

(別添3)



日米 EU 医薬品規制調和国際会議

ICH E2B 専門家作業部会

個別症例安全性報告 (ICSR) の電子的伝送に
係る実装ガイド

付録 I (G)

技術的情報

バージョン 1.01 2014年11月10日

文書の履歴

| 最終版 確定日 | 文書の標題 | バージョン | 発表 | WG |
|--------------|--------------------------------------------------------------------------------------|-------|-----------|---------------------|
| 2013年 4月 | 個別症例安全性報告 (ICSR) の電子的伝送 実装ガイドの付録 I (G) 技術的情報 | 1.00 | Step 4 文書 | E2B 専 門家作 業部会 |
| 2014年 11月 | 個別症例安全性報告 (ICSR) の電子的伝送 実装ガイドの付録 I (G) 技術的情報 校正実施。変更履歴の詳細は別添のシート 参照。 | 1.01 | Step 4 文書 | E2B 実装作 業部会 |

目次

| | | |
|----------|----------------------------------------------------------------------------|----|
| I. | 序..... | 4 |
| II. | 技術的情報..... | 4 |
| 1. | ICH データ型、HL7 データ型及び E2B (R3) データ項目の XPATH..... | 4 |
| 2. | 複数の XML 表現に関する XML 断片..... | 86 |
| 2.1 | 開始日、終了日及び持続期間..... | 86 |
| 2.1.1. | E.i.4「発現日」及び E.i.5「終了日」に入力するが、E.i.6「持続期間」は入力しない..... | 86 |
| 2.1.2. | E.i.4「発現日」(又は E.i.5「終了日」)及び E.i.6「持続期間」に入力する..... | 86 |
| 2.1.3. | E.i.4「発現日」、E.i.5「終了日」、及び E.i.6「持続期間」に入力する..... | 87 |
| 2.1.4. | G.k.4.r.4「開始日」及び G.k.4.r.5「終了日」に入力するが、G.k.4.r.6には入力しない..... | 88 |
| 2.1.5. | G.k.4.r.4「開始日」(又は G.k.4.r.5「終了日」)及び G.k.4.r.6に入力する..... | 88 |
| 2.1.6. | G.k.4.r.2及び G.k.4.r.3には入力しないが、G.k.4.r.5、G.k.4.7又は G.k.4.r.6のいずれかに入力する..... | 89 |
| 2.1.7. | G.k.4.r.4「開始日」、G.k.4.r.5「終了日」、及び G.k.4.r.8「持続期間」に入力する..... | 89 |
| 2.2. | F 検査結果..... | 90 |
| 2.2.1. | F.r.3.2 値及び限定子..... | 90 |
| 2.2.1.1. | 値 (例: "10 mg/dL")..... | 90 |
| 2.2.1.2. | 値より大きい (例: "> 10 mg/dL")..... | 90 |
| 2.2.1.3. | 値より小さい (例: "< 10 mg/dL")..... | 91 |
| 2.2.1.4. | 値以上 (例: "≥ 10 mg/dL")..... | 91 |
| 2.2.1.5. | 値以下 (例: "≤ 10 mg/dL")..... | 91 |
| 2.2.2. | F.r.3.2 及び F.r.3.3..... | 91 |
| 2.2.3. | F.r.3.1..... | 92 |
| 2.2.4. | F.r.3.4..... | 92 |
| 2.3. | G.k.4 投与量の例..... | 92 |
| 2.3.1. | 1日当たり 1/回..... | 92 |
| 2.3.2. | 1日当たり 1錠/回..... | 93 |
| 2.3.3. | 1日1回、1/4錠/回..... | 93 |

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

I. 序

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

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

II. 技術的情報

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

ICH 及び HL7 におけるデータ型を下表に示す。

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

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

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

| h:ヘッダ e:エンティ ティ | 項目番号 | 要素名 | ICH データ型 | HL7データ型 | HL7データ型 (下位構成要素) | 分類 | Xpath |
|-----------------------|---------|--------------------------------------------------|-------------|------------------------------------|-------------------------------------|-------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| h | N.1 | ICH ICSR 伝送識別子 (バッチ ラッパー: BATCH WRAPPER) | | | | | |
| e | N.1.1 | バッチ内のメッセージの種 類 | 11A | Character String with Code (SC) | code=Coded With Equivalents (CE) | 値 | /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/name[@codeSystem=2.16.840.1.113883.3.989.2.1.1.1][@code |
| | | バッチ内のメッセージの種 類に関する ICH コードリス トのバージョン | | | | | /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/name[@codeSystem=2.16.840.1.113883.3.989.2.1.1.1][@codeSystem Version |
| e | N.1.2 | バッチ番号 | 100AN | Instance Identifier (II) | extension=Character String (ST) | 値 | /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/id[@root=2.16.840.1.113883.3.989.2.1.3.22][@extension |
| e | N.1.3 | バッチ送信者識別子 | 60AN | Instance Identifier (II) | extension=Character String (ST) | 値 | /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/sender[@typeCode=SND]/device[@classCode=DEV][@determinerCo de=INSTANCE]/id[@root=2.16.840.1.113883.3.989.2.1.3.13][1][@extension |
| e | N.1.4 | バッチ受信者識別子 | 60AN | Instance Identifier (II) | extension=Character String (ST) | 値 | /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/receiver[@typeCode=RCV]/device[@classCode=DEV][@determinerC ode=INSTANCE]/id[@root=2.16.840.1.113883.3.989.2.1.3.14][1][@extension |
| e | N.1.5 | バッチ伝送の日付 | 日付/ 時間 | Point in Time (TS) | | 値 | /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/creationTime/@value |
| h | N.2.r | ICH ICSR メッセージヘッダ (メッセージラッパー) (必 要に応じ繰り返し) | | | | 繰り返し ノード | /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UV |
| e | N.2.r.1 | メッセージ識別子 | 100AN | Instance Identifier (II) | extension=Character String (ST) | 値 | /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UV[id/@root=2.16.840.1.113883.3.989.2.1.3.1][1] /@extension |
| e | N.2.r.2 | メッセージ送信者識別子 | 60AN | Instance Identifier (II) | extension=Character String (ST) | 値 | /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UV[id/@root=2.16.840.1.113883.3.989.2.1.3.11][1][@extension 'DEV'][@determinerCode=INSTANCE]/id[@root=2.16.840.1.113883.3.989.2.1.3.11][1][@extension |
| e | N.2.r.3 | メッセージ受信者識別子 | 60AN | Instance Identifier (II) | extension=Character String (ST) | 値 | /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UV[id/@root=2.16.840.1.113883.3.989.2.1.3.12][1][@extension =DEV][@determinerCode=INSTANCE]/id[@root=2.16.840.1.113883.3.989.2.1.3.12][1][@extension n |
| e | N.2.r.4 | メッセージ作成の日付 | 日付/時間 | Point in Time (TS) | | 値 | /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UV[id/@root=2.16.840.1.113883.3.989.2.1.3.11][1][@extension =DEV][@determinerCode=INSTANCE]/id[@root=2.16.840.1.113883.3.989.2.1.3.11][1][@extension n |
| h | C.1 | 症例安全性報告の識別 | | | | | |

(別添 3)

| | | | | | | | |
|---|-------------|----------------------------|--------|-------------------------------------|---------------------------------|---------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| e | C.1.1 | 送信者ごとに固有の(症例)安全性報告識別子 | 100AN | Instance Identifier (II) | extension=Character String (ST) | 値 | /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PARR_IN049016UV/r/controlActProcess[@classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUBJ][@codeSystem=INVESTG][@moodCode=EVN][@root=2.16.840.1.113883.3.989.2.1.3.1][1][@extension] |
| e | C.1.2 | 作成の日付 | 日付/時間 | Point in Time (TS) | | 値 | /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PARR_IN049016UV/r/controlActProcess[@classCode=CACT][@moodCode=EVN]/effectiveTime/@value |
| e | C.1.3 | 報告の種類 | 1N | Coded With Equivalents (CE) | code=Character String (ST) | 値 | /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PARR_IN049016UV/r/controlActProcess[@classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUBJ][1]/investigationEvent[@classCode=INVESTG][@moodCode=EVN]/subjectO2[@typeCode=SUBJ][1]/investigationCharacteristic[@code=1][@codeSystem=2.16.840.1.113883.3.989.2.1.1.23][1]/investigationCharacteristic[@classCode=OBS][@moodCode=EVN][value[@xsi:type=CE]][@codeSystem=2.16.840.1.113883.3.989.2.1.1.2][@code] |
| e | C.1.4 | 報告の種類に関する ICH コードリストのバージョン | 日付/時間 | Interval of Point in Time (IVL<TS>) | low=Interval Boundary (IVXB) | 値 | /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PARR_IN049016UV/r/controlActProcess[@classCode=CACT][@moodCode=EVN]/subjectO2[@typeCode=SUBJ][1]/investigationCharacteristic[@code=1][@codeSystem=2.16.840.1.113883.3.989.2.1.1.23][1]/investigationCharacteristic[@classCode=OBS][@moodCode=EVN][value[@xsi:type=CE]][@codeSystem=2.16.840.1.113883.3.989.2.1.1.2][@codeSystemVersion] |
| e | C.1.5 | 情報源から最初に報告が入手された日 | 日付/時間 | Point in Time (TS) | | 値 | /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PARR_IN049016UV/r/controlActProcess[@classCode=CACT][@moodCode=EVN]/effectiveTime/low/@value |
| e | C.1.5 | 本報告の最新情報入手日 | 日付/時間 | Point in Time (TS) | | 値 | /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PARR_IN049016UV/r/controlActProcess[@classCode=CACT][@moodCode=EVN]/availabilityTime/@value |
| h | C.1.6 | 送信者が保有している利用可能な他の資料 | | | | | |
| e | C.1.6.1 | 利用可能なその他の資料はあるか? | ブール型 | Boolean (BL) | | 値 | /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PARR_IN049016UV/r/controlActProcess[@classCode=CACT][@moodCode=EVN]/component[@typeCode=COMP][observationEvent/code[@code=1][@codeSystem=2.16.840.1.113883.3.989.2.1.1.19][1][@codeSystem=2.16.840.1.113883.3.989.2.1.1.19][1]/observationEvent[@classCode=OBS][@moodCode=EVN][value[@xsi:type=BL]][@value] |
| h | C.1.6.1.r | 送信者が保有している資料(必要に応じ繰り返し) | | | | 繰り返しノード | /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PARR_IN049016UV/r/controlActProcess[@classCode=CACT][@moodCode=EVN]/reference[@typeCode=SUBJ][1]/investigationEvent[@classCode=INVESTG][@moodCode=EVN]/reference[@typeCode=REFR][document/code[@code=1][@codeSystem=2.16.840.1.113883.3.989.2.1.1.27][1]] |
| e | C.1.6.1.r.1 | 送信者が保有している資料 | 2000AN | Character String (ST) | | 値 | /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PARR_IN049016UV/r/controlActProcess[@classCode=CACT][@moodCode=EVN]/reference[@typeCode=SUBJ][1]/investigationEvent[@classCode=INVESTG][@moodCode=EVN]/reference[@typeCode=REFR][document/code[@code=1][@codeSystem=2.16.840.1.113883.3.989.2.1.1.27][1]]/document[@classCode=DOC][@moodCode=EVN][title/text] |

(別添 3)

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

(別添 3)

| | | | | | | | |
|---|-------------|-----------------------------|--------|-----------------------------|----------------------------------------------|------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| e | | | | | | Nullflavor | /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UV/r/controlActProcess/@classCode=CACT][@moodCode=EVN]/subject/@typeCode=SUBJ[1]/investigationEvent/@classCode=INVTG][@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) | 100AN | Instance Identifier (II) | assigningAuthorityName=Character String (ST) | 値 | /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UV/r/controlActProcess/@classCode=CACT][@moodCode=EVN]/subject/@typeCode=SUBJ[1]/investigationEvent/@classCode=INVTG][@moodCode=EVN]/subjectOf1/@typeCode=SUBJ[1]/controlActEvent/id/@root=2.16.840.1.113883.3.989.2.1.3.3][1]/@assigningAuthorityName |
| e | C.1.9.1.r.1 | 症例識別子の情報源 | 100AN | Instance Identifier (II) | extension=Character String (ST) | 値 | /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UV/r/controlActProcess/@classCode=CACT][@moodCode=EVN]/subject/@typeCode=SUBJ[1]/investigationEvent/@classCode=INVTG][@moodCode=EVN]/subjectOf1/@typeCode=SUBJ[1]/controlActEvent/id/@root=2.16.840.1.113883.3.989.2.1.3.3][1]/@extension |
| e | C.1.10.r | 本報告と関連する報告の識別子 (必要に応じて繰り返す) | 100AN | Instance Identifier (II) | extension=Character String (ST) | 値 | /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UV/r/controlActProcess/@classCode=CACT][@moodCode=EVN]/subject/@typeCode=SUBJ[1]/investigationEvent/@classCode=INVTG][@moodCode=EVN]/subjectOf2/@typeCode=SUBJ[1]/relatedInvestigation/@code=@nullflavor=NA][1]/relatedInvestigation/@classCode=INVTG][@moodCode=EVN]/subjectOf2/@typeCode=SUBJ[1]/controlActEvent/@classCode=CACT][@moodCode=EVN]/value[@xsi:type=CE][@codeSystem=2.16.840.1.113883.3.989.2.1.1.23][1]/@extension |
| h | C.1.11 | 報告破棄/修正 | | | | | /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UV/r/controlActProcess/@classCode=CACT][@moodCode=EVN]/subject/@typeCode=SUBJ[1]/investigationEvent/@classCode=INVTG][@moodCode=EVN]/subjectOf2/@typeCode=SUBJ[1]/investigationCharacteristic/@code=3][@codeSystem=2.16.840.1.113883.3.989.2.1.1.23][1]/investigationCharacteristic/@classCode=OBS][@moodCode=EVN]/value[@xsi:type=CE][@codeSystem=2.16.840.1.113883.3.989.2.1.1.5]/@code |
| e | C.1.11.1 | 報告破棄/修正 | 1N | Coded With Equivalents (CE) | code=Character String (ST) | 値 | /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UV/r/controlActProcess/@classCode=CACT][@moodCode=EVN]/subject/@typeCode=SUBJ[1]/investigationEvent/@classCode=INVTG][@moodCode=EVN]/subjectOf2/@typeCode=SUBJ[1]/investigationCharacteristic/@code=3][@codeSystem=2.16.840.1.113883.3.989.2.1.1.23][1]/investigationCharacteristic/@classCode=OBS][@moodCode=EVN]/value[@xsi:type=CE][@codeSystem=2.16.840.1.113883.3.989.2.1.1.5]/@code |
| e | C.1.11.2 | 報告破棄/修正理由 | 2000AN | Coded With Equivalents (CE) | originalText = Encapsulated Data (ED) | 値 | /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UV/r/controlActProcess/@classCode=CACT][@moodCode=EVN]/subject/@typeCode=SUBJ[1]/investigationEvent/@classCode=INVTG][@moodCode=EVN]/subjectOf2/@typeCode=SUBJ[1.23][1]/investigationCharacteristic/@code=4][@codeSystem=2.16.840.1.113883.3.989.2.1.1.23][1]/investigationCharacteristic/@classCode=OBS][@moodCode=EVN]/value[@xsi:type=CE][originalText/text() |

(別添 3)

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

(別添 3)

| | | | | | | | |
|---|-----------|--------------|------|------------------------|--------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| e | | | | | NullFlavor | <pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/PORG_IN049016UVJ/controlActProcess/@classCode=CACT][@mood dCode=EVN]/subject/@typeCode=SUBJ][relatedInvestigation/@code=2][@code de=EVN]/outboundRelationship/@typeCode=SPRT][relatedInvestigation/@code=2][@code System=2,16.840.1.113883.3.989.2.1.1.22][relatedInvestigation/@classCode=INVSTG][@mood Code=EVN]/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=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/PORG_IN049016UVJ/controlActProcess/@classCode=CACT][@mood dCode=EVN]/subject/@typeCode=SUBJ][relatedInvestigation/@code=2][@code de=EVN]/outboundRelationship/@typeCode=SPRT][relatedInvestigation/@code=2][@code System=2,16.840.1.113883.3.989.2.1.1.22][relatedInvestigation/@classCode=INVSTG][@mood Code=EVN]/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=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/PORG_IN049016UVJ/controlActProcess/@classCode=CACT][@mood dCode=EVN]/subject/@typeCode=SUBJ][relatedInvestigation/@code=2][@code de=EVN]/outboundRelationship/@typeCode=SPRT][relatedInvestigation/@code=2][@code System=2,16.840.1.113883.3.989.2.1.1.22][relatedInvestigation/@classCode=INVSTG][@mood Code=EVN]/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 | | | | | <pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/PORG_IN049016UVJ/controlActProcess/@classCode=CACT][@mood dCode=EVN]/subject/@typeCode=SUBJ][relatedInvestigation/@code=2][@code de=EVN]/outboundRelationship/@typeCode=SPRT][relatedInvestigation/@code=2][@code System=2,16.840.1.113883.3.989.2.1.1.22][relatedInvestigation/@classCode=INVSTG][@mood Code=EVN]/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> |
| e | C.2.r.2.1 | 報告者の組織 | 60AN | Organization Name (ON) | name=Entity Name Part (ENXP) | 値 | <pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/PORG_IN049016UVJ/controlActProcess/@classCode=CACT][@mood dCode=EVN]/subject/@typeCode=SUBJ][relatedInvestigation/@code=2][@code de=EVN]/outboundRelationship/@typeCode=SPRT][relatedInvestigation/@code=2][@code System=2,16.840.1.113883.3.989.2.1.1.22][relatedInvestigation/@classCode=INVSTG][@mood Code=EVN]/subjectO2/@typeCode=SUBJ][controlActEvent/@classCode=CACT][@moodCode= EVN]/author/@typeCode=AUT][assignedEntity/@classCode=ASSIGNED]/representedOrganizatio n/@classCode=ORG][@determinerCode=INSTANCE]/assignedEntity/@classCode=ASSIGNED]/r epresentedOrganization/@classCode=ORG][@determinerCode=INSTANCE]/name/text() </pre> |
| e | | | | | NullFlavor | <pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/PORG_IN049016UVJ/controlActProcess/@classCode=CACT][@mood dCode=EVN]/subject/@typeCode=SUBJ][relatedInvestigation/@code=2][@code de=EVN]/outboundRelationship/@typeCode=SPRT][relatedInvestigation/@code=2][@code System=2,16.840.1.113883.3.989.2.1.1.22][relatedInvestigation/@classCode=INVSTG][@mood Code=EVN]/subjectO2/@typeCode=SUBJ][controlActEvent/@classCode=CACT][@moodCode= EVN]/author/@typeCode=AUT][assignedEntity/@classCode=ASSIGNED]/representedOrganizatio n/@classCode=ORG][@determinerCode=INSTANCE]/assignedEntity/@classCode=ASSIGNED]/r epresentedOrganization/@classCode=ORG][@determinerCode=INSTANCE]/name/@nullFlavor </pre> | |

