'] /codeSystem='2.16.840.1.113883.3.989.2.1.1.19' /observation[id][code='OBS'] /moodCode='OBS' /value
e	E.1.3.2a 死に至るもの	ブール型	Boolean (BL)	NullFlavor	値 /MCCI_IN200100UV01[@ITSVersion='XML_1.0']/@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd' /PORR_IN049016UV1/controlActProcess[@classCode='CACT'] /moodCode='EVN' /subject[@typeCode='SUBJ'] /investigationEvent[@classCode='INVESTG'] /moodCode='EVN' /component[@typeCode='COMP'] /adverseEventAssessment[1] /adverseEventAssessment[@classCode='INVESTG'] /moodCode='EVN' /subject1[@typeCode='SBJ'] /primaryRole[@classCode='INVSBJ'] /subjectOf2[@typeCode='SBJ'] /observation[id][code='29'] /codeSystem='2.16.840.1.113883.3.989.2.1.1.19' /observation[id][code='29'] /codeSystem='2.16.840.1.113883.3.989.2.1.1.19' /observation[id][code='34'] /codeSystem='2.16.840.1.113883.3.989.2.1.1.19' /observation[id][code='OBS'] /moodCode='OBS' /value
e	E.1.3.2b 生命を脅かすもの	ブール型	Boolean (BL)	値	値 /MCCI_IN200100UV01[@ITSVersion='XML_1.0']/@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd' /PORR_IN049016UV1/controlActProcess[@classCode='CACT'] /moodCode='EVN' /subject[@typeCode='SUBJ'] /investigationEvent[@classCode='INVESTG'] /moodCode='EVN' /component[@typeCode='COMP'] /adverseEventAssessment[1] /adverseEventAssessment[@classCode='INVESTG'] /moodCode='EVN' /subject1[@typeCode='SBJ'] /primaryRole[@classCode='INVSBJ'] /subjectOf2[@typeCode='SBJ'] /observation[id][code='29'] /codeSystem='2.16.840.1.113883.3.989.2.1.1.19' /observation[id][code='29'] /codeSystem='2.16.840.1.113883.3.989.2.1.1.19' /observation[id][code='21'] /codeSystem='2.16.840.1.113883.3.989.2.1.1.19' /observation[id][code='OBS'] /moodCode='OBS' /value

(別添 3)

e			NullFlavor	<pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/PORR_IN049016UV1/controlActProcess[@classCode=CACT][@moo dCode=EVN]/subject[@typeCode=SUBJ][@investigationEvent/@classCode=INVESTG][@moodCo de=EVN]/component[@typeCode=COMP][adverseEventAssessment][adverseEventAssessment /@classCode=INVESTG][@moodCode=EVN]/subject[(@typeCode=SBJ)[primaryRole/@classC ode=INVSBJ]/subjectO2[(@typeCode=SBJ)[observation][code=29][@codeSystem=2.1 6.840.1.113883.3.989.2.1.1.19]]][observation/@classCode=OBS][@moodCode=EVN]/outbound Relationship2[(@typeCode=PERT)[observation][code=21][@codeSystem=2.16.840.1.11388 3.3.989.2.1.1.19]][observation/@classCode=OBS][@moodCode=EVN]value[@xsi:type=BL][?y @nullFlavor </pre>
e	E.1.3.2c	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	Boolean (BL)	<pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/PORR_IN049016UV1/controlActProcess[@classCode=CACT][@moo dCode=EVN]/subject[@typeCode=SUBJ][@investigationEvent/@classCode=INVESTG][@moodCo de=EVN]/component[@typeCode=COMP][adverseEventAssessment][adverseEventAssessment /@classCode=INVESTG][@moodCode=EVN]/subject[(@typeCode=SBJ)[primaryRole/@classC ode=INVSBJ]/subjectO2[(@typeCode=SBJ)[observation][code=29][@codeSystem=2.1 6.840.1.113883.3.989.2.1.1.19]]][observation/@classCode=OBS][@moodCode=EVN]/outbound Relationship2[(@typeCode=PERT)[observation][code=33][@codeSystem=2.16.840.1.11388 3.3.989.2.1.1.19]][observation/@classCode=OBS][@moodCode=EVN]value[@xsi:type=BL][?y @value </pre>
e			NullFlavor	<pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/PORR_IN049016UV1/controlActProcess[@classCode=CACT][@moo dCode=EVN]/subject[@typeCode=SUBJ][@investigationEvent/@classCode=INVESTG][@moodCo de=EVN]/component[@typeCode=COMP][adverseEventAssessment][adverseEventAssessment /@classCode=INVESTG][@moodCode=EVN]/subject[(@typeCode=SBJ)[primaryRole/@classC ode=INVSBJ]/subjectO2[(@typeCode=SBJ)[observation][code=29][@codeSystem=2.1 6.840.1.113883.3.989.2.1.1.19]]][observation/@classCode=OBS][@moodCode=EVN]/outbound Relationship2[(@typeCode=PERT)[observation][code=33][@codeSystem=2.16.840.1.11388 3.3.989.2.1.1.19]][observation/@classCode=OBS][@moodCode=EVN]value[@xsi:type=BL][?y @nullFlavor </pre>
e	E.1.3.2d	永続的又は顕著な障害・機能 不全に陥るもの	Boolean (BL)	<pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/PORR_IN049016UV1/controlActProcess[@classCode=CACT][@moo dCode=EVN]/subject[@typeCode=SUBJ][@investigationEvent/@classCode=INVESTG][@moodCo de=EVN]/component[@typeCode=COMP][adverseEventAssessment][adverseEventAssessment /@classCode=INVESTG][@moodCode=EVN]/subject[(@typeCode=SBJ)[primaryRole/@classC ode=INVSBJ]/subjectO2[(@typeCode=SBJ)[observation][code=29][@codeSystem=2.1 6.840.1.113883.3.989.2.1.1.19]]][observation/@classCode=OBS][@moodCode=EVN]/outbound Relationship2[(@typeCode=PERT)[observation][code=35][@codeSystem=2.16.840.1.11388 3.3.989.2.1.1.19]][observation/@classCode=OBS][@moodCode=EVN]value[@xsi:type=BL][?y @value </pre>
e			NullFlavor	<pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/PORR_IN049016UV1/controlActProcess[@classCode=CACT][@moo dCode=EVN]/subject[@typeCode=SUBJ][@investigationEvent/@classCode=INVESTG][@moodCo de=EVN]/component[@typeCode=COMP][adverseEventAssessment][adverseEventAssessment /@classCode=INVESTG][@moodCode=EVN]/subject[(@typeCode=SBJ)[primaryRole/@classC ode=INVSBJ]/subjectO2[(@typeCode=SBJ)[observation][code=29][@codeSystem=2.1 6.840.1.113883.3.989.2.1.1.19]]][observation/@classCode=OBS][@moodCode=EVN]/outbound Relationship2[(@typeCode=PERT)[observation][code=35][@codeSystem=2.16.840.1.11388 3.3.989.2.1.1.19]][observation/@classCode=OBS][@moodCode=EVN]value[@xsi:type=BL][?y @nullFlavor </pre>