(別添 3)

| | | | | | | | |
|---|-----------|---------------|-------|------------------------|---------------------------------------|------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| e | C.2.r.2.2 | 報告者の部署 | 60AN | Organization Name (ON) | name=Entity Name Part (ENXP) | 値 | <pre> /MCCl_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCl_IN200100UV01.xsd']/PORG_IN049016UV/rj/controlActProcess[@classCode='CACT']/@moo dCode='EVN']/subject[@typeCode='SUBJ']/rj/investigationEvent[@classCode='INVESTG']/@moodCo de='EVN']/outboundRelationship[@typeCode='SPRT']/rj/relatedInvestigation/@code=@code=2]]/@code System=2.16.840.1.113883.3.989.2.1.1.22]]/rj/relatedInvestigation/@classCode='INVESTG']/@mood Code='EVN']/subjectOf2[@typeCode='SUBJ']/controlActEvent[@classCode='CACT']/@moodCode=' EVN']/author[@typeCode='AUT']/assignedEntity[@classCode='ASSIGNED']/representedOrganizatio n[@classCode='ORG']/@determinerCode='INSTANCE']/name/text() </pre> |
| e | | | | | | NullFlavor | <pre> /MCCl_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCl_IN200100UV01.xsd']/PORG_IN049016UV/rj/controlActProcess[@classCode='CACT']/@moo dCode='EVN']/subject[@typeCode='SUBJ']/rj/investigationEvent[@classCode='INVESTG']/@moodCo de='EVN']/outboundRelationship[@typeCode='SPRT']/rj/relatedInvestigation/@code=@code=2]]/@code System=2.16.840.1.113883.3.989.2.1.1.22]]/rj/relatedInvestigation/@classCode='INVESTG']/@mood Code='EVN']/subjectOf2[@typeCode='SUBJ']/controlActEvent[@classCode='CACT']/@moodCode=' EVN']/author[@typeCode='AUT']/assignedEntity[@classCode='ASSIGNED']/representedOrganizatio n[@classCode='ORG']/@determinerCode='INSTANCE']/name/@nullFlavor </pre> |
| e | C.2.r.2.3 | 報告者の住所 (番地) | 100AN | Postal Address (AD) | streetAddressLine=Address Part (ADXP) | 値 | <pre> /MCCl_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCl_IN200100UV01.xsd']/PORG_IN049016UV/rj/controlActProcess[@classCode='CACT']/@moo dCode='EVN']/subject[@typeCode='SUBJ']/rj/investigationEvent[@classCode='INVESTG']/@moodCo de='EVN']/outboundRelationship[@typeCode='SPRT']/rj/relatedInvestigation/@code=@code=2]]/@code System=2.16.840.1.113883.3.989.2.1.1.22]]/rj/relatedInvestigation/@classCode='INVESTG']/@mood Code='EVN']/subjectOf2[@typeCode='SUBJ']/controlActEvent[@classCode='CACT']/@moodCode=' EVN']/author[@typeCode='AUT']/assignedEntity[@classCode='ASSIGNED']/addr[1]/streetAddressLi ne[1]/text() </pre> |
| e | | | | | | NullFlavor | <pre> /MCCl_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCl_IN200100UV01.xsd']/PORG_IN049016UV/rj/controlActProcess[@classCode='CACT']/@moo dCode='EVN']/subject[@typeCode='SUBJ']/rj/investigationEvent[@classCode='INVESTG']/@moodCo de='EVN']/outboundRelationship[@typeCode='SPRT']/rj/relatedInvestigation/@code=@code=2]]/@code System=2.16.840.1.113883.3.989.2.1.1.22]]/rj/relatedInvestigation/@classCode='INVESTG']/@mood Code='EVN']/subjectOf2[@typeCode='SUBJ']/controlActEvent[@classCode='CACT']/@moodCode=' EVN']/author[@typeCode='AUT']/assignedEntity[@classCode='ASSIGNED']/addr[1]/streetAddressLi ne[1]/@nullFlavor </pre> |
| 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 | <pre> /MCCl_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCl_IN200100UV01.xsd']/PORG_IN049016UV/rj/controlActProcess[@classCode='CACT']/@moo dCode='EVN']/subject[@typeCode='SUBJ']/rj/investigationEvent[@classCode='INVESTG']/@moodCo de='EVN']/outboundRelationship[@typeCode='SPRT']/rj/relatedInvestigation/@code=@code=2]]/@code System=2.16.840.1.113883.3.989.2.1.1.22]]/rj/relatedInvestigation/@classCode='INVESTG']/@mood Code='EVN']/subjectOf2[@typeCode='SUBJ']/controlActEvent[@classCode='CACT']/@moodCode=' EVN']/author[@typeCode='AUT']/assignedEntity[@classCode='ASSIGNED']/addr[1]/city[1]/text() </pre> |
| e | | | | | | NullFlavor | <pre> /MCCl_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCl_IN200100UV01.xsd']/PORG_IN049016UV/rj/controlActProcess[@classCode='CACT']/@moo dCode='EVN']/subject[@typeCode='SUBJ']/rj/investigationEvent[@classCode='INVESTG']/@moodCo de='EVN']/outboundRelationship[@typeCode='SPRT']/rj/relatedInvestigation/@code=@code=2]]/@code System=2.16.840.1.113883.3.989.2.1.1.22]]/rj/relatedInvestigation/@classCode='INVESTG']/@mood Code='EVN']/subjectOf2[@typeCode='SUBJ']/controlActEvent[@classCode='CACT']/@moodCode=' EVN']/author[@typeCode='AUT']/assignedEntity[@classCode='ASSIGNED']/addr[1]/city[1]/@nullFla vor </pre> |

| | | | | | | | |
|---|-----------|---------------|------|---------------------------------|--------------------------------|------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| e | C.2.1.2.5 | 報告者の住所 (郵便番号) | 40AN | Postal Address (AD) | state=Address Part (ADXP) | 値 | <pre> /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UV/r/controlActProcess[@classCode=CACT][@mood dCode=EVN]/subject[@typeCode=SUBJ][r/investigationEvent[@classCode=INVTG][@moodCo de=EVN]/outboundRelationship[@typeCode=SPRT][relatedInvestigation/code/@code=2][@code System=2,16.840.1.113883.3.989.2.1.1.22][r/relatedInvestigation[@classCode=INVTG][@mood Code=EVN]/subjectOf2[@typeCode=SUBJ]/controlActEvent[@classCode=CACT][@moodCode= EVN]/author[@typeCode=AUT]/assignedEntity[@classCode=ASSIGNED][addrf1/statef1/textf) </pre> |
| e | | | | | | NullFlavor | <pre> /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UV/r/controlActProcess[@classCode=CACT][@mood dCode=EVN]/subject[@typeCode=SUBJ][r/investigationEvent[@classCode=INVTG][@moodCo de=EVN]/outboundRelationship[@typeCode=SPRT][relatedInvestigation/code/@code=2][@code System=2,16.840.1.113883.3.989.2.1.1.22][r/relatedInvestigation[@classCode=INVTG][@mood Code=EVN]/subjectOf2[@typeCode=SUBJ]/controlActEvent[@classCode=CACT][@moodCode= EVN]/author[@typeCode=AUT]/assignedEntity[@classCode=ASSIGNED][addrf1/statef1]/@nullFI avor </pre> |
| e | C.2.1.2.6 | 報告者の住所 (郵便番号) | 15AN | Postal Address (AD) | postalCode=Address Part (ADXP) | 値 | <pre> /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UV/r/controlActProcess[@classCode=CACT][@moo dCode=EVN]/subject[@typeCode=SUBJ][r/investigationEvent[@classCode=INVTG][@moodCo de=EVN]/outboundRelationship[@typeCode=SPRT][relatedInvestigation/code/@code=2][@code System=2,16.840.1.113883.3.989.2.1.1.22][r/relatedInvestigation[@classCode=INVTG][@mood Code=EVN]/subjectOf2[@typeCode=SUBJ]/controlActEvent[@classCode=CACT][@moodCode= EVN]/author[@typeCode=AUT]/assignedEntity[@classCode=ASSIGNED][addrf1]/postalCodef1[re xt) </pre> |
| e | | | | | | NullFlavor | <pre> /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UV/r/controlActProcess[@classCode=CACT][@moo dCode=EVN]/subject[@typeCode=SUBJ][r/investigationEvent[@classCode=INVTG][@moodCo de=EVN]/outboundRelationship[@typeCode=SPRT][relatedInvestigation/code/@code=2][@code System=2,16.840.1.113883.3.989.2.1.1.22][r/relatedInvestigation[@classCode=INVTG][@mood Code=EVN]/subjectOf2[@typeCode=SUBJ]/controlActEvent[@classCode=CACT][@moodCode= EVN]/author[@typeCode=AUT]/assignedEntity[@classCode=ASSIGNED][addrf1]/postalCodef1[@nullFlavor </pre> |
| e | C.2.1.2.7 | 報告者の電話番号 | 33AN | Telecommunication Address (TEL) | | 値 | <pre> substring(MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UV/r/controlActProcess[@classCode=CACT][@moo dCode=EVN]/subject[@typeCode=SUBJ][r/investigationEvent[@classCode=INVTG][@moodCo de=EVN]/outboundRelationship[@typeCode=SPRT][relatedInvestigation/code/@code=2][@code System=2,16.840.1.113883.3.989.2.1.1.22][r/relatedInvestigation[@classCode=INVTG][@mood Code=EVN]/subjectOf2[@typeCode=SUBJ]/controlActEvent[@classCode=CACT][@moodCode= EVN]/author[@typeCode=AUT]/assignedEntity[@classCode=ASSIGNED]/telecom starts-with(@v alue,tei:~)])[1](@value,5) </pre> |
| e | | | | | | NullFlavor | <pre> /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UV/r/controlActProcess[@classCode=CACT][@moo dCode=EVN]/subject[@typeCode=SUBJ][r/investigationEvent[@classCode=INVTG][@moodCo de=EVN]/outboundRelationship[@typeCode=SPRT][relatedInvestigation/code/@code=2][@code System=2,16.840.1.113883.3.989.2.1.1.22][r/relatedInvestigation[@classCode=INVTG][@mood Code=EVN]/subjectOf2[@typeCode=SUBJ]/controlActEvent[@classCode=CACT][@moodCode= EVN]/author[@typeCode=AUT]/assignedEntity[@classCode=ASSIGNED][telecom starts-with(@v alue,tei:~)])[1](@nullFlavor </pre> |

(別添 3)

| e | C.2.r.3 | 報告者の国コード | 2A | Concept Descriptor (CD) | code=Character String (ST) | 値 |
|---|---------|-------------------------|----|-----------------------------|----------------------------|------------|
| e | | | | Coded With Equivalents (CE) | code=Character String (ST) | NullFlavor |
| e | C.2.r.4 | 資格 | 1N | | | 値 |
| e | | 資格に関する ICH コードリストのハーシェン | | | | 値 |
| e | | | | | | NullFlavor |

(別添 3)

| | | | | | | | |
|---|---------|-------------------------------|-------|---------------------|----------------------------------------|---|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| e | C.3.3.3 | 送信者の名前 | 60AN | Person Name (PN) | given=Entity Name Part (ENXP) | 値 | /MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hi7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV1/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ']{1}/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/subjectOf1[@typeCode='SUBJ']{1}/controlActEvent/author/assignedEntity/code[@codeSystem='2.16.840.1.113883.3.989.2.1.1.7']{1}/controlActEvent[@classCode='CACT'][@moodCode='EVN']/author[@typeCode='AUT']/assignedEntity[@classCode='ASSIGNED']/assignedPerson[@classCode='PSN'][@determinerCode='INSTANCE']/name/given[1]/text() |
| e | C.3.3.4 | 送信者の中間名 | 60AN | Person Name (PN) | given=Entity Name Part (ENXP) | 値 | /MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hi7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV1/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ']{1}/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/subjectOf1[@typeCode='SUBJ']{1}/controlActEvent/author/assignedEntity/code[@codeSystem='2.16.840.1.113883.3.989.2.1.1.7']{1}/controlActEvent[@classCode='CACT'][@moodCode='EVN']/author[@typeCode='AUT']/assignedEntity[@classCode='ASSIGNED']/assignedPerson[@classCode='PSN'][@determinerCode='INSTANCE']/name/given[2]/text() |
| e | C.3.3.5 | 送信者の姓 | 60AN | Person Name (PN) | family=Entity Name Part (ENXP) | 値 | /MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hi7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV1/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ']{1}/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/subjectOf1[@typeCode='SUBJ']{1}/controlActEvent/author/assignedEntity/code[@codeSystem='2.16.840.1.113883.3.989.2.1.1.7']{1}/controlActEvent[@classCode='CACT'][@moodCode='EVN']/author[@typeCode='AUT']/assignedEntity[@classCode='ASSIGNED']/assignedPerson[@classCode='PSN'][@determinerCode='INSTANCE']/name/family[1]/text() |
| h | C.3.4 | 送信者の住所、FAX 番号、電話番号及び電子メールアドレス | | | | | |
| e | C.3.4.1 | 送信者の住所 (番地) | 100AN | Postal Address (AD) | streetAddress=line=Address Part (ADXP) | 値 | /MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hi7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV1/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ']{1}/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/subjectOf1[@typeCode='SUBJ']{1}/controlActEvent/author/assignedEntity/code[@codeSystem='2.16.840.1.113883.3.989.2.1.1.7']{1}/controlActEvent[@classCode='CACT'][@moodCode='EVN']/author[@typeCode='AUT']/assignedEntity[@classCode='ASSIGNED']/addr[1]/streetAddressLine[1]/text() |
| e | C.3.4.2 | 送信者の住所 (市町村等) | 35AN | Postal Address (AD) | city=Address Part (ADXP) | 値 | /MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hi7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV1/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ']{1}/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/subjectOf1[@typeCode='SUBJ']{1}/controlActEvent/author/assignedEntity/code[@codeSystem='2.16.840.1.113883.3.989.2.1.1.7']{1}/controlActEvent[@classCode='CACT'][@moodCode='EVN']/author[@typeCode='AUT']/assignedEntity[@classCode='ASSIGNED']/addr[1]/city[1]/text() |
| e | C.3.4.3 | 送信者の住所 (都道府県等) | 40AN | Postal Address (AD) | state=Address Part (ADXP) | 値 | /MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hi7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV1/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ']{1}/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/subjectOf1[@typeCode='SUBJ']{1}/controlActEvent/author/assignedEntity/code[@codeSystem='2.16.840.1.113883.3.989.2.1.1.7']{1}/controlActEvent[@classCode='CACT'][@moodCode='EVN']/author[@typeCode='AUT']/assignedEntity[@classCode='ASSIGNED']/addr[1]/state[1]/text() |

(別添3)

| | | | | | | | |
|---|---------|------------------|-------|---------------------------------|--------------------------------|-------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| e | C.3.4.4 | 送信者の住所 (郵便番号) | 15AN | Postal Address (AD) | postalCode=Address Part (ADXP) | 値 | <pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/PORR_IN049016UV/r/controlActProcess/@classCode=CACT][@moo dCode=EVN]/subject/@typeCode=SUBJ[1]/investigationEvent/@classCode=INVTG][@moodCo de=EVN]/subjectOf/@typeCode=SUBJ[1]/controlActEvent/author/assignedEntity/code/@codeSyste m=2.16.840.1.113883.3.989.2.1.1.7][1]/controlActEvent/@classCode=CACT][@moodCode=EVN] /author/@typeCode=AUT]/assignedEntity/@classCode=ASSIGNED][addr[1]/postalCode[1]/text() </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_IN049016UV/r/controlActProcess/@classCode=CACT][@moo dCode=EVN]/subject/@typeCode=SUBJ[1]/investigationEvent/@classCode=INVTG][@moodCo de=EVN]/subjectOf/@typeCode=SUBJ[1]/controlActEvent/author/assignedEntity/code/@codeSyste m=2.16.840.1.113883.3.989.2.1.1.7][1]/controlActEvent/@classCode=CACT][@moodCode=EVN] /author/@typeCode=AUT]/assignedEntity/@classCode=ASSIGNED][assignedPerson/@classCode =PSN][@determinerCode=INSTANCE]/asLocatedEntity/@classCode=LOCE[1]/location/@classC ode=COUNTRY][@determinerCode=INSTANCE]/code/@codeSystem=1.0.3166.1.2.2][@code substring(/MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/PORR_IN049016UV/r/controlActProcess/@classCode=CACT][@moo dCode=EVN]/subject/@typeCode=SUBJ[1]/investigationEvent/@classCode=INVTG][@moodCo de=EVN]/subjectOf/@typeCode=SUBJ[1]/controlActEvent/author/assignedEntity/code/@codeSyste m=2.16.840.1.113883.3.989.2.1.1.7][1]/controlActEvent/@classCode=CACT][@moodCode=EVN] /author/@typeCode=AUT]/assignedEntity/@classCode=ASSIGNED][telecom[starts-with(@value, 'tel:')]][1]/@value, 5) </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_IN049016UV/r/controlActProcess/@classCode=CACT][@moo dCode=EVN]/subject/@typeCode=SUBJ[1]/investigationEvent/@classCode=INVTG][@moodCo de=EVN]/subjectOf/@typeCode=SUBJ[1]/controlActEvent/author/assignedEntity/code/@codeSyste m=2.16.840.1.113883.3.989.2.1.1.7][1]/controlActEvent/@classCode=CACT][@moodCode=EVN] /author/@typeCode=AUT]/assignedEntity/@classCode=ASSIGNED][telecom[starts-with(@value, 'tel:')]][1]/@value, 5) </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_IN049016UV/r/controlActProcess/@classCode=CACT][@moo dCode=EVN]/subject/@typeCode=SUBJ[1]/investigationEvent/@classCode=INVTG][@moodCo de=EVN]/subjectOf/@typeCode=SUBJ[1]/controlActEvent/author/assignedEntity/code/@codeSyste m=2.16.840.1.113883.3.989.2.1.1.7][1]/controlActEvent/@classCode=CACT][@moodCode=EVN] /author/@typeCode=AUT]/assignedEntity/@classCode=ASSIGNED][telecom[starts-with(@value, 'fax:')]][1]/@value, 5) </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_IN049016UV/r/controlActProcess/@classCode=CACT][@moo dCode=EVN]/subject/@typeCode=SUBJ[1]/investigationEvent/@classCode=INVTG][@moodCo de=EVN]/subjectOf/@typeCode=SUBJ[1]/controlActEvent/author/assignedEntity/code/@codeSyste m=2.16.840.1.113883.3.989.2.1.1.7][1]/controlActEvent/@classCode=CACT][@moodCode=EVN] /author/@typeCode=AUT]/assignedEntity/@classCode=ASSIGNED][telecom[starts-with(@value, 'mailto:')]][1]/@value, 6) </pre> |
| h | C.4.r | 引用文献 (必要に応じ繰り返す) | | | | 繰り返し ノード | <pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/PORR_IN049016UV/r/controlActProcess/@classCode=CACT][@moo dCode=EVN]/subject/@typeCode=SUBJ[1]/investigationEvent/@classCode=INVTG][@moodCo de=EVN]/reference/@typeCode=REFR][document/code[@code=2][@codeSystem=2,16.840.1.11 3883.3.989.2.1.1.27]] </pre> |
| e | C.4.r.1 | 引用文献 | 500AN | Encapsulated Data (ED) | | 値 | <pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/PORR_IN049016UV/r/controlActProcess/@classCode=CACT][@moo dCode=EVN]/subject/@typeCode=SUBJ[1]/investigationEvent/@classCode=INVTG][@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=DOCI][@moodCode=EVN]/bibliographicDesignati onText(text) </pre> |

(別添 3)

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

(別添 3)

| | | | | | | |
|---|-------|-------------------------|--------|-----------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| e | | | | NullFlavor | /MCCI_IN200100UV01[@ITSVersion=XMML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UVJr/controlActProcess/@classCode=CACT][@moodCode=EVN]/subject/@typeCode=SUBJ][1]/investigationEvent/@classCode=INVTG][@moodCode=EVN]/component/@typeCode=COMP][adverseEventAssessment][1]/adverseEventAssessment/@classCode=INVTG][@moodCode=EVN]/subject1/@typeCode=SBJ][1]/primaryRole/@classCode=INVSBJ][subjectOf1/@typeCode=SBJ][1]/researchStudy/@classCode=CLNTRL][@moodCode=EVN]/authorization/@typeCode=AUTH][1]/studyRegistration/@classCode=ACT][@moodCode=EVN]/authority/@typeCode=AUT]/territorialAuthority/@classCode=TERR]/governingPlace/@classCode=COUNTRY][@determinerCode=INSTANCE]/code/@codeSystem=1.0.3166.1.2.2][@nullFlavor | |
| e | C.5.2 | 試験名 | 2000AN | Character String (ST) | 値 | /MCCI_IN200100UV01[@ITSVersion=XMML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UVJr/controlActProcess/@classCode=CACT][@moodCode=EVN]/subject/@typeCode=SUBJ][1]/investigationEvent/@classCode=INVTG][@moodCode=EVN]/component/@typeCode=COMP][adverseEventAssessment][1]/adverseEventAssessment/@classCode=INVTG][@moodCode=EVN]/subject1/@typeCode=SBJ][1]/primaryRole/@classCode=INVSBJ][subjectOf1/@typeCode=SBJ][1]/researchStudy/@classCode=CLNTRL][@moodCode=EVN]/title/text() |
| e | | | | NullFlavor | /MCCI_IN200100UV01[@ITSVersion=XMML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UVJr/controlActProcess/@classCode=CACT][@moodCode=EVN]/subject/@typeCode=SUBJ][1]/investigationEvent/@classCode=INVTG][@moodCode=EVN]/component/@typeCode=COMP][adverseEventAssessment][1]/adverseEventAssessment/@classCode=INVTG][@moodCode=EVN]/subject1/@typeCode=SBJ][1]/primaryRole/@classCode=INVSBJ][subjectOf1/@typeCode=SBJ][1]/researchStudy/@classCode=CLNTRL][@moodCode=EVN]/title/@nullFlavor | |
| e | C.5.3 | 試験依頼者 (スポンサー) の 試験番号 | 50AN | Instance Identifier (II) | 値 | /MCCI_IN200100UV01[@ITSVersion=XMML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UVJr/controlActProcess/@classCode=CACT][@moodCode=EVN]/subject/@typeCode=SUBJ][1]/investigationEvent/@classCode=INVTG][@moodCode=EVN]/component/@typeCode=COMP][adverseEventAssessment][1]/adverseEventAssessment/@classCode=INVTG][@moodCode=EVN]/subject1/@typeCode=SBJ][1]/primaryRole/@classCode=INVSBJ][subjectOf1/@typeCode=SBJ][1]/researchStudy/@classCode=CLNTRL][@moodCode=EVN]/id/@root=2.16.840.1.113883.3.989.2.1.3.5][@extension |
| e | | | | NullFlavor | /MCCI_IN200100UV01[@ITSVersion=XMML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UVJr/controlActProcess/@classCode=CACT][@moodCode=EVN]/subject/@typeCode=SUBJ][1]/investigationEvent/@classCode=INVTG][@moodCode=EVN]/component/@typeCode=COMP][adverseEventAssessment][1]/adverseEventAssessment/@classCode=INVTG][@moodCode=EVN]/subject1/@typeCode=SBJ][1]/primaryRole/@classCode=INVSBJ][subjectOf1/@typeCode=SBJ][1]/researchStudy/@classCode=CLNTRL][@moodCode=EVN]/id/@root=2.16.840.1.113883.3.989.2.1.3.5][@nullFlavor | |
| e | C.5.4 | 副作用 / 有害事象が観察された試験の種類 | 1N | Coded With Equivalents (CE) | 値 | /MCCI_IN200100UV01[@ITSVersion=XMML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UVJr/controlActProcess/@classCode=CACT][@moodCode=EVN]/subject/@typeCode=SUBJ][1]/investigationEvent/@classCode=INVTG][@moodCode=EVN]/component/@typeCode=COMP][adverseEventAssessment][1]/adverseEventAssessment/@classCode=INVTG][@moodCode=EVN]/subject1/@typeCode=SBJ][1]/primaryRole/@classCode=INVSBJ][subjectOf1/@typeCode=SBJ][1]/researchStudy/@classCode=CLNTRL][@moodCode=EVN]/code/@codeSystem=2.16.840.1.113883.3.989.2.1.1.87][@code |