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<p>e</p> <p>E.i.3.2e</p>	<p>先天異常を来すもの</p>	<p>Boolean (BL)</p> <p>ブール型</p>	<p>値</p>	<pre> /MCCI_IN200100UV01[@ITSVersion="XML_1.0"]/@xsi:schemaLocation="urn:hl7-org:v3 MCCI_IN200100UV01.xsd"/>PERR_IN049016UV/r/controlActProcess/@classCode=CACTI[@moodCode=EVN]/subject/@typeCode=SUBJ/1/investigationEvent/@classCode=INVTG/1/@moodCode=EVN/component/@typeCode=COMP/1/adverseEventAssessment/1/adverseEventAssessment/@classCode=INVTG/1/@moodCode=EVN/subject/1/@typeCode=SBJ/1/primaryRole/@classCode=INVSBJ/subjectC/2/@typeCode=SBJ/jobObservation/@code=29/@codeSystem=2.1/6.840.1.113883.3.989.2.1.1.19/1/observation/@classCode=OBS/1/@moodCode=EVN/1/1388Relationship2/@typeCode=PERT/jobObservation/@code=12/@codeSystem=2.16.840.1.113883.3.989.2.1.1.19/1/observation/@classCode=OBS/1/@moodCode=EVN/value/@xsi:type=BL/1/1/@value </pre>
<p>e</p>	<p>NullFlavor</p>	<p>Boolean (BL)</p> <p>ブール型</p>	<p>NullFlavor</p>	<pre> /MCCI_IN200100UV01[@ITSVersion="XML_1.0"]/@xsi:schemaLocation="urn:hl7-org:v3 MCCI_IN200100UV01.xsd"/>PERR_IN049016UV/r/controlActProcess/@classCode=CACTI[@moodCode=EVN]/subject/@typeCode=SUBJ/1/investigationEvent/@classCode=INVTG/1/@moodCode=EVN/component/@typeCode=COMP/1/adverseEventAssessment/1/adverseEventAssessment/@classCode=INVTG/1/@moodCode=EVN/subject/1/@typeCode=SBJ/1/primaryRole/@classCode=INVSBJ/subjectC/2/@typeCode=SBJ/jobObservation/@code=29/@codeSystem=2.1/6.840.1.113883.3.989.2.1.1.19/1/observation/@classCode=OBS/1/@moodCode=EVN/1/1388Relationship2/@typeCode=PERT/jobObservation/@code=12/@codeSystem=2.16.840.1.113883.3.989.2.1.1.19/1/observation/@classCode=OBS/1/@moodCode=EVN/value/@xsi:type=BL/1/1/@value </pre>
<p>e</p> <p>E.i.3.2f</p>	<p>その他の医学的に重要な状態</p>	<p>Boolean (BL)</p> <p>ブール型</p>	<p>値</p>	<pre> /MCCI_IN200100UV01[@ITSVersion="XML_1.0"]/@xsi:schemaLocation="urn:hl7-org:v3 MCCI_IN200100UV01.xsd"/>PERR_IN049016UV/r/controlActProcess/@classCode=CACTI[@moodCode=EVN]/subject/@typeCode=SUBJ/1/investigationEvent/@classCode=INVTG/1/@moodCode=EVN/component/@typeCode=COMP/1/adverseEventAssessment/1/adverseEventAssessment/@classCode=INVTG/1/@moodCode=EVN/subject/1/@typeCode=SBJ/1/primaryRole/@classCode=INVSBJ/subjectC/2/@typeCode=SBJ/jobObservation/@code=29/@codeSystem=2.1/6.840.1.113883.3.989.2.1.1.19/1/observation/@classCode=OBS/1/@moodCode=EVN/1/1388Relationship2/@typeCode=PERT/jobObservation/@code=26/@codeSystem=2.16.840.1.113883.3.989.2.1.1.19/1/observation/@classCode=OBS/1/@moodCode=EVN/value/@xsi:type=BL/1/1/@value </pre>
<p>e</p>	<p>NullFlavor</p>	<p>Boolean (BL)</p> <p>ブール型</p>	<p>NullFlavor</p>	<pre> /MCCI_IN200100UV01[@ITSVersion="XML_1.0"]/@xsi:schemaLocation="urn:hl7-org:v3 MCCI_IN200100UV01.xsd"/>PERR_IN049016UV/r/controlActProcess/@classCode=CACTI[@moodCode=EVN]/subject/@typeCode=SUBJ/1/investigationEvent/@classCode=INVTG/1/@moodCode=EVN/component/@typeCode=COMP/1/adverseEventAssessment/1/adverseEventAssessment/@classCode=INVTG/1/@moodCode=EVN/subject/1/@typeCode=SBJ/1/primaryRole/@classCode=INVSBJ/subjectC/2/@typeCode=SBJ/jobObservation/@code=29/@codeSystem=2.1/6.840.1.113883.3.989.2.1.1.19/1/observation/@classCode=OBS/1/@moodCode=EVN/1/1388Relationship2/@typeCode=PERT/jobObservation/@code=26/@codeSystem=2.16.840.1.113883.3.989.2.1.1.19/1/observation/@classCode=OBS/1/@moodCode=EVN/value/@xsi:type=BL/1/1/@value </pre>