(別添3)

| | | | | | | | |
|---|---------|--------------------------------|------|-------------------------|------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| h | D | 患者特性 | | | | | /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PDRR_IN049016UV01/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]/subjectOf1[@typeCode=SBJ][@researchStudy[@classCode=CLNTRL][@moodCode=EVN]/code[@codeSystem=2.16.840.1.113883.3.989.2.1.1.8]]/@codeSystemVersion |
| e | D.1 | 患者(名前又はイニシャル) | 60AN | Entity Name (EN) | 値 | /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PDRR_IN049016UV01/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][name1]/text() | |
| e | | | | | NullFlavor | /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PDRR_IN049016UV01/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][name1]/text() | |
| h | D.1.1 | 患者の診療記録番号及びその情報源(記載が許可されている場合) | | | | | |
| e | D.1.1.1 | 患者の診療記録番号及びその情報源(開業医診療記録番号) | 20AN | Instance Identifier (I) | 値 | /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PDRR_IN049016UV01/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][asIdentifierEntity][@classCode=IDENT][code1][@code=1][@codeSystem=2.16.840.1.113883.3.989.2.1.1.4]][1]/id/@root=2.16.840.1.113883.3.989.2.1.3.7][1]/@extension | |
| e | | | | | NullFlavor | /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PDRR_IN049016UV01/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][asIdentifierEntity][@classCode=IDENT][code1][@code=1][@codeSystem=2.16.840.1.113883.3.989.2.1.1.4]][1]/id/@root=2.16.840.1.113883.3.989.2.1.3.7][1]/@nullFlavor | |
| e | D.1.1.2 | 患者の診療記録番号及びその情報源(専門医診療記録番号) | 20AN | Instance Identifier (I) | 値 | /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PDRR_IN049016UV01/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][asIdentifierEntity][@classCode=IDENT][code1][@code=2][@codeSystem=2.16.840.1.113883.3.989.2.1.1.4]][1]/id/@root=2.16.840.1.113883.3.989.2.1.3.8][1]/@extension | |

(別添3)

| | | | | | | |
|---|----------|---------------------------|------|-----------------------------|------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| e | | | | | NullFlavor | /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UV/r/controlActProcess[@classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUBJ][1]/investigationEvent[@classCode=INVTG][@moodCode=EVN]/component[@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment[@classCode=INVTG][@moodCode=EVN]/subject1[@typeCode=SBJ][1]/primaryRole[@classCode=INVSBJ]/player1[@classCode=PSN][@determinerCode=INSTANCE]/birthTime[@nullFlavorCode=CE][@value] |
| 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_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UV/r/controlActProcess[@classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUBJ][1]/investigationEvent[@classCode=INVTG][@moodCode=EVN]/component[@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment[@classCode=INVTG][@moodCode=EVN]/subject1[@typeCode=SBJ][1]/primaryRole[@classCode=INVSBJ]/subjectOf2[@typeCode=SBJ][observation/code[@code=3][@codeSystem=2.16.840.1.113883.3.989.2.1.1.19][1]/observation[@classCode=OBS][@moodCode=EVN]/value[@xsi:type=PQ][1]/@value |
| e | D.2.2b | 副作用／有害事象発現時の年齢 (単位) | 50AN | Physical Quantity (PQ) | unit=Coded Simple Value (CS) | /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UV/r/controlActProcess[@classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUBJ][1]/investigationEvent[@classCode=INVTG][@moodCode=EVN]/component[@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment[@classCode=INVTG][@moodCode=EVN]/subject1[@typeCode=SBJ][1]/primaryRole[@classCode=INVSBJ]/subjectOf2[@typeCode=SBJ][observation/code[@code=3][@codeSystem=2.16.840.1.113883.3.989.2.1.1.19][1]/observation[@classCode=OBS][@moodCode=EVN]/value[@xsi:type=PQ][1]/@unit |
| e | D.2.2.1a | 胎児での副作用／有害事象発現時の妊娠期間 (数) | 3N | Physical Quantity (PQ) | value=Real Number (REAL) | /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UV/r/controlActProcess[@classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUBJ][1]/investigationEvent[@classCode=INVTG][@moodCode=EVN]/component[@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment[@classCode=INVTG][@moodCode=EVN]/subject1[@typeCode=SBJ][1]/primaryRole[@classCode=INVSBJ]/subjectOf2[@typeCode=SBJ][observation/code[@code=16][@codeSystem=2.16.840.1.113883.3.989.2.1.1.19][1]/observation[@classCode=OBS][@moodCode=EVN]/value[@xsi:type=PQ][1]/@value |
| e | D.2.2.1b | 胎児での副作用／有害事象発現時の妊娠期間 (単位) | 50AN | Physical Quantity (PQ) | unit=Coded Simple Value (CS) | /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UV/r/controlActProcess[@classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUBJ][1]/investigationEvent[@classCode=INVTG][@moodCode=EVN]/component[@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment[@classCode=INVTG][@moodCode=EVN]/subject1[@typeCode=SBJ][1]/primaryRole[@classCode=INVSBJ]/subjectOf2[@typeCode=SBJ][observation/code[@code=16][@codeSystem=2.16.840.1.113883.3.989.2.1.1.19][1]/observation[@classCode=OBS][@moodCode=EVN]/value[@xsi:type=PQ][1]/@unit |
| e | D.2.3 | 患者の年齢群 (報告者の表現による) | 1N | Coded With Equivalents (CE) | code=Character String (ST) | /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UV/r/controlActProcess[@classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUBJ][1]/investigationEvent[@classCode=INVTG][@moodCode=EVN]/component[@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment[@classCode=INVTG][@moodCode=EVN]/subject1[@typeCode=SBJ][1]/primaryRole[@classCode=INVSBJ]/subjectOf2[@typeCode=SBJ][observation/code[@code=4][@codeSystem=2.16.840.1.113883.3.989.2.1.1.19][1]/observation[@classCode=OBS][@moodCode=EVN]/value[@xsi:type=CE][@codeSystem=2.16.840.1.113883.3.989.2.1.1.9][1]/@code |

(別添 3)

| | | | | | | |
|---|-----|------------------------------------------|-------|-----------------------------|------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| e | D.3 | 患者の年齢群 (報告者の表現による)に関する ICH コード リストのパージョン | 6N | Physical Quantity (PQ) | 値 | <pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 /MCCL_IN200100UV01.xsd]/PDRR_IN049016UV/r/controlActProcess/@classCode=CACTT][@moo dCode=EVN]/subject/@typeCode=SUBJ][1]/investigationEvent/@classCode=INVSIG][@moodCo de=EVN]/component/@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment [@classCode=INVSIG][@moodCode=EVN]/subject1/@typeCode=SBJ][1]/primaryRole/@classC ode=INVSBJ][subjectOr2/@typeCode=SBJ][observation/code/@code=4][@codeSystem=2.16.84 0.1.113883.3.989.2.1.1.19][1]/observation/@classCode=OBS][@moodCode=EVN]/value/@xsi:typ e=CE][@codeSystem=2.16.840.1.113883.3.989.2.1.1.9][1] </pre> |
| e | D.3 | 体重 (kg) | 6N | Physical Quantity (PQ) | 値 | <pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 /MCCL_IN200100UV01.xsd]/PDRR_IN049016UV/r/controlActProcess/@classCode=CACTT][@moo dCode=EVN]/subject/@typeCode=SUBJ][1]/investigationEvent/@classCode=INVSIG][@moodCo de=EVN]/component/@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment [@classCode=INVSIG][@moodCode=EVN]/subject1/@typeCode=SBJ][1]/primaryRole/@classC ode=INVSBJ][subjectOr2/@typeCode=SBJ][observation/code/@code=7][@codeSystem=2.16.84 0.1.113883.3.989.2.1.1.19][1]/observation/@classCode=OBS][@moodCode=EVN]/value/@xsi:typ e=PQ][@unit=kg][1]@value </pre> |
| e | D.4 | 身長 (cm) | 3N | Physical Quantity (PQ) | 値 | <pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 /MCCL_IN200100UV01.xsd]/PDRR_IN049016UV/r/controlActProcess/@classCode=CACTT][@moo dCode=EVN]/subject/@typeCode=SUBJ][1]/investigationEvent/@classCode=INVSIG][@moodCo de=EVN]/component/@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment [@classCode=INVSIG][@moodCode=EVN]/subject1/@typeCode=SBJ][1]/primaryRole/@classC ode=INVSBJ][subjectOr2/@typeCode=SBJ][observation/code/@code=17][@codeSystem=2.16.8 40.1.113883.3.989.2.1.1.19][1]/observation/@classCode=OBS][@moodCode=EVN]/value/@xsi:typ e=PQ][@unit=cm][1]@value </pre> |
| e | D.5 | 性別 | 1N | Coded With Equivalents (CE) | 値 | <pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 /MCCL_IN200100UV01.xsd]/PDRR_IN049016UV/r/controlActProcess/@classCode=CACTT][@moo dCode=EVN]/subject/@typeCode=SUBJ][1]/investigationEvent/@classCode=INVSIG][@moodCo de=EVN]/component/@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment [@classCode=INVSIG][@moodCode=EVN]/subject1/@typeCode=SBJ][1]/primaryRole/@classC ode=INVSBJ][player1/@classCode=PSN][@determinerCode=INSTANCE]/administrativeGenderC ode/@codeSystem=1.0.52187/@code </pre> |
| e | | | | | NullFlavor | <pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 /MCCL_IN200100UV01.xsd]/PDRR_IN049016UV/r/controlActProcess/@classCode=CACTT][@moo dCode=EVN]/subject/@typeCode=SUBJ][1]/investigationEvent/@classCode=INVSIG][@moodCo de=EVN]/component/@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment [@classCode=INVSIG][@moodCode=EVN]/subject1/@typeCode=SBJ][1]/primaryRole/@classC ode=INVSBJ][player1/@classCode=PSN][@determinerCode=INSTANCE]/administrativeGenderC ode/@codeSystem=1.0.52187/@nullFlavor </pre> |
| e | D.6 | 最終月経日 | 日付/時間 | Point in Time (TS) | 値 | <pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 /MCCL_IN200100UV01.xsd]/PDRR_IN049016UV/r/controlActProcess/@classCode=CACTT][@moo dCode=EVN]/subject/@typeCode=SUBJ][1]/investigationEvent/@classCode=INVSIG][@moodCo de=EVN]/component/@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment [@classCode=INVSIG][@moodCode=EVN]/subject1/@typeCode=SBJ][1]/primaryRole/@classC ode=INVSBJ][subjectOr2/@typeCode=SBJ][observation/code/@code=22][@codeSystem=2.16.8 40.1.113883.3.989.2.1.1.19][1]/observation/@classCode=OBS][@moodCode=EVN]/value/@xsi:typ e=TS][1]@value </pre> |

(別添3)

| | | | | | | |
|---|------------|------------------------------------------|-------|------------------------------------|-------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| e | | | | | NullFlavor | /MCCI_IN200100UV01[@ITSVersion=XML_1_0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UV[1]/controlActProcess[@classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUBJ][1]/investigationEvent[@classCode=INVESTG][@moodCode=EVN]/component[@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment[@classCode=INVESTG][@moodCode=EVN]/subject[1]/primaryRole[1]/primaryRole[1]/observation/code[@code=22][@codeSystem=2.16.840.1.113883.3.989.2.1.1.19][1]/observation[@classCode=OBS][@moodCode=EVN]/value[@xsi:type=nullFlavor] |
| h | D.7 | 関連する治療歴及び随伴症状 (副作用/有害事象を除く) | | | | |
| h | D.7.1.r | 関連する治療歴及び随伴症状の構造化された情報 (必要に応じて繰り返す) | | | 繰り返し ノード | /MCCI_IN200100UV01[@ITSVersion=XML_1_0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UV[1]/controlActProcess[@classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUBJ][1]/investigationEvent[@classCode=INVESTG][@moodCode=EVN]/component[@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment[@classCode=INVESTG][@moodCode=EVN]/subject[1]/primaryRole[1]/primaryRole[1]/observation/code[@code=22][@codeSystem=2.16.840.1.113883.3.989.2.1.1.20][1]/organizer[@classCode=CATEGORY][@moodCode=EVN]/component[@typeCode=COMP][observation/code[@codeSystem=2.16.840.1.113883.3.989.2.1.1.19][1]] |
| 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) | 値 | /MCCI_IN200100UV01[@ITSVersion=XML_1_0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UV[1]/controlActProcess[@classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUBJ][1]/investigationEvent[@classCode=INVESTG][@moodCode=EVN]/component[@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment[@classCode=INVESTG][@moodCode=EVN]/subject[1]/primaryRole[1]/primaryRole[1]/observation/code[@code=22][@codeSystem=2.16.840.1.113883.3.989.2.1.1.20][1]/organizer[@classCode=CATEGORY][@moodCode=EVN]/component[@typeCode=COMP][observation/code[@codeSystem=2.16.840.1.113883.3.989.2.1.1.19][1]]/observation[@classCode=OBS][@moodCode=EVN]/code/@code |
| 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) | 値 | /MCCI_IN200100UV01[@ITSVersion=XML_1_0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UV[1]/controlActProcess[@classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUBJ][1]/investigationEvent[@classCode=INVESTG][@moodCode=EVN]/component[@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment[@classCode=INVESTG][@moodCode=EVN]/subject[1]/primaryRole[1]/primaryRole[1]/observation/code[@code=22][@codeSystem=2.16.840.1.113883.3.989.2.1.1.20][1]/organizer[@classCode=CATEGORY][@moodCode=EVN]/component[@typeCode=COMP][observation/code[@codeSystem=2.16.840.1.113883.3.989.2.1.1.19][1]]/observation[@classCode=OBS][@moodCode=EVN]/code/@code |
| e | D.7.1.r.2 | 開始日 | 日付/時間 | Interval of Point in Time (VL<TS>) | 値 | /MCCI_IN200100UV01[@ITSVersion=XML_1_0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UV[1]/controlActProcess[@classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUBJ][1]/investigationEvent[@classCode=INVESTG][@moodCode=EVN]/component[@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment[@classCode=INVESTG][@moodCode=EVN]/subject[1]/primaryRole[1]/primaryRole[1]/observation/code[@code=22][@codeSystem=2.16.840.1.113883.3.989.2.1.1.20][1]/organizer[@classCode=CATEGORY][@moodCode=EVN]/component[@typeCode=COMP][observation/code[@codeSystem=2.16.840.1.113883.3.989.2.1.1.19][1]]/effectiveTime[@xsi:type=IVL_TS][low/@value |

| | | | |
|---|------------------|---------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| e | | NullFlavor | <pre> /MCCI_IN200100UV01[@ITSVersion=XMML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UV/r/controlActProcess/@classCode=CACT][@moo dCode=EVN]/subject/@typeCode=SUBJ][@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment /@classCode=INVSCTG][@moodCode=EVN]/subject1/@typeCode=SBJ][@typeCode=SBJ][@primaryRole/@classC ode=INVSBJ]/subjectOr2/@typeCode=SBJ][organizer/@code=1][@codeSystem=2.16.840.1 .113883.3.989.2.1.1.20][1]/organizer/@classCode=CATEGORY][@moodCode=EVN]/component[@typeCode=COMP][observation/@code/@codeSystem=2.16.840.1.113883.3.989.2.1.1.19][r/observation/@ classCode=OBS][@moodCode=EVN]/effectiveTime/@xsi:type=VL_TS][low/@nullFlavor </pre> |
| e | D.7.1.r.3 継続 | Boolean (BL) ブール型 | <pre> /MCCI_IN200100UV01[@ITSVersion=XMML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UV/r/controlActProcess/@classCode=CACT][@moo dCode=EVN]/subject/@typeCode=SUBJ][@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment /@classCode=INVSCTG][@moodCode=EVN]/subject1/@typeCode=SBJ][@typeCode=SBJ][@primaryRole/@classC ode=INVSBJ]/subjectOr2/@typeCode=SBJ][organizer/@code=1][@codeSystem=2.16.840.1 .113883.3.989.2.1.1.20][1]/organizer/@classCode=CATEGORY][@moodCode=EVN]/component[@typeCode=COMP][observation/@code/@codeSystem=2.16.840.1.113883.3.989.2.1.1.19][r/observation/@code/ @code=13][@codeSystem=2.16.840.1.113883.3.989.2.1.1.19][1]/observation/@classCode=OBS][@moodCode=EVN]/value/@xsi:type=BL][1]/@value </pre> |
| e | D.7.1.r.4 終了日 | Interval of Point in Time (VL<TS>) 日付/時間 | <pre> /MCCI_IN200100UV01[@ITSVersion=XMML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UV/r/controlActProcess/@classCode=CACT][@moo dCode=EVN]/subject/@typeCode=SUBJ][@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment /@classCode=INVSCTG][@moodCode=EVN]/subject1/@typeCode=SBJ][@typeCode=SBJ][@primaryRole/@classC ode=INVSBJ]/subjectOr2/@typeCode=SBJ][organizer/@code=1][@codeSystem=2.16.840.1 .113883.3.989.2.1.1.20][1]/organizer/@classCode=CATEGORY][@moodCode=EVN]/component[@typeCode=COMP][observation/@code/@codeSystem=2.16.840.1.113883.3.989.2.1.1.19][r/observation/@code/ @code=13][@codeSystem=2.16.840.1.113883.3.989.2.1.1.19][1]/observation/@classCode=OBS][@moodCode=EVN]/value/@xsi:type=BL][1]/@value </pre> |
| e | | NullFlavor | <pre> /MCCI_IN200100UV01[@ITSVersion=XMML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UV/r/controlActProcess/@classCode=CACT][@moo dCode=EVN]/subject/@typeCode=SUBJ][@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment /@classCode=INVSCTG][@moodCode=EVN]/subject1/@typeCode=SBJ][@typeCode=SBJ][@primaryRole/@classC ode=INVSBJ]/subjectOr2/@typeCode=SBJ][organizer/@code=1][@codeSystem=2.16.840.1 .113883.3.989.2.1.1.20][1]/organizer/@classCode=CATEGORY][@moodCode=EVN]/component[@typeCode=COMP][observation/@code/@codeSystem=2.16.840.1.113883.3.989.2.1.1.19][r/observation/@code/ @code=13][@codeSystem=2.16.840.1.113883.3.989.2.1.1.19][1]/observation/@classCode=OBS][@moodCode=EVN]/value/@xsi:type=BL][1]/@value </pre> |

| | | | | | | |
|---|----------|---------------------------|---------------|--------------------------------|-------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| h | D.8.r | 関連する過去の医薬品使用歴 (必要に応じ繰り返す) | | | 繰り返し ノード | <pre> /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UV/r/controlActProcess[@classCode=CACT][@mo dCode=EVN]/subject[@typeCode=SUBJ][1]/investigationEvent[@classCode=INVTG][@mo de=EVN]/component[@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessm ent[@classCode=INVTG][@moodCode=EVN]/subject1[@typeCode=SBJ][1]/primaryRole[@class Code=INVSBJ]/subjectOr2[@typeCode=SBJ]/organizer/code[@code=2][@codeSystem=2.16.840.1 .113883.3.989.2.1.1.20][1]/organizer[@classCode=CATEGORY][@moodCode=EVN]/component[@typeCode=COMP][substanceAdministration] </pre> |
| e | D.8.r.1 | 医薬品名 (報告された表現) | 250AN | Entity Name (EN) | 値 | <pre> /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UV/r/controlActProcess[@classCode=CACT][@mo dCode=EVN]/subject[@typeCode=SUBJ][1]/investigationEvent[@classCode=INVTG][@mo de=EVN]/component[@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessm ent[@classCode=INVTG][@moodCode=EVN]/subject1[@typeCode=SBJ][1]/primaryRole[@class Code=INVSBJ]/subjectOr2[@typeCode=SBJ]/organizer/code[@code=2][@codeSystem=2.16.840.1 .113883.3.989.2.1.1.20][1]/organizer[@classCode=CATEGORY][@moodCode=EVN]/component[@typeCode=COMP][substanceAdministration][r/substanceAdministration[@classCode=SBADM][@moodCode=EVN]/consumable[@typeCode=CSM][1]/instanceOfKind[@classCode=INST]/kindO fProduct[@classCode=MMA1][@determinerCode=KIND]/name[1]/text() </pre> |
| e | D.8.r.2a | MPID バージョン日付/番号 | M5 ガイド を参照 | Coded With Equivalents (CE) | 値 | <pre> /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UV/r/controlActProcess[@classCode=CACT][@mo dCode=EVN]/subject[@typeCode=SUBJ][1]/investigationEvent[@classCode=INVTG][@mo de=EVN]/component[@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessm ent[@classCode=INVTG][@moodCode=EVN]/subject1[@typeCode=SBJ][1]/primaryRole[@class Code=INVSBJ]/subjectOr2[@typeCode=SBJ]/organizer/code[@code=2][@codeSystem=2.16.840.1 .113883.3.989.2.1.1.20][1]/organizer[@classCode=CATEGORY][@moodCode=EVN]/component[@typeCode=COMP][substanceAdministration][r/substanceAdministration[@classCode=SBADM][@moodCode=EVN]/consumable[@typeCode=CSM][1]/instanceOfKind[@classCode=INST]/kindO fProduct[@classCode=MMA1][@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) | 値 | <pre> /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UV/r/controlActProcess[@classCode=CACT][@mo dCode=EVN]/subject[@typeCode=SUBJ][1]/investigationEvent[@classCode=INVTG][@mo de=EVN]/component[@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessm ent[@classCode=INVTG][@moodCode=EVN]/subject1[@typeCode=SBJ][1]/primaryRole[@class Code=INVSBJ]/subjectOr2[@typeCode=SBJ]/organizer/code[@code=2][@codeSystem=2.16.840.1 .113883.3.989.2.1.1.20][1]/organizer[@classCode=CATEGORY][@moodCode=EVN]/component[@typeCode=COMP][substanceAdministration][r/substanceAdministration[@classCode=SBADM][@moodCode=EVN]/consumable[@typeCode=CSM][1]/instanceOfKind[@classCode=INST]/kindO fProduct[@classCode=MMA1][@determinerCode=KIND]/code[@codeSystem=TBD-MPID]/@cod eSystemVersion </pre> |

(別添 3)

| | | | | | | |
|---|----------|--------------------|-----|-----------------------------|------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| e | | | | | NullFlavor | <pre> /MCCI_IN200100UV01[@ITSVersion=XMML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UV/r/controlActProcess/@classCode=CACTT[@moo dCode=EVN]/subject/@typeCode=SUBJ[1]/investigationEvent/@classCode=INVTG[@moodCo de=EVN]/component/@typeCode=COMP[1]/adverseEventAssessment[1]/adverseEventAssessment [@classCode=INVTG][@moodCode=EVN]/subject1/@typeCode=SBJ[1]/primaryRole/@classC ode=INVSBJ[1]/subjectOr2/@typeCode=SBJ[1]/organizer/code/@code=2[1]@codeSystem=2.16.840.1 .113883.3.989.2.1.1.20[1]/organizer/@classCode=CATEGORY[1]@moodCode=EVN/component[@typeCode=COMP][substanceAdministration]/substanceAdministration/@classCode=SBADM[1] @moodCode=EVN/effectiveTime[@xsi:type=IVL_TS]/high/@nullFlavor </pre> |
| e | D.8.r.6a | 使用理由の MedDRA バージョン | 4AN | Coded With Equivalents (CE) | 値 | <pre> /MCCI_IN200100UV01[@ITSVersion=XMML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UV/r/controlActProcess/@classCode=CACTT[@moo dCode=EVN]/subject/@typeCode=SUBJ[1]/investigationEvent/@classCode=INVTG[@moodCo de=EVN]/component/@typeCode=COMP[1]/adverseEventAssessment[1]/adverseEventAssessment [@classCode=INVTG][@moodCode=EVN]/subject1/@typeCode=SBJ[1]/primaryRole/@classC ode=INVSBJ[1]/subjectOr2/@typeCode=SBJ[1]/organizer/code/@code=2[1]@codeSystem=2.16.840.1 .113883.3.989.2.1.1.20[1]/organizer/@classCode=CATEGORY[1]@moodCode=EVN/component[@typeCode=COMP][substanceAdministration]/substanceAdministration/@classCode=SBADM[1] @moodCode=EVN/outboundRelationship2/@typeCode=RSO[1]/observation/code/@code=19[1]@ codeSystem=2.16.840.1.113883.3.989.2.1.1.19[1]/observation/@classCode=OBS[1]@moodCode =EVN/value[@xsi:type=CE][@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) | 値 | <pre> /MCCI_IN200100UV01[@ITSVersion=XMML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UV/r/controlActProcess/@classCode=CACTT[@moo dCode=EVN]/subject/@typeCode=SUBJ[1]/investigationEvent/@classCode=INVTG[@moodCo de=EVN]/component/@typeCode=COMP[1]/adverseEventAssessment[1]/adverseEventAssessment [@classCode=INVTG][@moodCode=EVN]/subject1/@typeCode=SBJ[1]/primaryRole/@classC ode=INVSBJ[1]/subjectOr2/@typeCode=SBJ[1]/organizer/code/@code=2[1]@codeSystem=2.16.840.1 .113883.3.989.2.1.1.20[1]/organizer/@classCode=CATEGORY[1]@moodCode=EVN/component[@typeCode=COMP][substanceAdministration]/substanceAdministration/@classCode=SBADM[1] @moodCode=EVN/outboundRelationship2/@typeCode=RSO[1]/observation/code/@code=19[1]@ codeSystem=2.16.840.1.113883.3.989.2.1.1.19[1]/observation/@classCode=OBS[1]@moodCode =EVN/value[@xsi:type=CE][@codeSystem=2.16.840.1.113883.6.163][1]/@codeSystemVersion </pre> |
| e | D.8.r.7a | 副作用の MedDRA バージョン | 4AN | Coded With Equivalents (CE) | 値 | <pre> /MCCI_IN200100UV01[@ITSVersion=XMML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UV/r/controlActProcess/@classCode=CACTT[@moo dCode=EVN]/subject/@typeCode=SUBJ[1]/investigationEvent/@classCode=INVTG[@moodCo de=EVN]/component/@typeCode=COMP[1]/adverseEventAssessment[1]/adverseEventAssessment [@classCode=INVTG][@moodCode=EVN]/subject1/@typeCode=SBJ[1]/primaryRole/@classC ode=INVSBJ[1]/subjectOr2/@typeCode=SBJ[1]/organizer/code/@code=2[1]@codeSystem=2.16.840.1 .113883.3.989.2.1.1.20[1]/organizer/@classCode=CATEGORY[1]@moodCode=EVN/component[@typeCode=COMP][substanceAdministration]/substanceAdministration/@classCode=SBADM[1] @moodCode=EVN/outboundRelationship2/@typeCode=CAUS[1]/observation/code/@code=29[1]@ codeSystem=2.16.840.1.113883.3.989.2.1.1.19[1]/observation/@classCode=OBS[1]@moodCode =EVN/value[@xsi:type=CE][@codeSystem=2.16.840.1.113883.6.163][1]/@codeSystemVersion </pre> |

| | | | | | | | |
|---|------------|-------------------------|-------|-----------------------------|------------------------------------------|------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| e | D.9.2.1.2 | 報告された死因 (自由記載) | 250AN | Coded With Equivalents (CE) | originalText = Encapsulated Data (ED) | 値 | /MCC1_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCC1_IN200100UV01.xsd]/PORR_IN049016UV01/controlActProcess[@classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUBJ][1]/investigationEvent[@classCode=INVTG][1]/component[@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment[@classCode=INVTG][1]/moodCode=EVN]/subject1[@typeCode=SBJ][1]/primaryRole[@classCode=INVSBJ]/subjectOr2[@typeCode=SBJ][observation/code[@code=32][@codeSystem=2.16.84.0.1.113883.3.989.2.1.1.19][1]/observation[@classCode=OBS][1]/originalText/text] |
| e | D.9.3 | 割換は実施されたか? | ブール型 | Boolean (BL) | | 値 | /MCC1_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCC1_IN200100UV01.xsd]/PORR_IN049016UV01/controlActProcess[@classCode=CACT][1]/moodCode=EVN]/component[@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment[@classCode=INVTG][1]/moodCode=EVN]/subject1[@typeCode=SBJ][1]/primaryRole[@classCode=INVSBJ]/subjectOr2[@typeCode=SBJ][observation/code[@code=5][@codeSystem=2.16.84.0.1.113883.3.989.2.1.1.19][1]/observation[@classCode=OBS][1]/value[@xsi:type=BL][1]/@value |
| e | | | | | | NullFlavor | /MCC1_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCC1_IN200100UV01.xsd]/PORR_IN049016UV01/controlActProcess[@classCode=CACT][1]/moodCode=EVN]/component[@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment[@classCode=INVTG][1]/moodCode=EVN]/subject1[@typeCode=SBJ][1]/primaryRole[@classCode=INVSBJ]/subjectOr2[@typeCode=SBJ][observation/code[@code=5][@codeSystem=2.16.84.0.1.113883.3.989.2.1.1.19][1]/observation[@classCode=OBS][1]/value[@xsi:type=BL][1]/@nullFlavor |
| h | D.9.4.r | 割換(による死因 (必要に応じ 繰り返し返す) | | | | 繰り返し返す ノード | /MCC1_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCC1_IN200100UV01.xsd]/PORR_IN049016UV01/controlActProcess[@classCode=CACT][1]/moodCode=EVN]/component[@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment[@classCode=INVTG][1]/moodCode=EVN]/subject1[@typeCode=SBJ][1]/primaryRole[@classCode=INVSBJ]/subjectOr2[@typeCode=SBJ][observation/code[@code=5][@codeSystem=2.16.84.0.1.113883.3.989.2.1.1.19][1]/observation[@classCode=OBS][1]/outboundRelationship2[@typeCode=DRIV][observation/code[@code=8][@codeSystem=2.16.84.0.1.113883.3.989.2.1.1.19]] |
| e | D.9.4.r.1a | 割換による死因の MedDRA バージョン | 4AN | Coded With Equivalents (CE) | codeSystemVersion= Character String (ST) | 値 | /MCC1_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCC1_IN200100UV01.xsd]/PORR_IN049016UV01/controlActProcess[@classCode=CACT][1]/moodCode=EVN]/component[@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment[@classCode=INVTG][1]/moodCode=EVN]/subject1[@typeCode=SBJ][1]/primaryRole[@classCode=INVSBJ]/subjectOr2[@typeCode=SBJ][observation/code[@code=5][@codeSystem=2.16.84.0.1.113883.3.989.2.1.1.19][1]/observation[@classCode=OBS][1]/outboundRelationship2[@typeCode=DRIV][observation/code[@code=8][@codeSystem=2.16.84.0.1.113883.3.989.2.1.1.19]]/@codeSystemVersion |

(別添 3)

| | | | | | | | |
|---|------------|----------------------|-------|-----------------------------|---------------------------------------|---|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| e | D.9.4.r.1b | 剖検による死因 (MedDRA コード) | 8N | Coded With Equivalents (CE) | code=Character String (ST) | 値 | /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UV/r/controlActProcess[@classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUBJ][1]/investigationEvent[@classCode=INVESTG][@moodCode=EVN]/component[@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment[@classCode=INVESTG][@moodCode=EVN]/subject[1]/primaryRole[@classCode=INVSBJ]/subjectOf2[@typeCode=SBJ][observation/code[@code=5][@codeSystem=2.16.84.0.1.1.19][1]/observation[1]/observation[@classCode=OBS][@moodCode=EVN]/outboundRelationship2[@typeCode=DRV]/observation/code[@code=8][@codeSystem=2.16.84.0.1.1.13883.3.98.9.2.1.1.19][1]/observation[@classCode=OBS][@moodCode=EVN]/value[@xsi:type=CE][@codeSystem=2.16.84.0.1.1.13883.3.98.9.2.1.1.19][1]]@code |
| e | D.9.4.r.2 | 剖検による死因 (自由記載) | 250AN | Coded With Equivalents (CE) | originalText = Encapsulated Data (ED) | 値 | /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UV/r/controlActProcess[@classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUBJ][1]/investigationEvent[@classCode=INVESTG][@moodCode=EVN]/component[@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment[@classCode=INVESTG][@moodCode=EVN]/subject[1]/primaryRole[@classCode=INVSBJ]/subjectOf2[@typeCode=SBJ][observation/code[@code=5][@codeSystem=2.16.84.0.1.1.19][1]/observation[1]/observation[@classCode=OBS][@moodCode=EVN]/outboundRelationship2[@typeCode=DRV]/observation/code[@code=8][@codeSystem=2.16.84.0.1.1.13883.3.98.9.2.1.1.19][1]/observation[@classCode=OBS][@moodCode=EVN]/value[@xsi:type=CE][@codeSystem=2.16.84.0.1.1.13883.3.98.9.2.1.1.19][1]]/originalText/text() |
| h | D.10 | 親子/胎児報告における、親に関する情報 | | | | | |
| e | D.10.1 | 親の識別 | 60AN | Entity Name (EN) | name=Entity Name Part (ENXP) | 値 | /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UV/r/controlActProcess[@classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUBJ][1]/investigationEvent[@classCode=INVESTG][@moodCode=EVN]/component[@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment[@classCode=INVESTG][@moodCode=EVN]/subject[1]/primaryRole[@classCode=INVSBJ]/player1[@classCode=PSN][@determinerCode=INSTANCE]/role[@classCode=PR S][1]/associatedPerson[@classCode=PSN][@determinerCode=INSTANCE]/name[1]/text() |
| e | | | | | NullFlavor | | /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UV/r/controlActProcess[@classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUBJ][1]/investigationEvent[@classCode=INVESTG][@moodCode=EVN]/component[@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment[@classCode=INVESTG][@moodCode=EVN]/subject[1]/primaryRole[@classCode=INVSBJ]/player1[@classCode=PSN][@determinerCode=INSTANCE]/role[@classCode=PR S][1]/associatedPerson[@classCode=PSN][@determinerCode=INSTANCE]/name[1]/@nullFlavor |
| h | D.10.2 | 親の年齢情報 | | | | | /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UV/r/controlActProcess[@classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUBJ][1]/investigationEvent[@classCode=INVESTG][@moodCode=EVN]/component[@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment[@classCode=INVESTG][@moodCode=EVN]/subject[1]/primaryRole[@classCode=INVSBJ]/player1[@classCode=PSN][@determinerCode=INSTANCE]/role[@classCode=PR S][1]/associatedPerson[@classCode=PSN][@determinerCode=INSTANCE]/birthTime/@value |
| e | D.10.2.1 | 親の生年月日 | 日付/時間 | Point in Time (TS) | | 値 | /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UV/r/controlActProcess[@classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUBJ][1]/investigationEvent[@classCode=INVESTG][@moodCode=EVN]/component[@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment[@classCode=INVESTG][@moodCode=EVN]/subject[1]/primaryRole[@classCode=INVSBJ]/player1[@classCode=PSN][@determinerCode=INSTANCE]/role[@classCode=PR S][1]/associatedPerson[@classCode=PSN][@determinerCode=INSTANCE]/birthTime/@value |

| | | | | | | |
|---|-----------|-----------|-------|------------------------|------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| e | | | | | NullFlavor | <pre> /MCCI_IN200100UV01[@ITSVersion=XMML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UV/r/controlActProcess/@classCode=CACTT][@moo dCode=EVN]/subject/@typeCode=SUBJ[1]/investigationEvent/@classCode=INVTG][@moodCo de=EVN]/component/@typeCode=COMP[adverseEventAssessment[1]/adverseEventAssessment /@classCode=INVTG][@moodCode=EVN]/subject1/@typeCode=SBJ[1]/primaryRole/@classC ode=INVSBJ/player1/@classCode=PSN][@determinerCode=INSTANCE]/role/@classCode=PR S][1]/associatedPerson/@classCode=PSN][@determinerCode=INSTANCE]/birthTime/@nullFlavor / </pre> |
| e | D.10.2.2a | 親の年齢 (数) | 3N | Physical Quantity (PQ) | value=Real Number (REAL) | <pre> /MCCI_IN200100UV01[@ITSVersion=XMML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UV/r/controlActProcess/@classCode=CACTT][@moo dCode=EVN]/subject/@typeCode=SUBJ[1]/investigationEvent/@classCode=INVTG][@moodCo de=EVN]/component/@typeCode=COMP[adverseEventAssessment[1]/adverseEventAssessment /@classCode=INVTG][@moodCode=EVN]/subject1/@typeCode=SBJ[1]/primaryRole/@classC ode=INVSBJ/player1/@classCode=PSN][@determinerCode=INSTANCE]/role/@classCode=PR S][1]/subjectOf2/@typeCode=SBJ[1]/observation/code/@code=3][@codeSystem=2.16.840.1.11388 3.3.989.2.1.1.19][1]/observation/@classCode=OBS][@moodCode=EVN]/value/@xsi:type=PQ][1] /@value </pre> |
| e | D.10.2.2b | 親の年齢 (単位) | 50AN | Physical Quantity (PQ) | unit=Coded Simple Value (CS) | <pre> /MCCI_IN200100UV01[@ITSVersion=XMML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UV/r/controlActProcess/@classCode=CACTT][@moo dCode=EVN]/subject/@typeCode=SUBJ[1]/investigationEvent/@classCode=INVTG][@moodCo de=EVN]/component/@typeCode=COMP[adverseEventAssessment[1]/adverseEventAssessment /@classCode=INVTG][@moodCode=EVN]/subject1/@typeCode=SBJ[1]/primaryRole/@classC ode=INVSBJ/player1/@classCode=PSN][@determinerCode=INSTANCE]/role/@classCode=PR S][1]/subjectOf2/@typeCode=SBJ[1]/observation/code/@code=3][@codeSystem=2.16.840.1.11388 3.3.989.2.1.1.19][1]/observation/@classCode=OBS][@moodCode=EVN]/value/@xsi:type=PQ][1] /@unit </pre> |
| e | D.10.3 | 親の最終月経日 | 日付/時間 | Point in Time (TS) | | <pre> /MCCI_IN200100UV01[@ITSVersion=XMML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UV/r/controlActProcess/@classCode=CACTT][@moo dCode=EVN]/subject/@typeCode=SUBJ[1]/investigationEvent/@classCode=INVTG][@moodCo de=EVN]/component/@typeCode=COMP[adverseEventAssessment[1]/adverseEventAssessment /@classCode=INVTG][@moodCode=EVN]/subject1/@typeCode=SBJ[1]/primaryRole/@classC ode=INVSBJ/player1/@classCode=PSN][@determinerCode=INSTANCE]/role/@classCode=PR S][1]/subjectOf2/@typeCode=SBJ[1]/observation/code/@code=22][@codeSystem=2.16.840.1.1138 83.3.989.2.1.1.19][1]/observation/@classCode=OBS][@moodCode=EVN]/value/@xsi:type=TS][1] /@value </pre> |
| e | | | | | NullFlavor | <pre> /MCCI_IN200100UV01[@ITSVersion=XMML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UV/r/controlActProcess/@classCode=CACTT][@moo dCode=EVN]/subject/@typeCode=SUBJ[1]/investigationEvent/@classCode=INVTG][@moodCo de=EVN]/component/@typeCode=COMP[adverseEventAssessment[1]/adverseEventAssessment /@classCode=INVTG][@moodCode=EVN]/subject1/@typeCode=SBJ[1]/primaryRole/@classC ode=INVSBJ/player1/@classCode=PSN][@determinerCode=INSTANCE]/role/@classCode=PR S][1]/subjectOf2/@typeCode=SBJ[1]/observation/code/@code=22][@codeSystem=2.16.840.1.1138 83.3.989.2.1.1.19][1]/observation/@classCode=OBS][@moodCode=EVN]/value/@xsi:type=TS][1] / </pre> |

(別添 3)

| | | | | | | | |
|---|---------------|--------------------------------------------|-------|-------------------------------------|------------------------------------------|---|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| e | D.10.7.1.r.1a | 親の関連する治療歴及び随伴症状の MedDRA パージョ | 4AN | Concept Descriptor (CD) | codeSystemVersion= Character String (ST) | 値 | /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UV/r/controlActProcess[@classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUBJ][1]/investigationEvent[@classCode=INVTG][@moodCode=EVN]/component[@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment[@classCode=INVTG][@moodCode=EVN]/subject1[@typeCode=SBJ][1]/primaryRole[@classCode=INVSBJ]/player1[@classCode=PSN][@determinerCode=INSTANCE]/role[@classCode=PR S][1]/subjectOr2[@typeCode=SBJ]/organizer/code[@code=1][@codeSystem=2.16.840.1.113883.3.989.2.1.1.20][1]/organizer[@classCode=CATEGORY][@moodCode=EVN]/component[@typeCode=COMP][observation/code[@codeSystem=2.16.840.1.113883.6.163][1]/observation/@classCode=OBS][@moodCode=EVN]/code/@codeSystemVersion |
| e | D.10.7.1.r.1b | 親の関連する治療歴及び随伴症状 (疾病/手術処置/その他) (MedDRA コード) | 8N | Concept Descriptor (CD) | code=Character String (ST) | 値 | /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UV/r/controlActProcess[@classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUBJ][1]/investigationEvent[@classCode=INVTG][@moodCode=EVN]/component[@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment[@classCode=INVTG][@moodCode=EVN]/subject1[@typeCode=SBJ][1]/primaryRole[@classCode=INVSBJ]/player1[@classCode=PSN][@determinerCode=INSTANCE]/role[@classCode=PR S][1]/subjectOr2[@typeCode=SBJ]/organizer/code[@code=1][@codeSystem=2.16.840.1.113883.3.989.2.1.1.20][1]/organizer[@classCode=CATEGORY][@moodCode=EVN]/component[@typeCode=COMP][observation/code[@codeSystem=2.16.840.1.113883.6.163][1]/observation/@classCode=OBS][@moodCode=EVN]/code/@code |
| e | D.10.7.1.r.2 | 開始日 | 日付/時間 | Interval of Point in Time (IVL<TS>) | low=Interval Boundary (IVXB) | 値 | /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UV/r/controlActProcess[@classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUBJ][1]/investigationEvent[@classCode=INVTG][@moodCode=EVN]/component[@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment[@classCode=INVTG][@moodCode=EVN]/subject1[@typeCode=SBJ][1]/primaryRole[@classCode=INVSBJ]/player1[@classCode=PSN][@determinerCode=INSTANCE]/role[@classCode=PR S][1]/subjectOr2[@typeCode=SBJ]/organizer/code[@code=1][@codeSystem=2.16.840.1.113883.3.989.2.1.1.20][1]/organizer[@classCode=CATEGORY][@moodCode=EVN]/component[@typeCode=COMP][observation/code[@codeSystem=2.16.840.1.113883.6.163][1]/observation/@classCode=OBS][@moodCode=EVN]/effectiveTime[@xsi:type=IVL_TS]/low/@value |
| e | | | | | NullFlavor | | /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UV/r/controlActProcess[@classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUBJ][1]/investigationEvent[@classCode=INVTG][@moodCode=EVN]/component[@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment[@classCode=INVTG][@moodCode=EVN]/subject1[@typeCode=SBJ][1]/primaryRole[@classCode=INVSBJ]/player1[@classCode=PSN][@determinerCode=INSTANCE]/role[@classCode=PR S][1]/subjectOr2[@typeCode=SBJ]/organizer/code[@code=1][@codeSystem=2.16.840.1.113883.3.989.2.1.1.20][1]/organizer[@classCode=CATEGORY][@moodCode=EVN]/component[@typeCode=COMP][observation/code[@codeSystem=2.16.840.1.113883.6.163][1]/observation/@classCode=OBS][@moodCode=EVN]/effectiveTime[@xsi:type=IVL_TS]/low/@nullFlavor |