(別添 3)

e	E.I.4 副作用／有害事象の発現日	日付／時間	1.E.I.4、E.I.5 及び E.I.6 のすべての項目が表示されない場合 HL7 データ型: Interval of Point in Time (VL<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 (VXB)	値	/MCCLI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCLI_IN200100UV01.xsd]/PARR_IN049016UVJ[controlActProcess/@classCode=CACT][@moodCode=EVN]/subject/@typeCode=SUBJ[adverseEventAssessment[adverseEventAssessment[@classCode=INVSBJ]/subject/@typeCode=SBJ][primaryRole/@classCode=INVSBJ]/subjectOrZ/@typeCode=SBJ][observation[@code=29][@codeSystem=2.16.840.1.113883.3.989.2.1.1.19]]][observation/@classCode=OBS][@moodCode=EVN]/effectiveTime[@xsi:type=IVL_TS]/low/@value
e				NullFlavor	NullFlavor	/MCCLI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCLI_IN200100UV01.xsd]/PARR_IN049016UVJ[controlActProcess/@classCode=CACT][@moodCode=EVN]/subject/@typeCode=SUBJ[adverseEventAssessment[adverseEventAssessment[@classCode=INVSBJ]/subject/@typeCode=SBJ][primaryRole/@classCode=INVSBJ]/subjectOrZ/@typeCode=SBJ][observation[@code=29][@codeSystem=2.16.840.1.113883.3.989.2.1.1.19]]][observation/@classCode=OBS][@moodCode=EVN]/effectiveTime[@xsi:type=IVL_TS]/low/@nullFlavor
e			2.E.I.4、E.I.5 及び E.I.6 のすべての項目が表示されない場合 データ型 SXPB を伴う最初の comp 項目 HL7 データ型: Parenthetic Set Expression of Point in Time (SXPB<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ない場合 データ型 SXPB を伴う最初の comp 項目 comp/low=Interval Boundary (VXB)	値	/MCCLI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCLI_IN200100UV01.xsd]/PARR_IN049016UVJ[controlActProcess/@classCode=CACT][@moodCode=EVN]/component/@typeCode=COMP[adverseEventAssessment[adverseEventAssessment[@classCode=INVSBJ]/subject/@typeCode=SBJ][primaryRole/@classCode=INVSBJ]/subjectOrZ/@typeCode=SBJ][observation[@code=29][@codeSystem=2.16.840.1.113883.3.989.2.1.1.19]]][comp/@xsi:type=IVL_TS]/low/@value
e				NullFlavor	NullFlavor	/MCCLI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCLI_IN200100UV01.xsd]/PARR_IN049016UVJ[controlActProcess/@classCode=CACT][@moodCode=EVN]/subject/@typeCode=SUBJ[adverseEventAssessment[adverseEventAssessment[@classCode=INVSBJ]/subject/@typeCode=SBJ][primaryRole/@classCode=INVSBJ]/subjectOrZ/@typeCode=SBJ][observation[@code=29][@codeSystem=2.16.840.1.113883.3.989.2.1.1.19]]][comp/@xsi:type=IVL_TS]/low/@nullFlavor

(別添3)