| | | | | | | |
|---|--------------|-----|--------|-------------------------------------|------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| e | D.10.7.1.r.3 | 継続 | ブール型 | Boolean (BL) | 値 | <pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/PDRR_IN049016UV[r]/controlActProcess[@classCode=CACT][@mo dCode=EVN]/subject[@typeCode=SUBJ][r]/investigationEvent[@classCode=INVESTG][@mo dCode=EVN]/component[@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment [@classCode=INVESTG][@moodCode=EVN]/subject1[@typeCode=SBJ][r]/primaryRole[@classC ode=INVSBJ]/player1[@classCode=PSN][@determinerCode=INSTANCE]/role[@classCode=PR S][r]/subjectOf2[@typeCode=SBJ][organizer/code[@code=1][@codeSystem=2.16.840.1.113883. 3.989.2.1.1.20][r]/organizer[@classCode=CATEGORY][@moodCode=EVN]/component[@typeC ode=COMP][observation/code[@codeSystem=2.16.840.1.113883.6.163][r]/observation[@classCo de=OBS][@moodCode=EVN]/inboundRelationship[@typeCode=REFR][observation/code[@code =13][@codeSystem=2.16.840.1.113883.3.989.2.1.1.19][r]/observation[@classCode=OBS][@mo odCode=EVN]/value[@xsi:type=BL][r]/@value </pre> |
| e | D.10.7.1.r.4 | 終了日 | 日付/時間 | Interval of Point in Time (IVL<TS>) | 値 high=Interval Boundary (IVXB) | <pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/PDRR_IN049016UV[r]/controlActProcess[@classCode=CACT][@mo dCode=EVN]/subject[@typeCode=SUBJ][r]/investigationEvent[@classCode=INVESTG][@mo dCode=EVN]/component[@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment [@classCode=INVESTG][@moodCode=EVN]/subject1[@typeCode=SBJ][r]/primaryRole[@classC ode=INVSBJ]/player1[@classCode=PSN][@determinerCode=INSTANCE]/role[@classCode=PR S][r]/subjectOf2[@typeCode=SBJ][organizer/code[@code=1][@codeSystem=2.16.840.1.113883. 3.989.2.1.1.20][r]/organizer[@classCode=CATEGORY][@moodCode=EVN]/component[@typeC ode=COMP][observation/code[@codeSystem=2.16.840.1.113883.6.163][r]/observation[@classCo de=OBS][@moodCode=EVN]/effectiveTime[@xsi:type=IVL_TS]/high/@value </pre> |
| e | | | | | Null Flavor | <pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/PDRR_IN049016UV[r]/controlActProcess[@classCode=CACT][@mo dCode=EVN]/subject[@typeCode=SUBJ][r]/investigationEvent[@classCode=INVESTG][@mo dCode=EVN]/component[@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment [@classCode=INVESTG][@moodCode=EVN]/subject1[@typeCode=SBJ][r]/primaryRole[@classC ode=INVSBJ]/player1[@classCode=PSN][@determinerCode=INSTANCE]/role[@classCode=PR S][r]/subjectOf2[@typeCode=SBJ][organizer/code[@code=1][@codeSystem=2.16.840.1.113883. 3.989.2.1.1.20][r]/organizer[@classCode=CATEGORY][@moodCode=EVN]/component[@typeC ode=COMP][observation/code[@codeSystem=2.16.840.1.113883.6.163][r]/observation[@classCo de=OBS][@moodCode=EVN]/effectiveTime[@xsi:type=IVL_TS]/high/@nullFlavor </pre> |
| e | D.10.7.1.r.5 | 備考 | 2000AN | Encapsulated Data (ED) | 値 | <pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/PDRR_IN049016UV[r]/controlActProcess[@classCode=CACT][@mo dCode=EVN]/subject[@typeCode=SUBJ][r]/investigationEvent[@classCode=INVESTG][@mo dCode=EVN]/component[@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment [@classCode=INVESTG][@moodCode=EVN]/subject1[@typeCode=SBJ][r]/primaryRole[@classC ode=INVSBJ]/player1[@classCode=PSN][@determinerCode=INSTANCE]/role[@classCode=PR S][r]/subjectOf2[@typeCode=SBJ][organizer/code[@code=1][@codeSystem=2.16.840.1.113883. 3.989.2.1.1.20][r]/organizer[@classCode=CATEGORY][@moodCode=EVN]/component[@typeC ode=COMP][observation/code[@codeSystem=2.16.840.1.113883.6.163][r]/observation[@classCo de=OBS][@moodCode=EVN]/outboundRelationship2[@typeCode=COMP][observation/code[@co de=10][@codeSystem=2.16.840.1.113883.3.989.2.1.1.19][r]/observation[@classCode=OBS][@ moodCode=EVN]/value[@xsi:type=ED][r]/@next() </pre> |

| | | | | | | |
|---|-------------|-----------------------------|----------------------|-----------------------------|-----------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| e | D.10.7.2 | 薬の関連する治療歴及び随伴症状の記述情報 | 10000AN | Encapsulated Data (ED) | 値 | /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UV/r/controlAct/process/@classCode=CACTT[@moodCode=EVN]/subject/@typeCode=SUBJ[1]/investigationEvent/@classCode=INVTG[@moodCode=EVN]/component/@typeCode=COMP[adverseEventAssessment[1]/adverseEventAssessment/@classCode=INVTG][@moodCode=EVN]/subject1/@typeCode=SBJ[1]/primaryRole/@classCode=INVSBJ/player1/@classCode=PSN[1]/determinerCode=INSTANCE/role/@classCode=PR S[1]/subjectOf2/@typeCode=SBJ[organizer/code/@code=1][@codeSystem=2.16.840.1.113883.3.989.2.1.1.20][1]organizer/@classCode=CATEGORY[1][@moodCode=EVN]/component/@typeCode=COMP[observation/code/@code=18][@codeSystem=2.16.840.1.113883.3.989.2.1.1.19][1]observation/@classCode=OBS[1][@moodCode=EVN]/value/@xsi:type=ED[1]/text() |
| h | D.10.8.r | 薬の関連する過去の医薬品使用歴（必要に応じ繰り返しす） | | | 繰り返し ノード | /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UV/r/controlAct/process/@classCode=CACTT[@moodCode=EVN]/component/@typeCode=SUBJ[1]/investigationEvent/@classCode=INVTG[@moodCode=EVN]/component/@typeCode=COMP[adverseEventAssessment[1]/adverseEventAssessment/@classCode=INVTG][@moodCode=EVN]/subject1/@typeCode=SBJ[1]/primaryRole/@classCode=INVSBJ/player1/@classCode=PSN[1]/determinerCode=INSTANCE/role/@classCode=PR S[1]/subjectOf2/@typeCode=SBJ[organizer/code/@code=2][@codeSystem=2.16.840.1.113883.3.989.2.1.1.20][1]organizer/@classCode=CATEGORY[1][@moodCode=EVN]/component/@typeCode=COMP[substanceAdministration] |
| e | D.10.8.r.1 | 医薬品名（報告された表現） | 250AN | Entity Name (EN) | name=Entity Name Part (ENXP) | /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UV/r/controlAct/process/@classCode=CACTT[@moodCode=EVN]/component/@typeCode=SUBJ[1]/investigationEvent/@classCode=INVTG[@moodCode=EVN]/component/@typeCode=COMP[adverseEventAssessment[1]/adverseEventAssessment/@classCode=INVTG][@moodCode=EVN]/subject1/@typeCode=SBJ[1]/primaryRole/@classCode=INVSBJ/player1/@classCode=PSN[1]/determinerCode=INSTANCE/role/@classCode=PR S[1]/subjectOf2/@typeCode=SBJ[organizer/code/@code=2][@codeSystem=2.16.840.1.113883.3.989.2.1.1.20][1]organizer/@classCode=CATEGORY[1][@moodCode=EVN]/component/@typeCode=COMP[substanceAdministration]/instanceOfKind/@classCode=INST[kindOfProduct/@classCode=MMAAT][@determinerCode=KIND]/name[1]/text() |
| e | D.10.8.r.2a | MPID バージョン日付/番号 | M5 ガイド ラインを参 照 | Coded With Equivalents (CE) | codeSystemVersion=Character String (ST) | /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UV/r/controlAct/process/@classCode=CACTT[@moodCode=EVN]/subject/@typeCode=SUBJ[1]/investigationEvent/@classCode=INVTG[@moodCode=EVN]/component/@typeCode=COMP[adverseEventAssessment[1]/adverseEventAssessment/@classCode=INVTG][@moodCode=EVN]/subject1/@typeCode=SBJ[1]/primaryRole/@classCode=INVSBJ/player1/@classCode=PSN[1]/determinerCode=INSTANCE/role/@classCode=PR S[1]/subjectOf2/@typeCode=SBJ[organizer/code/@code=2][@codeSystem=2.16.840.1.113883.3.989.2.1.1.20][1]organizer/@classCode=CATEGORY[1][@moodCode=EVN]/component/@typeCode=COMP[substanceAdministration]/instanceOfKind/@classCode=INST[kindOfProduct/@classCode=MMAAT][@determinerCode=KIND]/code/@code/@codeSystem=TBD-MPID/@codeSystemVersion |

(別添 3)

| | |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <p>e</p> <p>D.10.8.r.2b</p> <p>医薬品製品識別子 (MPID)</p> <p>M5 ガイド ラインを参 照</p> <p>Coded With Equivalents (CE)</p> <p>code=Character String (ST)</p> | <pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/PORR_IN049016UV/r/controlActProcess/@classCode=CACT][@moo dCode=EVN]/subject/@typeCode=SUBJ][1]/investigationEvent/@classCode=INVSCTG][@moodCo de=EVN]/component/@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment /@classCode=INVSCTG][@moodCode=EVN]/subject1/@typeCode=SBJ][1]/primaryRole/@classC ode=INVSBJ/player1/@classCode=PSN][@determinerCode=INSTANCE]/role/@classCode=PR S][1]/subjectOf2/@typeCode=SBJ][organizer/@code=2][@codeSystem=2.16.840.1.113883. 3.989.2.1.1.20][1]/organizer/@classCode=CATEGORY][@moodCode=EVN]/component/@typeC ode=COMP][substanceAdministration]/substanceAdministration/@classCode=SBADM][@mood Code=EVN]/consumable/@typeCode=CSM][1]/instanceOfKind/@classCode=INST]/kindOfProduc t/@classCode=MMA][@determinerCode=KIND]/code/@codeSystem=TBD-PhPID]/@code </pre> |
| <p>e</p> <p>D.10.8.r.3a</p> <p>PhPID パージョン日付／番 号</p> <p>M5 ガイド ラインを参 照</p> <p>Coded With Equivalents (CE)</p> <p>code=SystemVersion= Character String (ST)</p> | <pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/PORR_IN049016UV/r/controlActProcess/@classCode=CACT][@moo dCode=EVN]/subject/@typeCode=SUBJ][1]/investigationEvent/@classCode=INVSCTG][@moodCo de=EVN]/component/@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment /@classCode=INVSCTG][@moodCode=EVN]/subject1/@typeCode=SBJ][1]/primaryRole/@classC ode=INVSBJ/player1/@classCode=PSN][@determinerCode=INSTANCE]/role/@classCode=PR S][1]/subjectOf2/@typeCode=SBJ][organizer/@code=2][@codeSystem=2.16.840.1.113883. 3.989.2.1.1.20][1]/organizer/@classCode=CATEGORY][@moodCode=EVN]/component/@typeC ode=COMP][substanceAdministration]/substanceAdministration/@classCode=SBADM][@mood Code=EVN]/consumable/@typeCode=CSM][1]/instanceOfKind/@classCode=INST]/kindOfProduc t/@classCode=MMA][@determinerCode=KIND]/code/@codeSystem=TBD-PhPID]/@codeSyste mVersion </pre> |
| <p>e</p> <p>D.10.8.r.3b</p> <p>製剤識別子 (PhPID)</p> <p>M5 ガイド ラインを参 照</p> <p>Coded With Equivalents (CE)</p> <p>code=Character String (ST)</p> | <pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/PORR_IN049016UV/r/controlActProcess/@classCode=CACT][@moo dCode=EVN]/subject/@typeCode=SUBJ][1]/investigationEvent/@classCode=INVSCTG][@moodCo de=EVN]/component/@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment /@classCode=INVSCTG][@moodCode=EVN]/subject1/@typeCode=SBJ][1]/primaryRole/@classC ode=INVSBJ/player1/@classCode=PSN][@determinerCode=INSTANCE]/role/@classCode=PR S][1]/subjectOf2/@typeCode=SBJ][organizer/@code=2][@codeSystem=2.16.840.1.113883. 3.989.2.1.1.20][1]/organizer/@classCode=CATEGORY][@moodCode=EVN]/component/@typeC ode=COMP][substanceAdministration]/substanceAdministration/@classCode=SBADM][@mood Code=EVN]/consumable/@typeCode=CSM][1]/instanceOfKind/@classCode=INST]/kindOfProduc t/@classCode=MMA][@determinerCode=KIND]/code/@codeSystem=TBD-PhPID]/@code </pre> |
| <p>e</p> <p>D.10.8.r.4</p> <p>開始日</p> <p>日付／時間</p> <p>Interval of Point in Time (IVL<TS>)</p> <p>low=Interval Boundary (IVXB)</p> | <pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/PORR_IN049016UV/r/controlActProcess/@classCode=CACT][@moo dCode=EVN]/subject/@typeCode=SUBJ][1]/investigationEvent/@classCode=INVSCTG][@moodCo de=EVN]/component/@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment /@classCode=INVSCTG][@moodCode=EVN]/subject1/@typeCode=SBJ][1]/primaryRole/@classC ode=INVSBJ/player1/@classCode=PSN][@determinerCode=INSTANCE]/role/@classCode=PR S][1]/subjectOf2/@typeCode=SBJ][organizer/@code=2][@codeSystem=2.16.840.1.113883. 3.989.2.1.1.20][1]/organizer/@classCode=CATEGORY][@moodCode=EVN]/component/@typeC ode=COMP][substanceAdministration]/substanceAdministration/@classCode=SBADM][@mood Code=EVN]/effectiveTime/@xsi:type=IVL_TS]/low/@value </pre> |

| | | | | | | | |
|----------|--------------------|----------------------|--------------|--------------------------------------------------|-------------------------------------------------|-------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <p>e</p> | <p>D.10.8.r.5</p> | <p>終了日</p> | <p>日付/時間</p> | <p>Interval of Point in Time (IVL<TS>)</p> | <p>high=Interval Boundary (VXB)</p> | <p>NullFlavor</p> | <pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/PDRR_IN049016UV/r/controlActProcess[@classCode=CACT][@mood dCode=EVN]/subject[@typeCode=SUBJ][1]/investigationEvent[@classCode=INVTG][1]/adverseEventAssessment de=EVN]/component[@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment [@classCode=INVTG][1]/moodCode=EVN]/subject[1]/primaryRole[@classCode=PR ode=INVSBJ]/player1[@classCode=PSN][1]/determinerCode=INSTANCE/role[@classCode=PR S][1]/subjectOf2[@typeCode=SBJ][1]/organizer/code[@code=2][1]/codeSystem=2.16.840.1.113883. 3.989.2.1.1.20][1]/organizer/@classCode=CATEGORY][1]/moodCode=EVN]/component/@typeC ode=COMP][substanceAdministration][1]/substanceAdministration/@classCode=SBADM][1]/mood Code=EVN]/effectiveTime/@xsi:type=IVL_TS/low/@nullFlavor </pre> |
| <p>e</p> | <p>D.10.8.r.5</p> | <p>終了日</p> | <p>日付/時間</p> | <p>Interval of Point in Time (IVL<TS>)</p> | <p>high=Interval Boundary (VXB)</p> | <p>値</p> | <pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/PDRR_IN049016UV/r/controlActProcess[@classCode=CACT][@mood dCode=EVN]/subject[@typeCode=SUBJ][1]/investigationEvent[@classCode=INVTG][1]/adverseEventAssessment de=EVN]/component[@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment [@classCode=INVTG][1]/moodCode=EVN]/subject[1]/primaryRole[@classCode=PR ode=INVSBJ]/player1[@classCode=PSN][1]/determinerCode=INSTANCE/role[@classCode=PR S][1]/subjectOf2[@typeCode=SBJ][1]/organizer/code[@code=2][1]/codeSystem=2.16.840.1.113883. 3.989.2.1.1.20][1]/organizer/@classCode=CATEGORY][1]/moodCode=EVN]/component/@typeC ode=COMP][substanceAdministration][1]/substanceAdministration/@classCode=SBADM][1]/mood Code=EVN]/effectiveTime/@xsi:type=IVL_TS/high/@value </pre> |
| <p>e</p> | <p>D.10.8.r.5</p> | <p>終了日</p> | <p>日付/時間</p> | <p>Interval of Point in Time (IVL<TS>)</p> | <p>high=Interval Boundary (VXB)</p> | <p>NullFlavor</p> | <pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/PDRR_IN049016UV/r/controlActProcess[@classCode=CACT][@mood dCode=EVN]/subject[@typeCode=SUBJ][1]/investigationEvent[@classCode=INVTG][1]/adverseEventAssessment de=EVN]/component[@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment [@classCode=INVTG][1]/moodCode=EVN]/subject[1]/primaryRole[@classCode=PR ode=INVSBJ]/player1[@classCode=PSN][1]/determinerCode=INSTANCE/role[@classCode=PR S][1]/subjectOf2[@typeCode=SBJ][1]/organizer/code[@code=2][1]/codeSystem=2.16.840.1.113883. 3.989.2.1.1.20][1]/organizer/@classCode=CATEGORY][1]/moodCode=EVN]/component/@typeC ode=COMP][substanceAdministration][1]/substanceAdministration/@classCode=SBADM][1]/mood Code=EVN]/effectiveTime/@xsi:type=IVL_TS/high/@value </pre> |
| <p>e</p> | <p>D.10.8.r.6a</p> | <p>使用理由の シヨン</p> | <p>4AN</p> | <p>Coded With Equivalents (CE)</p> | <p>codeSystemVersion= Character String (ST)</p> | <p>値</p> | <pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/PDRR_IN049016UV/r/controlActProcess[@classCode=CACT][@mood dCode=EVN]/subject[@typeCode=SUBJ][1]/investigationEvent[@classCode=INVTG][1]/adverseEventAssessment de=EVN]/component[@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment [@classCode=INVTG][1]/moodCode=EVN]/subject[1]/primaryRole[@classCode=PR ode=INVSBJ]/player1[@classCode=PSN][1]/determinerCode=INSTANCE/role[@classCode=PR S][1]/subjectOf2[@typeCode=SBJ][1]/organizer/code[@code=2][1]/codeSystem=2.16.840.1.113883. 3.989.2.1.1.20][1]/organizer/@classCode=CATEGORY][1]/moodCode=EVN]/component/@typeC ode=COMP][substanceAdministration][1]/substanceAdministration/@classCode=SBADM][1]/mood Code=EVN]/outboundRelationship2[@typeCode=RSN][1]/observation/code[@code=19][1]/codeSy stem=2.16.840.1.113883.3.989.2.1.1.19][1]/observation/@classCode=OBS[1]/moodCode=EVN]/ value[@xsi:type=CE][1]/codeSystem=2.16.840.1.113883.6.163][1]/codeSystemVersion </pre> |