		<p>3.E.I.4, E.I.5 及び E.I.6 のすべての項目が表示される場合、 データ型 SXPX を伴う 2 番目の comp 項目 HL7 データ型: Parenthetic Set Expression of Point in Time (SXPX<TS>)</p>	<p>3.E.I.4, E.I.5 及び E.I.6 のすべての項目が表示される場合 データ型 SXPX を伴う 2 番目の comp 項目 comp/low=Interval Boundary (IVXB)</p>	値	<pre> /MCCI_IN200100UV01[@ITSVersion='XML_1.0']/@xsi:schemaLocation='urn:hl7-org:v3 /MCCI_IN200100UV01.xsd/PORR_IN049016UV7/controlActProcess[@classCode='CACT']/@moodCode='EVN'/subject[@typeCode='SUBJ']/investigationEvent[@classCode='INVTG']/@moodCode='EVN'/component[@typeCode='COMP']/adverseEventAssessment[1]/adverseEventAssessment[@classCode='INVTG']/@moodCode='EVN'/subject[1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ']/observation[1]/code[@code='29']/@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']/observation/@classCode='OBS'/@operator='A'/low/@value </pre>
			NullFlavor	NullFlavor	<pre> /MCCI_IN200100UV01[@ITSVersion='XML_1.0']/@xsi:schemaLocation='urn:hl7-org:v3 /MCCI_IN200100UV01.xsd/PORR_IN049016UV7/controlActProcess[@classCode='CACT']/@moodCode='EVN'/subject[@typeCode='SUBJ']/investigationEvent[@classCode='INVTG']/@moodCode='EVN'/component[@typeCode='COMP']/adverseEventAssessment[1]/adverseEventAssessment[@classCode='INVTG']/@moodCode='EVN'/subject[1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ']/observation[1]/code[@code='29']/@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']/observation/@classCode='OBS'/@operator='A'/low/@nullFlavor </pre>
<p>E.I.5 副作用/有害事象の終了日 日付/時間</p>		<p>1.E.I.4, E.I.5 及び E.I.6 のすべての項目が表示されない場合 HL7 データ型: Interval of Point in Time (IVL<TS>)</p>	<p>1.E.I.4, E.I.5 及び E.I.6 のすべての項目が表示されない場合 high=Interval Boundary (IVXB)</p>	値	<pre> /MCCI_IN200100UV01[@ITSVersion='XML_1.0']/@xsi:schemaLocation='urn:hl7-org:v3 /MCCI_IN200100UV01.xsd/PORR_IN049016UV7/controlActProcess[@classCode='CACT']/@moodCode='EVN'/subject[@typeCode='SUBJ']/investigationEvent[@classCode='INVTG']/@moodCode='EVN'/component[@typeCode='COMP']/adverseEventAssessment[1]/adverseEventAssessment[@classCode='INVTG']/@moodCode='EVN'/subject[1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ']/observation[1]/code[@code='29']/@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']/observation/@classCode='OBS'/@operator='A'/high/@value </pre>
			NullFlavor	NullFlavor	<pre> /MCCI_IN200100UV01[@ITSVersion='XML_1.0']/@xsi:schemaLocation='urn:hl7-org:v3 /MCCI_IN200100UV01.xsd/PORR_IN049016UV7/controlActProcess[@classCode='CACT']/@moodCode='EVN'/subject[@typeCode='SUBJ']/investigationEvent[@classCode='INVTG']/@moodCode='EVN'/component[@typeCode='COMP']/adverseEventAssessment[1]/adverseEventAssessment[@classCode='INVTG']/@moodCode='EVN'/subject[1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ']/observation[1]/code[@code='29']/@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']/observation/@classCode='OBS'/@operator='A'/high/@nullFlavor </pre>