(別添 3)

| | | | | | | | |
|---|-------------|---------------------------|-----|-----------------------------|----------------------------|-----------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| e | D.10.8.r.6b | 使用理由 (MedDRA コード) | 8N | Coded With Equivalents (CE) | code=Character String (ST) | 値 | /MCCI_IN200100UV01[@ITSVersion="XML_1.0"]/@xsi:schemaLocation="urn:hl7-org:v3 MCCI_IN200100UV01.xsd"/PORR_IN049016UVJ/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="PR S"]/subjectOf2[@typeCode="SBJ"]/organizer/code/@code="2"[@codeSystem="2.16.840.1.113883.3.989.2.1.1.20"]/organizer/@classCode="CATEGORY"/@moodCode="EVN"/component/@typeCode="COMP"/substanceAdministration[7]/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"]/1/1/@code |
| e | D.10.8.r.7a | 副作用の MedDRA ノード | 4AN | 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_IN049016UVJ/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="PR S"]/subjectOf2[@typeCode="SBJ"]/organizer/code/@code="2"[@codeSystem="2.16.840.1.113883.3.989.2.1.1.20"]/organizer/@classCode="CATEGORY"/@moodCode="EVN"/component/@typeCode="COMP"/substanceAdministration[7]/substanceAdministration[@classCode="SBADM"]/@moodCode="EVN"/outboundRelationship2[@typeCode="RSON"]/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"]/1/1/@code |
| e | D.10.8.r.7b | 副作用 (MedDRA コード) | 8N | Coded With Equivalents (CE) | code=Character String (ST) | 値 | /MCCI_IN200100UV01[@ITSVersion="XML_1.0"]/@xsi:schemaLocation="urn:hl7-org:v3 MCCI_IN200100UV01.xsd"/PORR_IN049016UVJ/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="PR S"]/subjectOf2[@typeCode="SBJ"]/organizer/code/@code="2"[@codeSystem="2.16.840.1.113883.3.989.2.1.1.20"]/organizer/@classCode="CATEGORY"/@moodCode="EVN"/component/@typeCode="COMP"/substanceAdministration[7]/substanceAdministration[@classCode="SBADM"]/@moodCode="EVN"/outboundRelationship2[@typeCode="RSON"]/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"]/1/1/@code |
| h | E.i | 副作用 / 有害事象 (必要に応じて繰り返し返す) | | | | 繰り返し返すノード | |
| 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.i.1.1.a | 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 | <pre> /MCCL_IN200100UV01[@ITSVersion='XML_1.0']/@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd/PORR_IN049016UV/r/controlActProcess/@classCode=CACTI/@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']/observation[@code='29']/@codeSystem='2.1.6.840.1.113883.3.989.2.1.1.19']]/observation/@classCode='OBS']]/moodCode='EVN']/value[@xsi:type='CE']/@codeSystem='2.1.6.840.1.113883.6.163']]/originalText/text() </pre> |
| e | E.i.1.1.b | 第一次情報源により報告された副作用/有害事象の言語 | 3A | Coded With Equivalents (CE) | originalText/language = Coded Simple Value (CS) | 値 | <pre> /MCCL_IN200100UV01[@ITSVersion='XML_1.0']/@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd/PORR_IN049016UV/r/controlActProcess/@classCode=CACTI/@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']/observation[@code='29']/@codeSystem='2.1.6.840.1.113883.3.989.2.1.1.19']]/observation/@classCode='OBS']]/moodCode='EVN']/value[@xsi:type='CE']/@codeSystem='2.1.6.840.1.113883.6.163']]/originalText/language </pre> |
| e | E.i.1.2 | 翻訳された、第一次情報源により報告された副作用/有害事象 | 250AN | Encapsulated Data (ED) | Encapsulated Data (ED) | 値 | <pre> /MCCL_IN200100UV01[@ITSVersion='XML_1.0']/@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd/PORR_IN049016UV/r/controlActProcess/@classCode=CACTI/@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']/observation[@code='29']/@codeSystem='2.1.6.840.1.113883.3.989.2.1.1.19']]/observation/@classCode='OBS']]/moodCode='EVN']/outboundRelationship2/@typeCode='PERT']]/observation/@code='30']/@codeSystem='2.1.6.840.1.113883.3.989.2.1.1.19']]/observation/@classCode='OBS']]/moodCode='EVN']/value[@xsi:type='ED']]/text() </pre> |
| e | E.i.2.1.a | 副作用 / 有害事象の MedDRA パージョン | 4AN | Coded With Equivalents (CE) | codeSystem/Version = Character String (ST) | 値 | <pre> /MCCL_IN200100UV01[@ITSVersion='XML_1.0']/@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd/PORR_IN049016UV/r/controlActProcess/@classCode=CACTI/@moodCode=EVN]/component/@typeCode='COMP']]/adverseEventAssessment[1]/adverseEventAssessment[@classCode='INVTG']/@moodCode='EVN']/subject1[@typeCode='SBJ']]/primaryRole/@classCode='INVSBJ']/subjectOr2/@typeCode='SBJ']/observation[@code='29']/@codeSystem='2.1.6.840.1.113883.3.989.2.1.1.19']]/observation/@classCode='OBS']]/moodCode='EVN']/value[@xsi:type='CE']/@codeSystem='2.1.6.840.1.113883.6.163']]/codeSystemVersion </pre> |
| e | E.i.2.1.b | 副作用 / 有害事象 (MedDRA コード) | 8N | Coded With Equivalents (CE) | code = Character String (ST) | 値 | <pre> /MCCL_IN200100UV01[@ITSVersion='XML_1.0']/@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd/PORR_IN049016UV/r/controlActProcess/@classCode=CACTI/@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']/observation[@code='29']/@codeSystem='2.1.6.840.1.113883.3.989.2.1.1.19']]/observation/@classCode='OBS']]/moodCode='EVN']/value[@xsi:type='CE']/@codeSystem='2.1.6.840.1.113883.6.163']]/code </pre> |

| | | | | | |
|--------------------------|---------------------------------------------------|-------------|------------------------------------|-----------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <p>e</p> <p>E.i.3.1</p> | <p>報告者によって重要とされた副作用/有害事象</p> | <p>1N</p> | <p>Coded With Equivalents (CE)</p> | <p>code=Character String (ST)</p> | <p>値</p> <pre> /MCCL_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCL_IN200100UV01.xsd']/PORR_IN049016UV/r/controlActProcess[@classCode='CACT']/@moodCode='EVN']/subject[@typeCode='SUBJ']/investigationEvent[@classCode='INVESTG']/@moodCode='EVN']/component[@typeCode='COMP']/adverseEventAssessment[1]/adverseEventAssessment[@classCode='INVESTG']/@moodCode='EVN']/subject1[@typeCode='SBJ']/primaryRole[classCode='INVSBJ']/subjectOf2[@typeCode='SBJ']/observation[@classCode='OBS']/@moodCode='EVN']/outboundRelationship2[@typeCode='PERT']/observation/codel[@code='37']/@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']/observation/@classCode='OBS']/@moodCode='EVN']/value[@xsi:type='CE']/@codeSystem='2.16.840.1.113883.3.989.2.1.1.10']/1/1/@code </pre> |
| <p>h</p> <p>E.i.3.2</p> | <p>報告者によって重要とされた副作用/有害事象に関する ICH コードリストのパラジョン</p> | | | | <pre> /MCCL_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCL_IN200100UV01.xsd']/PORR_IN049016UV/r/controlActProcess[@classCode='CACT']/@moodCode='EVN']/subject[@typeCode='SUBJ']/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[@classCode='OBS']/@moodCode='EVN']/outboundRelationship2[@typeCode='PERT']/observation/codel[@code='37']/@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']/1/1/observation/@classCode='OBS']/@moodCode='EVN']/value[@xsi:type='CE']/@codeSystem='2.16.840.1.113883.3.989.2.1.1.10']/1/1/@codeSystemVersion </pre> |
| <p>e</p> <p>E.i.3.2a</p> | <p>有害事象ごとの重篤性の基準</p> <p>死に至るもの</p> | <p>ブール型</p> | <p>Boolean (BL)</p> | <p>値</p> | <pre> /MCCL_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCL_IN200100UV01.xsd']/PORR_IN049016UV/r/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[@classCode='OBS']/@moodCode='EVN']/outboundRelationship2[@typeCode='PERT']/observation/codel[@code='34']/@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']/1/1/observation/@classCode='OBS']/@moodCode='EVN']/value[@xsi:type='BL']/1/@value </pre> |
| <p>e</p> | | | | <p>NullFlavor</p> | <pre> /MCCL_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCL_IN200100UV01.xsd']/PORR_IN049016UV/r/controlActProcess[@classCode='CACT']/@moodCode='EVN']/subject[@typeCode='SUBJ']/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[@classCode='OBS']/@moodCode='EVN']/outboundRelationship2[@typeCode='PERT']/observation/codel[@code='34']/@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']/1/1/observation/@classCode='OBS']/@moodCode='EVN']/value[@xsi:type='BL']/1/@nullFlavor </pre> |

(別添 3)

| | | | | | | |
|---|----------|-----------------------------------|------|--------------|------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| e | E.i.3.2b | 生命を脅かすもの | ブール型 | Boolean (BL) | 値 | <pre> /MCCL_IN200100UV01[@ITSVersion=XMML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/PORR_IN049016UVJr/controlActProcess/@classCode=CACT][@moo dCode=EVN]/subject/@typeCode=SUBJ][1]/investigationEvent/@classCode=INVTG][@moodCo de=EVN]/component/@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment [@classCode=INVTG][@moodCode=EVN]/subject1/@typeCode=SBJ][1]/primaryRole/@classC ode=INVSBJ/subjectOf2/@typeCode=SBJ][observation/@classCode=OBS][@moodCode=EVN]/outbound Relationship2/@typeCode=PERT][observation/codel/@code=21][@codeSystem=2.16.840.1.11388 3.3.989.2.1.1.19][1]/observation/@classCode=OBS][@moodCode=EVN]/value[@xsi:type=BL][1]/ @value </pre> |
| e | | | | | NullFlavor | <pre> /MCCL_IN200100UV01[@ITSVersion=XMML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/PORR_IN049016UVJr/controlActProcess/@classCode=CACT][@moo dCode=EVN]/subject/@typeCode=SUBJ][1]/investigationEvent/@classCode=INVTG][@moodCo de=EVN]/component/@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment [@classCode=INVTG][@moodCode=EVN]/subject1/@typeCode=SBJ][1]/primaryRole/@classC ode=INVSBJ/subjectOf2/@typeCode=SBJ][observation/@classCode=OBS][@moodCode=EVN]/outbound Relationship2/@typeCode=PERT][observation/codel/@code=21][@codeSystem=2.16.840.1.11388 3.3.989.2.1.1.19][1]/observation/@classCode=OBS][@moodCode=EVN]/value[@xsi:type=BL][1]/ @nullFlavor </pre> |
| e | E.i.3.2c | 治療のための入院又は入院 期間の延長が必要であるも の | ブール型 | Boolean (BL) | 値 | <pre> /MCCL_IN200100UV01[@ITSVersion=XMML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/PORR_IN049016UVJr/controlActProcess/@classCode=CACT][@moo dCode=EVN]/subject/@typeCode=SUBJ][1]/investigationEvent/@classCode=INVTG][@moodCo de=EVN]/component/@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment [@classCode=INVTG][@moodCode=EVN]/subject1/@typeCode=SBJ][1]/primaryRole/@classC ode=INVSBJ/subjectOf2/@typeCode=SBJ][observation/@classCode=OBS][@moodCode=EVN]/outbound Relationship2/@typeCode=PERT][observation/codel/@code=33][@codeSystem=2.16.840.1.11388 3.3.989.2.1.1.19][1]/observation/@classCode=OBS][@moodCode=EVN]/value[@xsi:type=BL][1]/ @value </pre> |
| e | | | | | NullFlavor | <pre> /MCCL_IN200100UV01[@ITSVersion=XMML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/PORR_IN049016UVJr/controlActProcess/@classCode=CACT][@moo dCode=EVN]/subject/@typeCode=SUBJ][1]/investigationEvent/@classCode=INVTG][@moodCo de=EVN]/component/@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment [@classCode=INVTG][@moodCode=EVN]/subject1/@typeCode=SBJ][1]/primaryRole/@classC ode=INVSBJ/subjectOf2/@typeCode=SBJ][observation/@classCode=OBS][@moodCode=EVN]/outbound Relationship2/@typeCode=PERT][observation/codel/@code=33][@codeSystem=2.16.840.1.11388 3.3.989.2.1.1.19][1]/observation/@classCode=OBS][@moodCode=EVN]/value[@xsi:type=BL][1]/ @nullFlavor </pre> |
| e | E.i.3.2d | 永続的又は顕著な障害・機能 不全に陥るもの | ブール型 | Boolean (BL) | 値 | <pre> /MCCL_IN200100UV01[@ITSVersion=XMML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/PORR_IN049016UVJr/controlActProcess/@classCode=CACT][@moo dCode=EVN]/subject/@typeCode=SUBJ][1]/investigationEvent/@classCode=INVTG][@moodCo de=EVN]/component/@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment [@classCode=INVTG][@moodCode=EVN]/subject1/@typeCode=SBJ][1]/primaryRole/@classC ode=INVSBJ/subjectOf2/@typeCode=SBJ][observation/@classCode=OBS][@moodCode=EVN]/outbound Relationship2/@typeCode=PERT][observation/codel/@code=35][@codeSystem=2.16.840.1.11388 3.3.989.2.1.1.19][1]/observation/@classCode=OBS][@moodCode=EVN]/value[@xsi:type=BL][1]/ @value </pre> |

(別添 3)

| | | | | | |
|---|------------|--------------|------|---------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| e | NullFlavor | | | | <pre> /MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 dCode='EVN']/subject[@typeCode='SUBJ']/investigationEvent[@classCode='CACT']/@moodCo de='EVN']/component[@typeCode='COMP']/adverseEventAssessment[1]/adverseEventAssessment [@classCode='INVTG']/@moodCode='EVN']/subject[1]/primaryRole/@classC ode='INVSBJ']/subjectOf2[@typeCode='SBJ']/observation[id]@[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[id]@[code='35']/@codeSystem='2.16.840.1.11388 3.3.989.2.1.1.19']/observation[@classCode='OBS']/@moodCode='EVN']/value[@xsi:type='BL']/ @value </pre> |
| e | 値 | Boolean (BL) | ブール型 | 先天異常を来すもの | <pre> /MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 dCode='EVN']/subject[@typeCode='SUBJ']/investigationEvent[@classCode='CACT']/@moodCo de='EVN']/component[@typeCode='COMP']/adverseEventAssessment[1]/adverseEventAssessment [@classCode='INVTG']/@moodCode='EVN']/subject[1]/primaryRole/@classC ode='INVSBJ']/subjectOf2[@typeCode='SBJ']/observation[id]@[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[id]@[code='12']/@codeSystem='2.16.840.1.11388 3.3.989.2.1.1.19']/observation[@classCode='OBS']/@moodCode='EVN']/value[@xsi:type='BL']/ @value </pre> |
| e | NullFlavor | | | その他の医学的に重要な状態 | <pre> /MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 dCode='EVN']/subject[@typeCode='SUBJ']/investigationEvent[@classCode='CACT']/@moodCo de='EVN']/component[@typeCode='COMP']/adverseEventAssessment[1]/adverseEventAssessment [@classCode='INVTG']/@moodCode='EVN']/subject[1]/primaryRole/@classC ode='INVSBJ']/subjectOf2[@typeCode='SBJ']/observation[id]@[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[id]@[code='12']/@codeSystem='2.16.840.1.11388 3.3.989.2.1.1.19']/observation[@classCode='OBS']/@moodCode='EVN']/value[@xsi:type='BL']/ @value </pre> |
| e | 値 | Boolean (BL) | ブール型 | その他の医学的に重要な状態 | <pre> /MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 dCode='EVN']/subject[@typeCode='SUBJ']/investigationEvent[@classCode='CACT']/@moodCo de='EVN']/component[@typeCode='COMP']/adverseEventAssessment[1]/adverseEventAssessment [@classCode='INVTG']/@moodCode='EVN']/subject[1]/primaryRole/@classC ode='INVSBJ']/subjectOf2[@typeCode='SBJ']/observation[id]@[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[id]@[code='26']/@codeSystem='2.16.840.1.11388 3.3.989.2.1.1.19']/observation[@classCode='OBS']/@moodCode='EVN']/value[@xsi:type='BL']/ @value </pre> |
| e | NullFlavor | | | | <pre> /MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 dCode='EVN']/subject[@typeCode='SUBJ']/investigationEvent[@classCode='CACT']/@moodCo de='EVN']/component[@typeCode='COMP']/adverseEventAssessment[1]/adverseEventAssessment [@classCode='INVTG']/@moodCode='EVN']/subject[1]/primaryRole/@classC ode='INVSBJ']/subjectOf2[@typeCode='SBJ']/observation[id]@[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[id]@[code='26']/@codeSystem='2.16.840.1.11388 3.3.989.2.1.1.19']/observation[@classCode='OBS']/@moodCode='EVN']/value[@xsi:type='BL']/ @value </pre> |

(別添 3)

| | | | | | |
|-----------------------|---------------------|--------------|-------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <p>e</p> <p>E.i.4</p> | <p>副作用/有害事象の発現日</p> | <p>日付/時間</p> | <p>1.E.i.4、E.i.5及びE.i.6のすべての項目が表示されない場合</p> <p>HL7 データ型: Interval of Point in Time (IVL<TS>)</p> | <p>1.E.i.4、E.i.5及びE.i.6のすべての項目が表示されない場合</p> <p>low=Interval Boundary (IVXB)</p> | <p>値</p> <p>/MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UV[r]/controlActProcess[@classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUBJ][1]/investigationEvent[@classCode=INVESTG][@moodCode=EVN]/component[@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment[@classCode=INVESTG][@moodCode=EVN]/subject1[@typeCode=SBJ][1]/primaryRole[@classCode=INVSBJ/subjectOr2[@typeCode=SBJ][observation[id][code]=29][@codeSystem=2.1.6.840.1.113883.3.989.2.1.1.19]]/observation[@classCode=OBS][@moodCode=EVN]/effectiveTime[@xsi:type=IVL_TS]/low/@value</p> |
| <p>e</p> | | | | <p>NullFlavor</p> | <p>/MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UV[r]/controlActProcess[@classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUBJ][1]/investigationEvent[@classCode=INVESTG][@moodCode=EVN]/component[@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment[@classCode=INVESTG][@moodCode=EVN]/subject1[@typeCode=SBJ][1]/primaryRole[@classCode=INVSBJ/subjectOr2[@typeCode=SBJ][observation[id][code]=29][@codeSystem=2.1.6.840.1.113883.3.989.2.1.1.19]]/observation[@classCode=OBS][@moodCode=EVN]/effectiveTime[@xsi:type=IVL_TS]/low/@nullFlavor</p> |
| <p>e</p> | | | <p>2.E.i.4、E.i.5及びE.i.6のすべての項目が表示される場合</p> <p>データ型 SXPRT を伴う最初の comp 項目</p> <p>HL7 データ型: Parenthetic Set Expression of Point in Time (SXPRTS>)</p> | <p>2.E.i.4、E.i.5及びE.i.6のすべての項目が表示される場合</p> <p>データ型 SXPRT を伴う最初の comp 項目</p> <p>comp/low=Interval Boundary (IVXB)</p> | <p>値</p> <p>/MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UV[r]/investigationEvent[@classCode=CACT][@moodCode=EVN]/component[@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment[@classCode=INVESTG][@moodCode=EVN]/subject1[@typeCode=SBJ][1]/primaryRole[@classCode=INVSBJ/subjectOr2[@typeCode=SBJ][observation[id][code]=29][@codeSystem=2.1.6.840.1.113883.3.989.2.1.1.19]]/observation[@classCode=OBS][@moodCode=EVN]/effectiveTime[@xsi:type=SXPRTS]/comp/@value</p> |
| <p>e</p> | | | | <p>NullFlavor</p> | <p>/MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UV[r]/controlActProcess[@classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUBJ][1]/investigationEvent[@classCode=INVESTG][@moodCode=EVN]/component[@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment[@classCode=INVESTG][@moodCode=EVN]/subject1[@typeCode=SBJ][1]/primaryRole[@classCode=INVSBJ/subjectOr2[@typeCode=SBJ][observation[id][code]=29][@codeSystem=2.1.6.840.1.113883.3.989.2.1.1.19]]/observation[@classCode=OBS][@moodCode=EVN]/effectiveTime[@xsi:type=SXPRTS]/comp/@nullFlavor</p> |

| | | | | |
|----------|---------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--|
| | <p>3.E.i.4、E.i.5及びE.i.6のすべての項目が表示される場合</p> <p>データ型 SXPTR を伴う 2 番目の comp 項目</p> <p>HL7 データ型: Parenthetic Set Expression of Point in Time (SXPTR<TS>)</p> | <p>3.E.i.4、E.i.5及びE.i.6のすべての項目が表示される場合</p> <p>データ型 SXPTR を伴う 2 番目の comp 項目</p> <p>comp/low=Interval Boundary (IVXB)</p> | <p>値</p> <pre> /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UV[r]/controlActProcess[@classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUBJ][r]/investigationEvent[@classCode=INVTG][@moodCode=EVN]/component[@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment[@classCode=INVTG][@moodCode=EVN]/subject[1]/typeCode=SBJ][r1]/primaryRole[@classCode=INVSBJ]/subjectOf2[@typeCode=SBJ]/observation[id][code][@code=29][@codeSystem=2.16.840.1.113883.3.989.2.1.1.19][r]/observation[@classCode=OBS][@moodCode=EVN]/effectiveTime[@xsi:type=SXPTR_TS]/comp[@xsi:type=IVL_TS][@operator=A]/low/@value </pre> | |
| | | <p>NullFlavor</p> | <p>値</p> <pre> /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UV[r]/controlActProcess[@classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUBJ][r]/investigationEvent[@classCode=INVTG][@moodCode=EVN]/component[@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment[@classCode=INVTG][@moodCode=EVN]/subject[1]/typeCode=SBJ][r1]/primaryRole[@classCode=INVSBJ]/subjectOf2[@typeCode=SBJ]/observation[id][code][@code=29][@codeSystem=2.16.840.1.113883.3.989.2.1.1.19][r]/observation[@classCode=OBS][@moodCode=EVN]/effectiveTime[@xsi:type=SXPTR_TS]/comp[@xsi:type=IVL_TS][@operator=A]/low/@nullFlavor </pre> | |
| <p>e</p> | <p>1.E.i.4、E.i.5及びE.i.6のすべての項目が表示されない場合</p> <p>HL7 データ型: Interval of Point in Time (IVL<TS>)</p> | <p>1.E.i.4、E.i.5及びE.i.6のすべての項目が表示されない場合</p> <p>high=Interval Boundary (IVXB)</p> | <p>値</p> <pre> /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UV[r]/controlActProcess[@classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUBJ][r]/investigationEvent[@classCode=INVTG][@moodCode=EVN]/component[@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment[@classCode=INVTG][@moodCode=EVN]/subject[1]/typeCode=SBJ][r1]/primaryRole[@classCode=INVSBJ]/subjectOf2[@typeCode=SBJ]/observation[id][code][@code=29][@codeSystem=2.16.840.1.113883.3.989.2.1.1.19][r]/observation[@classCode=OBS][@moodCode=EVN]/effectiveTime[@xsi:type=IVL_TS]/high/@value </pre> | |
| <p>e</p> | <p>副作用/有害事象の終了日</p> <p>日付/時間</p> | <p>NullFlavor</p> | <p>値</p> <pre> /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UV[r]/controlActProcess[@classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUBJ][r]/investigationEvent[@classCode=INVTG][@moodCode=EVN]/component[@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment[@classCode=INVTG][@moodCode=EVN]/subject[1]/typeCode=SBJ][r1]/primaryRole[@classCode=INVSBJ]/subjectOf2[@typeCode=SBJ]/observation[id][code][@code=29][@codeSystem=2.16.840.1.113883.3.989.2.1.1.19][r]/observation[@classCode=OBS][@moodCode=EVN]/effectiveTime[@xsi:type=IVL_TS]/high/@nullFlavor </pre> | |

| | | | | | |
|---|--|-------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------|------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| e | | <p>2.E.i.4, E.i.5 及び E.i.6 のすべての項目が表示される場合</p> <p>データ型 SXPRT を伴う最初の comp 項目</p> <p>HL7 データ型: Parenthetic Set Expression of Point in Time (SXPRT<TS>)</p> | <p>2.E.i.4, E.i.5 及び E.i.6 のすべての項目が表示される場合</p> <p>データ型 SXPRT を伴う最初の comp 項目</p> <p>comp/high=Interval Boundary (IVXB)</p> | 値 | <pre> /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UV1[controlActProcess/@classCode=CACTT][@moodCode=EVN]/subject/@typeCode=SUBJ[1]/investigationEvent[1]/controlActProcess/@classCode=INVTG[1][@moodCode=EVN]/component[1]/typeCode=COMP[1]/adverseEventAssessment[1]/adverseEventAssessment[1]/classCode=INVTG[1][@moodCode=EVN]/subject1/@typeCode=SBJ[1]/primaryRole/@classCode=INVSBJ[1]/subjectOf2/@typeCode=EVN][observation][code][@code=29][@codeSystem=2.16.840.1.113883.3.989.2.1.1.19][1][observation][classCode=OBS][@moodCode=EVN]/effectiveTime[@xsi:type=SXPRT][comp][@xsi:type=IVL_TS]/high/@value </pre> |
| e | | <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 SXPRT を伴う 2 番目の comp 項目</p> <p>HL7 データ型: Parenthetic Set Expression of Point in Time (SXPRT<TS>)</p> | <p>NullFlavor</p> | NullFlavor | <pre> /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UV1[controlActProcess/@classCode=CACTT][@moodCode=EVN]/subject/@typeCode=SUBJ[1]/investigationEvent[1]/controlActProcess/@classCode=INVTG[1][@moodCode=EVN]/component[1]/typeCode=COMP[1]/adverseEventAssessment[1]/adverseEventAssessment[1]/classCode=INVTG[1][@moodCode=EVN]/subject1/@typeCode=SBJ[1]/primaryRole/@classCode=INVSBJ[1]/subjectOf2/@typeCode=EVN][observation][code][@code=29][@codeSystem=2.16.840.1.113883.3.989.2.1.1.19][1][observation][classCode=OBS][@moodCode=EVN]/effectiveTime[@xsi:type=SXPRT][comp][@xsi:type=IVL_TS]/high/@nullFlavor </pre> |
| | | <p>3.E.i.4, E.i.5 及び E.i.6 のすべての項目が表示される場合</p> <p>データ型 SXPRT を伴う 2 番目の comp 項目</p> <p>HL7 データ型: Parenthetic Set Expression of Point in Time (SXPRT<TS>)</p> | <p>値</p> | 値 | <pre> /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UV1[controlActProcess/@classCode=CACTT][@moodCode=EVN]/subject/@typeCode=SUBJ[1]/investigationEvent[1]/controlActProcess/@classCode=INVTG[1][@moodCode=EVN]/component[1]/typeCode=COMP[1]/adverseEventAssessment[1]/adverseEventAssessment[1]/classCode=INVTG[1][@moodCode=EVN]/subject1/@typeCode=SBJ[1]/primaryRole/@classCode=INVSBJ[1]/subjectOf2/@typeCode=EVN][observation][code][@code=29][@codeSystem=2.16.840.1.113883.3.989.2.1.1.19][1][observation][classCode=OBS][@moodCode=EVN]/effectiveTime[@xsi:type=SXPRT][comp][@xsi:type=IVL_TS][@operator=A]/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 SXPRT を伴う最初の comp 項目</p> <p>HL7 データ型: Parenthetic Set Expression of Point in Time (SXPRT<TS>)</p> | <p>NullFlavor</p> | NullFlavor | <pre> /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UV1[controlActProcess/@classCode=CACTT][@moodCode=EVN]/subject/@typeCode=SUBJ[1]/investigationEvent[1]/controlActProcess/@classCode=INVTG[1][@moodCode=EVN]/component[1]/typeCode=COMP[1]/adverseEventAssessment[1]/adverseEventAssessment[1]/classCode=INVTG[1][@moodCode=EVN]/subject1/@typeCode=SBJ[1]/primaryRole/@classCode=INVSBJ[1]/subjectOf2/@typeCode=EVN][observation][code][@code=29][@codeSystem=2.16.840.1.113883.3.989.2.1.1.19][1][observation][classCode=OBS][@moodCode=EVN]/effectiveTime[@xsi:type=SXPRT][comp][@xsi:type=IVL_TS][@operator=A]/high/@nullFlavor </pre> |

| | | | | | |
|------------------------|---------------------------|-------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <p>e</p> <p>E.i.6a</p> | <p>副作用／有害事象の持続期間 (数)</p> | <p>5N</p> | <p>1.E.i.4、E.i.5 及び E.i.6 のすべての項目が表示されない場合</p> <p>HL7 データ型: Interval of Point in Time (IVL<TS>)</p> | <p>1.E.i.4、E.i.5 及び E.i.6 のすべての項目が表示されない場合</p> <p>width/value=Real Number (REAL)</p> | <p>値</p> <p>/MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UV01/controlActProcess[@classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUBJ][1]/investigationEvent[@classCode=INVESTG][@moodCode=EVN]/component[@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment[@classCode=INVESTG][@moodCode=EVN]/subject1[@typeCode=SBJ][1]/primaryRole[@classCode=INVSBJ]/subjectOf2[@typeCode=SBJ][observationId][code][@code=29][@codeSystem=2.1.6.840.1.113883.3.989.2.1.1.19][1]]/observation[@classCode=OBS][@moodCode=EVN]/effectiveTime[@xsi:type=IVL_TS]/width/@value</p> |
| <p>e</p> | | | <p>2.E.i.4、E.i.5 及び E.i.6 のすべての項目が表示される場合</p> <p>データ型 SXPTR を伴う最初の comp 項目</p> <p>HL7 データ型: Parenthetic Set Expression of Point in Time (SXPTR<TS>)</p> | <p>2.E.i.4、E.i.5 及び E.i.6 のすべての項目が表示される場合</p> <p>データ型 SXPTR を伴う最初の comp 項目</p> <p>comp/width/value=Real Number (REAL)</p> | <p>値</p> <p>/MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UV01/controlActProcess[@classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUBJ][1]/investigationEvent[@classCode=INVESTG][@moodCode=EVN]/component[@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment[@classCode=INVESTG][@moodCode=EVN]/subject1[@typeCode=SBJ][1]/primaryRole[@classCode=INVSBJ]/subjectOf2[@typeCode=SBJ][observationId][code][@code=29][@codeSystem=2.1.6.840.1.113883.3.989.2.1.1.19][1]]/observation[@classCode=OBS][@moodCode=EVN]/effectiveTime[@xsi:type=SXPTR_TS]/comp[@xsi:type=IVL_TS]/width/@value</p> |
| | | | <p>3.E.i.4、E.i.5 及び E.i.6 のすべての項目が表示される場合</p> <p>データ型 SXPTR を伴う 2 番目の comp 項目</p> <p>HL7 データ型: Parenthetic Set Expression of Point in Time (SXPTR<TS>)</p> | <p>3.E.i.4、E.i.5 及び E.i.6 のすべての項目が表示される場合</p> <p>データ型 SXPTR を伴う 2 番目の comp 項目</p> <p>comp/width/value=Real Number (REAL)</p> | <p>値</p> <p>/MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UV01/controlActProcess[@classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUBJ][1]/investigationEvent[@classCode=INVESTG][@moodCode=EVN]/component[@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment[@classCode=INVESTG][@moodCode=EVN]/subject1[@typeCode=SBJ][1]/primaryRole[@classCode=INVSBJ]/subjectOf2[@typeCode=SBJ][observationId][code][@code=29][@codeSystem=2.1.6.840.1.113883.3.989.2.1.1.19][1]]/observation[@classCode=OBS][@operator=A][width/@value</p> |
| <p>e</p> <p>E.i.6b</p> | <p>副作用／有害事象の持続期間 (単位)</p> | <p>50AN</p> | <p>1.E.i.4、E.i.5 及び E.i.6 のすべての項目が表示されない場合</p> <p>HL7 データ型: Interval of Point in Time (IVL<TS>)</p> | <p>1.E.i.4、E.i.5 及び E.i.6 のすべての項目が表示されない場合</p> <p>width/unit=Coded Simple Value (CS)</p> | <p>値</p> <p>/MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UV01/controlActProcess[@classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUBJ][1]/investigationEvent[@classCode=INVESTG][@moodCode=EVN]/component[@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment[@classCode=INVESTG][@moodCode=EVN]/subject1[@typeCode=SBJ][1]/primaryRole[@classCode=INVSBJ]/subjectOf2[@typeCode=SBJ][observationId][code][@code=29][@codeSystem=2.1.6.840.1.113883.3.989.2.1.1.19][1]]/observation[@classCode=OBS][@moodCode=EVN]/effectiveTime[@xsi:type=IVL_TS]/width/@unit</p> |

(別添 3)

| | | | | | | |
|---|-------|-------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------|---|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| e | | | <p>2.E.i.4、E.i.5及びE.i.6のすべての項目が表示される場合データ型 SXPР を伴う最初の comp 項目 HL7 データ型: Parenthetic Set Expression of Point in Time (SXPР<TS>)</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 SXPР を伴う 2 番目の comp 項目 HL7 データ型: Parenthetic Set Expression of Point in Time (SXPР<TS>)</p> | <p>2.E.i.4、E.i.5及びE.i.6のすべての項目が表示される場合データ型 SXPР を伴う最初の comp 項目 comp/width/unit=Coded Simple Value (CS)</p> | 値 | <pre>/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3:MCCI_IN200100UV01.xsd']/PORR_IN049016UV1r/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']/observation[code='29']/@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']/observation[@classCode='OBS']/@moodCode='EVN']/effectiveTime[@xsi:type='SXPR_TS']/comp[@xsi:type='IVL_TS']/width/@unit</pre> |
| e | E.i.7 | 最終観察時の副作用/有害事象の転帰 | <p>1N</p> | <p>code=Character String (ST)</p> | 値 | <pre>/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3:MCCI_IN200100UV01.xsd']/PORR_IN049016UV1r/controlActProcess[@classCode='CACT']/@moodCode=EVN]/component[@typeCode='COMP']/adverseEventAssessment[1]/adverseEventAssessment[@classCode='INVTG']/@moodCode=EVN]/subject1[@typeCode='SBJ']/primaryRole[@classCode='INVSBJ']/subjectOr2[@typeCode='SBJ']/observation[code='29']/@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']/observation[@classCode='OBS']/@moodCode='EVN']/outboundRelationship2[@typeCode='PER']/observation/code[@code='27']/@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']/observation[@classCode='OBS']/@moodCode='EVN']/value[@xsi:type='CE']/@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']/@code</pre> |
| | | 最終観察時の副作用/有害事象の転帰の ICH コードリストのパージョン | | | | <pre>/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3:MCCI_IN200100UV01.xsd']/PORR_IN049016UV1r/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']/observation[code='29']/@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']/observation[@classCode='OBS']/@moodCode='EVN']/outboundRelationship2[@typeCode='PER']/observation/code[@code='27']/@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']/observation[@classCode='OBS']/@moodCode='EVN']/value[@xsi:type='CE']/@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']/@codeSystemVersion</pre> |

| | | | | | | | |
|---|----------|----------------------------------|-------|-----------------------------|-------------------------------------|---|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| e | F.r.2.1 | 検査名 (自由記載) | 250AN | Concept Descriptor (CD) | originalText=Encapsulated Data (ED) | 値 | /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UV01/controlActProcess[@classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUBJ][1]/investigationEvent[@classCode=INVTG][@moodCode=EVN]/component[@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment[@classCode=INVTG][@moodCode=EVN]/subject1[@typeCode=SBJ][1]/primaryRole[@classCode=INVSBJ]/subjectOr2[@typeCode=SBJ]/organizer/code[@code=3][@codeSystem=2.16.840.1.113883.3.989.2.1.1.20][1]/organizer[@classCode=CATEGORY][@moodCode=EVN]/component[@typeCode=COMP][observation/code[@codeSystem=2.16.840.1.113883.6.163][1]/observation/@classCode=OBS][@moodCode=EVN]/code/originalText/text() |
| e | F.r.2.2a | 検査名の MedDRA パージョン | 4AN | Concept Descriptor (CD) | code=Character String (ST) | 値 | /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UV01/controlActProcess[@classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUBJ][1]/investigationEvent[@classCode=INVTG][@moodCode=EVN]/component[@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment[@classCode=INVTG][@moodCode=EVN]/subject1[@typeCode=SBJ][1]/primaryRole[@classCode=INVSBJ]/subjectOr2[@typeCode=SBJ]/organizer/code[@code=3][@codeSystem=2.16.840.1.113883.3.989.2.1.1.20][1]/organizer[@classCode=CATEGORY][@moodCode=EVN]/component[@typeCode=COMP][observation/code[@codeSystem=2.16.840.1.113883.6.163][1]/observation/@classCode=OBS][@moodCode=EVN]/code/@codeSystemVersion |
| e | F.r.2.2b | 検査名 (MedDRA コード) | 8N | Concept Descriptor (CD) | code=Character String (ST) | 値 | /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UV01/controlActProcess[@classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUBJ][1]/investigationEvent[@classCode=INVTG][@moodCode=EVN]/component[@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment[@classCode=INVTG][@moodCode=EVN]/subject1[@typeCode=SBJ][1]/primaryRole[@classCode=INVSBJ]/subjectOr2[@typeCode=SBJ]/organizer/code[@code=3][@codeSystem=2.16.840.1.113883.3.989.2.1.1.20][1]/organizer[@classCode=CATEGORY][@moodCode=EVN]/component[@typeCode=COMP][observation/code[@codeSystem=2.16.840.1.113883.6.163][1]/observation/@classCode=OBS][@moodCode=EVN]/code/@code |
| h | F.r.3 | 検査結果 | | | | | /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UV01/controlActProcess[@classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUBJ][1]/investigationEvent[@classCode=INVTG][@moodCode=EVN]/component[@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment[@classCode=INVTG][@moodCode=EVN]/subject1[@typeCode=SBJ][1]/primaryRole[@classCode=INVSBJ]/subjectOr2[@typeCode=SBJ]/organizer/code[@code=3][@codeSystem=2.16.840.1.113883.3.989.2.1.1.20][1]/organizer[@classCode=CATEGORY][@moodCode=EVN]/component[@typeCode=COMP][interpretation/code[@codeSystem=2.16.840.1.113883.6.163][1]/interpretation/@classCode=OBS][@moodCode=EVN]/code |
| e | F.r.3.1 | 検査結果 (コード) | 1N | Coded With Equivalents (CE) | code=Character String (ST) | 値 | /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UV01/controlActProcess[@classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUBJ][1]/investigationEvent[@classCode=INVTG][@moodCode=EVN]/component[@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment[@classCode=INVTG][@moodCode=EVN]/subject1[@typeCode=SBJ][1]/primaryRole[@classCode=INVSBJ]/subjectOr2[@typeCode=SBJ]/organizer/code[@code=3][@codeSystem=2.16.840.1.113883.3.989.2.1.1.20][1]/organizer[@classCode=CATEGORY][@moodCode=EVN]/component[@typeCode=COMP][observation/code[@codeSystem=2.16.840.1.113883.6.163][1]/observation/@classCode=OBS][@moodCode=EVN]/code |
| | | 検査結果 (コード) に関する ICH コードリストのパージョン | | | | | /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UV01/controlActProcess[@classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUBJ][1]/investigationEvent[@classCode=INVTG][@moodCode=EVN]/component[@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment[@classCode=INVTG][@moodCode=EVN]/subject1[@typeCode=SBJ][1]/primaryRole[@classCode=INVSBJ]/subjectOr2[@typeCode=SBJ]/organizer/code[@code=3][@codeSystem=2.16.840.1.113883.3.989.2.1.1.20][1]/organizer[@classCode=CATEGORY][@moodCode=EVN]/component[@typeCode=COMP][observation/code[@codeSystem=2.16.840.1.113883.6.163][1]/observation/@classCode=OBS][@moodCode=EVN]/code/@codeSystemVersion |

(別添 3)

| | | | | | | | |
|---|---------|--------------|-----|-----------------------------------------|---------------------------------------|---|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| e | F.r.3.2 | 検査結果 (値/限定子) | 50N | Interval of Physical Quantity (IVL<PQ>) | 1.EQ center=Physical Quantity (PQ) | 値 | /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UV/rj/controlActProcess[@classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUBJ][1]/investigationEvent[@classCode=INVTG][@moodCode=EVN]/component[@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment[@classCode=INVTG][@moodCode=EVN]/subject[1]/primaryRole/@classCode=INVSBJ]/subjectOf2[@typeCode=SBJ][1]/organizer/code[@code=3][@codeSystem=2.16.840.1.13883.3.989.2.1.1.20][1]/organizer/@classCode=CATEGORY][@moodCode=EVN]/component[@typeCode=COMP][observation/code/@codeSystem=2.16.840.1.13883.6.163][rj/observation/@classCode=OBS][@moodCode=EVN]/value[@xsi:type=IVL_PQ][rj/center/@value |
| e | | | | | 2.GT low=Interval Boundary (IVXB) | 値 | /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UV/rj/controlActProcess[@classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUBJ][1]/investigationEvent[@classCode=INVTG][@moodCode=EVN]/component[@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment[@classCode=INVTG][@moodCode=EVN]/subject[1]/primaryRole/@classCode=INVSBJ]/subjectOf2[@typeCode=SBJ][1]/organizer/code[@code=3][@codeSystem=2.16.840.1.13883.3.989.2.1.1.20][1]/organizer/@classCode=CATEGORY][@moodCode=EVN]/component[@typeCode=COMP][observation/code/@codeSystem=2.16.840.1.13883.6.163][rj/observation/@classCode=OBS][@moodCode=EVN]/value[@xsi:type=IVL_PQ][rj/high/@nullFlavor=PINF][1]/low/@inclusive=false][@value |
| e | | | | | 3.GE low=Interval Boundary (IVXB) | 値 | /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UV/rj/controlActProcess[@classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUBJ][1]/investigationEvent[@classCode=INVTG][@moodCode=EVN]/component[@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment[@classCode=INVTG][@moodCode=EVN]/subject[1]/primaryRole/@classCode=INVSBJ]/subjectOf2[@typeCode=SBJ][1]/organizer/code[@code=3][@codeSystem=2.16.840.1.13883.3.989.2.1.1.20][1]/organizer/@classCode=CATEGORY][@moodCode=EVN]/component[@typeCode=COMP][observation/code/@codeSystem=2.16.840.1.13883.6.163][rj/observation/@classCode=OBS][@moodCode=EVN]/value[@xsi:type=IVL_PQ][rj/high/@nullFlavor=PINF][1]/low/@inclusive=true][@value |
| e | | | | | 4.LT high=Interval Boundary (IVXB) | 値 | /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UV/rj/controlActProcess[@classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUBJ][1]/investigationEvent[@classCode=INVTG][@moodCode=EVN]/component[@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment[@classCode=INVTG][@moodCode=EVN]/subject[1]/primaryRole/@classCode=INVSBJ]/subjectOf2[@typeCode=SBJ][1]/organizer/code[@code=3][@codeSystem=2.16.840.1.13883.3.989.2.1.1.20][1]/organizer/@classCode=CATEGORY][@moodCode=EVN]/component[@typeCode=COMP][observation/code/@codeSystem=2.16.840.1.13883.6.163][rj/observation/@classCode=OBS][@moodCode=EVN]/value[@xsi:type=IVL_PQ][low/@nullFlavor=NINF][1]/high/@inclusive=false][@value |
| e | | | | | 5.LE high=Interval Boundary (IVXB) | 値 | /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UV/rj/controlActProcess[@classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUBJ][1]/investigationEvent[@classCode=INVTG][@moodCode=EVN]/component[@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment[@classCode=INVTG][@moodCode=EVN]/subject[1]/primaryRole/@classCode=INVSBJ]/subjectOf2[@typeCode=SBJ][1]/organizer/code[@code=3][@codeSystem=2.16.840.1.13883.3.989.2.1.1.20][1]/organizer/@classCode=CATEGORY][@moodCode=EVN]/component[@typeCode=COMP][observation/code/@codeSystem=2.16.840.1.13883.6.163][rj/observation/@classCode=OBS][@moodCode=EVN]/value[@xsi:type=IVL_PQ][low/@nullFlavor=NINF][1]/high/@inclusive=true][@value |

(別添3)

| | | | | | | |
|---|---------|-----------|------|-----------------------------------------|--------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| e | F.r.3.3 | 検査結果 (単位) | 50AN | Interval of Physical Quantity (IVL<PQ>) | 1.EQ center/value/unit=Physical Quantity (PQ) | /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UV/r/controlActProcess[@classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUBJ][1]/investigationEvent[@classCode=INVTG][@moodCode=EVN]/component[@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment[@classCode=INVTG][@moodCode=EVN]/subject1[@typeCode=SBJ][1]/primaryRole[@classCode=INVSBJ]/subjectO2[@typeCode=SBJ]/organizer/code[@code=3][@codeSystem=2.16.840.1.113883.3.989.2.1.1.20][1]/organizer[@classCode=CATEGORY][@moodCode=EVN]/component[@typeCode=COMP][observation/code[@codeSystem=2.16.840.1.113883.6.163][r/observation/@classCode=OBS][@moodCode=EVN]/value[@xsi:type=IVL_PQ][1]/center/@unit |
| e | | | | | 2.GT low/value/unit=Coded Simple Value (CS) | /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UV/r/controlActProcess[@classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUBJ][1]/investigationEvent[@classCode=INVTG][@moodCode=EVN]/component[@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment[@classCode=INVTG][@moodCode=EVN]/subject1[@typeCode=SBJ][1]/primaryRole[@classCode=INVSBJ]/subjectO2[@typeCode=SBJ]/organizer/code[@code=3][@codeSystem=2.16.840.1.113883.3.989.2.1.1.20][1]/organizer[@classCode=CATEGORY][@moodCode=EVN]/component[@typeCode=COMP][observation/code[@codeSystem=2.16.840.1.113883.6.163][r/observation/@classCode=OBS][@moodCode=EVN]/value[@xsi:type=IVL_PQ][high/@nullFlavor=PINF][1]/low/@inclusive=false/@unit |
| e | | | | | 3.GE low/value/unit=Coded Simple Value (CS) | /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UV/r/controlActProcess[@classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUBJ][1]/investigationEvent[@classCode=INVTG][@moodCode=EVN]/component[@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment[@classCode=INVTG][@moodCode=EVN]/subject1[@typeCode=SBJ][1]/primaryRole[@classCode=INVSBJ]/subjectO2[@typeCode=SBJ]/organizer/code[@code=3][@codeSystem=2.16.840.1.113883.3.989.2.1.1.20][1]/organizer[@classCode=CATEGORY][@moodCode=EVN]/component[@typeCode=COMP][observation/code[@codeSystem=2.16.840.1.113883.6.163][r/observation/@classCode=OBS][@moodCode=EVN]/value[@xsi:type=IVL_PQ][high/@nullFlavor=PINF][1]/low/@inclusive=true/@unit |
| e | | | | | 4.LT high/value/unit=Coded Simple Value (CS) | /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UV/r/controlActProcess[@classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUBJ][1]/investigationEvent[@classCode=INVTG][@moodCode=EVN]/component[@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment[@classCode=INVTG][@moodCode=EVN]/subject1[@typeCode=SBJ][1]/primaryRole[@classCode=INVSBJ]/subjectO2[@typeCode=SBJ]/organizer/code[@code=3][@codeSystem=2.16.840.1.113883.3.989.2.1.1.20][1]/organizer[@classCode=CATEGORY][@moodCode=EVN]/component[@typeCode=COMP][observation/code[@codeSystem=2.16.840.1.113883.6.163][r/observation/@classCode=OBS][@moodCode=EVN]/value[@xsi:type=IVL_PQ][low/@nullFlavor=NINF][1]/high/@inclusive=false/@unit |