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		<p>2.E.i.4、E.i.5 及び E.i.6 のすべての項目が表示される場合</p> <p>データ型 SXPB を伴う最初の comp 項目</p> <p>HL7 データ型: Parenthetic Set Expression of Point In Time (SXPB<TS>)</p>	<p>値</p>	<pre> /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UVI/controlAct/process[@classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUBJ]/investigationEvent[@classCode=INVESTG][@moodCode=EVN]/component[@typeCode=COMP]/adverseEventAssessment[1]/adverseEventAssessment[@classCode=INVESTG][@moodCode=EVN]/subject[1]/primaryRole[@classCode=INVSBJ/subjectO2][@typeCode=SBJ]/observation[id][code=@code=29][@codeSystem=2.16.840.1.113883.3.989.2.1.1.19][/]observation[@classCode=OBS][@moodCode=EVN]/effectiveTime[@xsi:type=SXPB_TS]/comp[@xsi:type=IVL_TS]/high/@value </pre>
		<p>2.E.i.4、E.i.5 及び E.i.6 のすべての項目が表示される場合</p> <p>データ型 SXPB を伴う最初の comp 項目</p> <p>HL7 データ型: Parenthetic Set Expression of Point In Time (SXPB<TS>)</p>	<p>NullFlavor</p>	<pre> /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UVI/controlAct/process[@classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUBJ]/investigationEvent[@classCode=INVESTG][@moodCode=EVN]/component[@typeCode=COMP]/adverseEventAssessment[1]/adverseEventAssessment[@classCode=INVESTG][@moodCode=EVN]/subject[1]/primaryRole[@classCode=INVSBJ/subjectO2][@typeCode=SBJ]/observation[id][code=@code=29][@codeSystem=2.16.840.1.113883.3.989.2.1.1.19][/]observation[@classCode=OBS][@moodCode=EVN]/effectiveTime[@xsi:type=SXPB_TS]/comp[@xsi:type=IVL_TS]/high/@value </pre>
		<p>3.E.i.4、E.i.5 及び E.i.6 のすべての項目が表示される場合</p> <p>データ型 SXPB を伴う 2 番目の comp 項目</p> <p>HL7 データ型: Parenthetic Set Expression of Point In Time (SXPB<TS>)</p>	<p>値</p>	<pre> /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UVI/controlAct/process[@classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUBJ]/investigationEvent[@classCode=INVESTG][@moodCode=EVN]/component[@typeCode=COMP]/adverseEventAssessment[1]/adverseEventAssessment[@classCode=INVESTG][@moodCode=EVN]/subject[1]/primaryRole[@classCode=INVSBJ/subjectO2][@typeCode=SBJ]/observation[id][code=@code=29][@codeSystem=2.16.840.1.113883.3.989.2.1.1.19][/]observation[@classCode=OBS][@moodCode=EVN]/effectiveTime[@xsi:type=SXPB_TS]/comp[@xsi:type=IVL_TS][@operator=A]/high/@value </pre>
		<p>3.E.i.4、E.i.5 及び E.i.6 のすべての項目が表示される場合</p> <p>データ型 SXPB を伴う 2 番目の comp 項目</p> <p>HL7 データ型: Parenthetic Set Expression of Point In Time (SXPB<TS>)</p>	<p>NullFlavor</p>	<pre> /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UVI/controlAct/process[@classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUBJ]/investigationEvent[@classCode=INVESTG][@moodCode=EVN]/component[@typeCode=COMP]/adverseEventAssessment[1]/adverseEventAssessment[@classCode=INVESTG][@moodCode=EVN]/subject[1]/primaryRole[@classCode=INVSBJ/subjectO2][@typeCode=SBJ]/observation[id][code=@code=29][@codeSystem=2.16.840.1.113883.3.989.2.1.1.19][/]observation[@classCode=OBS][@moodCode=EVN]/effectiveTime[@xsi:type=SXPB_TS]/comp[@xsi:type=IVL_TS][@operator=A]/high/@value </pre>