(別添 3)

| | | | | | | |
|---|---------|------------------------|--------|--------------------------------------------------|---|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| e | | | | 5.LE highValue/unit=Code Simple Value (CS) | 値 | /MCCL_IN200100UV01@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/PORR_IN049016UV1/controlActProcess[@classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUBJ][1]/investigationEvent[@classCode=INVESTG][@moodCode=EVN]/component[@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment[1]/classCode=INVESTG][@moodCode=EVN]/subject1[@typeCode=SBJ][1]/primaryRole[classCode=INVSBJ]/subjectOf2[@typeCode=SBJ][organizer/code[@code=3]][@codeSystem=2.16.840.1.113883.3.989.2.1.1.20][1]/organizer[@classCode=CATEGORY][@moodCode=EVN]/component[1]@typeCode=COMP][observation/code[@codeSystem=2.16.840.1.113883.6.163][r/observation/@classCode=OBS][@moodCode=EVN]/value[@xsi:type=IVL_PQ][low/@nullFlavor=NINF][1]/high/@inclusive=true][@unit |
| e | F.r.3.4 | 検査結果に関する非構造化データ (自由記載) | 2000AN | Encapsulated Data (ED) | 値 | /MCCL_IN200100UV01@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/PORR_IN049016UV1/controlActProcess[@classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUBJ][1]/investigationEvent[@classCode=INVESTG][@moodCode=EVN]/component[@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment[1]/classCode=INVESTG][@moodCode=EVN]/subject1[@typeCode=SBJ][1]/primaryRole[classCode=INVSBJ]/subjectOf2[@typeCode=SBJ][organizer/code[@code=3]][@codeSystem=2.16.840.1.113883.3.989.2.1.1.20][1]/organizer[@classCode=CATEGORY][@moodCode=EVN]/component[1]@typeCode=COMP][observation/code[@codeSystem=2.16.840.1.113883.6.163][r/observation/@classCode=OBS][@moodCode=EVN]/value[@xsi:type=ED][1]/text() |
| e | F.r.4 | 正常範囲 低値 | 50AN | Physical Quantity (PQ) | 値 | /MCCL_IN200100UV01@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/PORR_IN049016UV1/controlActProcess[@classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUBJ][1]/investigationEvent[@classCode=INVESTG][@moodCode=EVN]/component[@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment[1]/classCode=INVESTG][@moodCode=EVN]/subject1[@typeCode=SBJ][1]/primaryRole[classCode=INVSBJ]/subjectOf2[@typeCode=SBJ][organizer/code[@code=3]][@codeSystem=2.16.840.1.113883.3.989.2.1.1.20][1]/organizer[@classCode=CATEGORY][@moodCode=EVN]/component[1]@typeCode=COMP][observation/code[@codeSystem=2.16.840.1.113883.6.163][r/observation/@classCode=OBS][@moodCode=EVN]/referenceRange[@typeCode=REFV][observationRange/interpretationCode[@code=L][@codeSystem=2.16.840.1.113883.5.83][1]/observationRange/@classCode=OBS][@moodCode=EVN.CRT]/value[@xsi:type=PQ][@value |
| e | F.r.5 | 正常範囲 高値 | 50AN | Physical Quantity (PQ) | 値 | /MCCL_IN200100UV01@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/PORR_IN049016UV1/controlActProcess[@classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUBJ][1]/investigationEvent[@classCode=INVESTG][@moodCode=EVN]/component[@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment[1]/classCode=INVESTG][@moodCode=EVN]/subject1[@typeCode=SBJ][1]/primaryRole[classCode=INVSBJ]/subjectOf2[@typeCode=SBJ][organizer/code[@code=3]][@codeSystem=2.16.840.1.113883.3.989.2.1.1.20][1]/organizer[@classCode=CATEGORY][@moodCode=EVN]/component[1]@typeCode=COMP][observation/code[@codeSystem=2.16.840.1.113883.6.163][r/observation/@classCode=OBS][@moodCode=EVN]/referenceRange[@typeCode=REFV][observationRange/interpretationCode[@code=H][@codeSystem=2.16.840.1.113883.5.83][1]/observationRange/@classCode=OBS][@moodCode=EVN.CRT]/value[@xsi:type=PQ][@value |

(別添 3)

| | | | | | | |
|---|-------|------------------|--------|-----------------------------|-------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| e | F.r.6 | 備考 | 2000AN | Encapsulated Data (ED) | 値 | <pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hi7-org:v3 MCCL_IN200100UV01.xsd]/PORR_IN049016UV/r/controlActProcess/@classCode=CACT][@moo dCode=EVN]/subject/@typeCode=SUBJ][1]/investigationEvent/@classCode=INVSCTG][@moodCo de=EVN]/component/@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment [@classCode=INVSCTG][@moodCode=EVN]/subject1/@typeCode=SBJ][1]/primaryRole/@classC ode=INVSBJJ/subjectOf2/@typeCode=SBJ][organizer/@code=3][@codeSystem=2.16.840.1 .113883.3.989.2.1.1.20][1]/organizer/@classCode=CATEGORY][@moodCode=EVN]/component[@typeCode=COMP][observation/code/@codeSystem=2.16.840.1.113883.3.989.2.1.1.19][r/observation/@ classCode=OBS][@moodCode=EVN]/outboundRelationship2/@typeCode=PERT][observation/co de/@code=10][@codeSystem=2.16.840.1.113883.3.989.2.1.1.19][text()]]/@moodCode=EVN][value[@xsi:type=ED][1]/text() </pre> |
| e | F.r.7 | その他の情報 | ブール型 | Boolean (BL) | 値 | <pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hi7-org:v3 MCCL_IN200100UV01.xsd]/PORR_IN049016UV/r/controlActProcess/@classCode=CACT][@moo dCode=EVN]/subject/@typeCode=SUBJ][1]/investigationEvent/@classCode=INVSCTG][@moodCo de=EVN]/component/@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment [@classCode=INVSCTG][@moodCode=EVN]/subject1/@typeCode=SBJ][1]/primaryRole/@classC ode=INVSBJJ/subjectOf2/@typeCode=SBJ][organizer/@code=3][@codeSystem=2.16.840.1 .113883.3.989.2.1.1.20][1]/organizer/@classCode=CATEGORY][@moodCode=EVN]/component[@typeCode=COMP][observation/code/@codeSystem=2.16.840.1.113883.3.989.2.1.1.19][r/observation/@ classCode=OBS][@moodCode=EVN]/outboundRelationship2/@typeCode=REFR][observation/co de/@code=25][@codeSystem=2.16.840.1.113883.3.989.2.1.1.19][value[@xsi:type=BL][1]/@value]]/@moodCode=EVN][value[@xsi:type=BL][1]/@value </pre> |
| h | G.k | 医薬品情報（必要に応じ繰り返す） | | | 繰り返し ノード | <pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hi7-org:v3 MCCL_IN200100UV01.xsd]/PORR_IN049016UV/r/controlActProcess/@classCode=CACT][@moo dCode=EVN]/subject/@typeCode=SUBJ][1]/investigationEvent/@classCode=INVSCTG][@moodCo de=EVN]/component/@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment [@classCode=INVSCTG][@moodCode=EVN]/subject1/@typeCode=SBJ][1]/primaryRole/@classC ode=INVSBJJ/subjectOf2/@typeCode=SBJ][organizer/@code=3][@codeSystem=2.16.840.1 .113883.3.989.2.1.1.20][1]/organizer/@classCode=CATEGORY][@moodCode=EVN]/component[@typeCode=COMP][substanceAdministration/id </pre> |
| e | G.k.1 | 医薬品関与の位置付け | 1N | Coded With Equivalents (CE) | 値 | <pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hi7-org:v3 MCCL_IN200100UV01.xsd]/PORR_IN049016UV/r/controlActProcess/@classCode=CACT][@moo dCode=EVN]/subject/@typeCode=SUBJ][1]/investigationEvent/@classCode=INVSCTG][@moodCo de=EVN]/component/@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment [@classCode=INVSCTG][@moodCode=EVN]/component/@typeCode=COMP][causalityAssessme nt/code/@code=20][@codeSystem=2.16.840.1.113883.3.989.2.1.1.19][causalityAssessment/@cl assCode=OBS][@moodCode=EVN]/subject2/@typeCode=SUBJ]/productUserReference/@classCo de=SBADM][@moodCode=EVN]/id[@root=UUUD of drug]/value[@xsi:type=CE][1]/@code </pre> |

| | | | | |
|----------------------------------------|--------------------------|----------------------------------------|-----------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <p>医薬品関与の位置付けに関する ICH コードリストのバージョン</p> | <p>医薬品の識別</p> | <p>医薬品の固有識別子/製剤の固有識別子</p> | <p>値</p> | <pre> /MCCI_IN200100UV01[@ITSVersion="XML_1.0"]/@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd/PORR_IN049076UV1/controlActProcess[@classCode="CACT"]/@moodCode=EVN]/subject[@typeCode="SUBJ"]/investigationEvent[@classCode="INVESTG"]/@moodCode=EVN]/component[@typeCode="COMP"]/adverseEventAssessment[1]/adverseEventAssessment[@classCode="INVESTG"]/@moodCode=EVN]/component[@typeCode="COMP"]/causalityAssessment[1]/code[@code="20"]/@codeSystem=2.16.840.1.113883.3.989.2.1.1.19]/causalityAssessment[@classCode="OBS"]/@moodCode=EVN]/subject2[@typeCode="SUBJ"]/productUseReference[@classCode="SBADM"]/@moodCode=EVN]/id[@root="UID" of k-th drug]/value[@xsi:type="CE"]/@codeSystem=2.16.840.1.113883.3.989.2.1.1.13]/@codeSystemVersion </pre> |
| <p>G.k.2</p> | <p>医薬品の識別</p> | <p>医薬品の固有識別子/製剤の固有識別子</p> | <p>値</p> | <pre> /MCCI_IN200100UV01[@ITSVersion="XML_1.0"]/@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd/PORR_IN049076UV1/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="INVESTG"]/@moodCode=EVN]/subjectOr2[@typeCode="SBJ"]/organizer/code[@code="4"]/@codeSystem=2.16.840.1.113883.3.989.2.1.1.20]/organizer/@classCode="CATEGORY"]/@moodCode=EVN]/component[@typeCode="COMP"]/substanceAdministration[id]/substanceAdministration[@classCode="SBADM"]/@moodCode=EVN]/consumable/@typeCode="CSM"]/@instanceOfKind[@classCode="INST"]/kindOfProduct[@classCode="MMAT"]/@determinerCode="KIND"]/@code/@codeSystem="TBD-MPID"]/@codeSystemVersion </pre> |
| <p>G.k.2.1.1a</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> |
| <p>G.k.2.1.1b</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> |
| <p>G.k.2.1.2a</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> |

| | | | | | |
|-----------------------------|-------------------------------------------|-------------------------------|----------------------------------------|-----------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <p>e</p> <p>G.k.2.1.2b</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"/PORR_IN049016UV/r/controlActProcess/@classCode="CACTI"[@moodCo dCode="EVN"/subject/@typeCode="SUBJ"/investigationEvent/@classCode="INVTG"[@moodCo de="EVN"/component/@typeCode="COMP"/adverseEventAssessment/1/adverseEventAssessment /@classCode="INVTG"[@moodCode="EVN"/subject/1/@typeCode="SBJ"/1/primaryRole/@classC ode="INVSBJ"/subjectOr2/@typeCode="SBJ"/organizer/code/@code="4"]/@codeSystem="2.16.840.1 .113883.3.989.2.1.1.20"/1/organizer/@classCode="CATEGORY"/1/@moodCode="EVN"/component/ 1/@typeCode="COMP"/substanceAdministration/id[k]/substanceAdministration/@classCode="SBADM "/1/@moodCode="EVN"/consumable/@typeCode="CSMT"/1/instanceOfKind/@classCode="INST"/kind OfProduct/@classCode="MMAT"/1/@determinerCode="KIND"/code/@codeSystem="TBD-PhPID"/@c ode </pre> |
| <p>e</p> <p>G.k.2.2</p> | <p>第一次情報源により報告さ れた医薬品名</p> | <p>250AN</p> | <p>Entity Name (EN)</p> | <p>name=Entity Name Part (ENXP)</p> | <p>値</p> <pre> /MCCI_IN200100UV01[@ITSVersion="XML_1.0"]/@xsi:schemaLocation="urn:hl7-org:v3 MCCI_IN200100UV01.xsd"/PORR_IN049016UV/r/controlActProcess/@classCode="CACTI"[@moodCo dCode="EVN"/subject/@typeCode="SUBJ"/investigationEvent/@classCode="INVTG"[@moodCo de="EVN"/component/@typeCode="COMP"/adverseEventAssessment/1/adverseEventAssessment /@classCode="INVTG"[@moodCode="EVN"/subject/1/@typeCode="SBJ"/1/primaryRole/@classC ode="INVSBJ"/subjectOr2/@typeCode="SBJ"/organizer/code/@code="4"]/@codeSystem="2.16.840.1 .113883.3.989.2.1.1.20"/1/organizer/@classCode="CATEGORY"/1/@moodCode="EVN"/component/ 1/@typeCode="COMP"/substanceAdministration/id[k]/substanceAdministration/@classCode="SBADM "/1/@moodCode="EVN"/consumable/@typeCode="CSMT"/1/instanceOfKind/@classCode="INST"/kind OfProduct/@classCode="MMAT"/1/@determinerCode="KIND"/name/1/text </pre> |
| <p>h</p> <p>G.k.2.3.r</p> | <p>成分/特定成分の識別子と 含量 (必要に応じて繰り返し返す)</p> | <p>繰り返し返す ノード</p> | <p>Entity Name (EN)</p> | <p>name=Entity Name Part (ENXP)</p> | <p>値</p> <pre> /MCCI_IN200100UV01[@ITSVersion="XML_1.0"]/@xsi:schemaLocation="urn:hl7-org:v3 MCCI_IN200100UV01.xsd"/PORR_IN049016UV/r/controlActProcess/@classCode="CACTI"[@moodCo dCode="EVN"/subject/@typeCode="SUBJ"/investigationEvent/@classCode="INVTG"[@moodCo de="EVN"/component/@typeCode="COMP"/adverseEventAssessment/1/adverseEventAssessment /@classCode="INVTG"[@moodCode="EVN"/subject/1/@typeCode="SBJ"/1/primaryRole/@classC ode="INVSBJ"/subjectOr2/@typeCode="SBJ"/organizer/code/@code="4"]/@codeSystem="2.16.840.1 .113883.3.989.2.1.1.20"/1/organizer/@classCode="CATEGORY"/1/@moodCode="EVN"/component/ 1/@typeCode="COMP"/substanceAdministration/id[k]/substanceAdministration/@classCode="SBADM "/1/@moodCode="EVN"/consumable/@typeCode="CSMT"/1/instanceOfKind/@classCode="INST"/kind OfProduct/@classCode="MMAT"/1/@determinerCode="KIND"/ingredient/@classCode="ACTI" </pre> |
| <p>e</p> <p>G.k.2.3.r.1</p> | <p>成分/特定成分名</p> | <p>250AN</p> | <p>Trivial Name (TN)</p> | <p>name=Entity Name Part (ENXP)</p> | <p>値</p> <pre> /MCCI_IN200100UV01[@ITSVersion="XML_1.0"]/@xsi:schemaLocation="urn:hl7-org:v3 MCCI_IN200100UV01.xsd"/PORR_IN049016UV/r/controlActProcess/@classCode="CACTI"[@moodCo dCode="EVN"/subject/@typeCode="SUBJ"/investigationEvent/@classCode="INVTG"[@moodCo de="EVN"/component/@typeCode="COMP"/adverseEventAssessment/1/adverseEventAssessment /@classCode="INVTG"[@moodCode="EVN"/subject/1/@typeCode="SBJ"/1/primaryRole/@classC ode="INVSBJ"/subjectOr2/@typeCode="SBJ"/organizer/code/@code="4"]/@codeSystem="2.16.840.1 .113883.3.989.2.1.1.20"/1/organizer/@classCode="CATEGORY"/1/@moodCode="EVN"/component/ 1/@typeCode="COMP"/substanceAdministration/id[k]/substanceAdministration/@classCode="SBADM "/1/@moodCode="EVN"/consumable/@typeCode="CSMT"/1/instanceOfKind/@classCode="INST"/kind OfProduct/@classCode="MMAT"/1/@determinerCode="KIND"/ingredient/@classCode="ACTI" </pre> |

(別添 3)

| | | | | | |
|------------------------------|------------------------------------|-------------------------------|----------------------------------------|------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <p>e</p> <p>G.k.2.3.r.2a</p> | <p>成分/特定成分の ID パー ジョン日付/番号</p> | <p>M5 ガイド ラインを参 照</p> | <p>Coded With Equivalents (CE)</p> | <p>code=SystemVersion= Character String (ST)</p> | <pre>/MCCL_IN200100UV01/@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/PORR_IN049016UV/r/controlActProcess/@classCode=CACT][@moo dCode=EVN]/subject/@typeCode=SUBJ][1]/investigationEvent/@classCode=INVTG][@moodCo de=EVN]/component/@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment /@classCode=INVTG][@moodCode=EVN]/subject[1]/typeCode=SBJ][1]/primaryRole/@classC ode=INVSBJ]/subjectOr2/@typeCode=SBJ]/organizer/code/@code=4][@codeSystem=2.16.840.1 113883.3.989.2.1.1.20][1]/organizer/@classCode=CATEGORY][@moodCode=EVN]/component[1]/typeCode=COMP][substanceAdministration/for[k]/substanceAdministration/@classCode=SBADM][@moodCode=EVN]/consumable/@typeCode=CSM][1]/instanceOfKind/@classCode=INST]/kind OfProduct/@classCode=MMAT][@determinerCode=KIND]/ingredient/@classCode=ACT][r]/ingre dientSubstance/@classCode=MMAT][@determinerCode=KIND]/code/@codeSystem=TBD-Substa nce]/@codeSystemVersion</pre> |
| <p>e</p> <p>G.k.2.3.r.2b</p> | <p>成分/特定成分の ID</p> | <p>M5 ガイド ラインを参 照</p> | <p>Coded With Equivalents (CE)</p> | <p>code=Character String (ST)</p> | <pre>/MCCL_IN200100UV01/@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/PORR_IN049016UV/r/controlActProcess/@classCode=CACT][@moo dCode=EVN]/subject/@typeCode=SUBJ][1]/investigationEvent/@classCode=INVTG][@moodCo de=EVN]/component/@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment /@classCode=INVTG][@moodCode=EVN]/subject[1]/typeCode=SBJ][1]/primaryRole/@classC ode=INVSBJ]/subjectOr2/@typeCode=SBJ]/organizer/code/@code=4][@codeSystem=2.16.840.1 113883.3.989.2.1.1.20][1]/organizer/@classCode=CATEGORY][@moodCode=EVN]/component[1]/typeCode=COMP][substanceAdministration/for[k]/substanceAdministration/@classCode=SBADM][@moodCode=EVN]/consumable/@typeCode=CSM][1]/instanceOfKind/@classCode=INST]/kind OfProduct/@classCode=MMAT][@determinerCode=KIND]/ingredient/@classCode=ACT][r]/ingre dientSubstance/@classCode=MMAT][@determinerCode=KIND]/code/@codeSystem=TBD-Substa nce]/@code</pre> |
| <p>e</p> <p>G.k.2.3.r.3a</p> | <p>含量 (数)</p> | <p>10N</p> | <p>Physical Quantity (PQ)</p> | <p>value=Real Number (REAL)</p> | <pre>/MCCL_IN200100UV01/@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/PORR_IN049016UV/r/controlActProcess/@classCode=CACT][@moo dCode=EVN]/subject/@typeCode=SUBJ][1]/investigationEvent/@classCode=INVTG][@moodCo de=EVN]/component/@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment /@classCode=INVTG][@moodCode=EVN]/subject[1]/typeCode=SBJ][1]/primaryRole/@classC ode=INVSBJ]/subjectOr2/@typeCode=SBJ]/organizer/code/@code=4][@codeSystem=2.16.840.1 113883.3.989.2.1.1.20][1]/organizer/@classCode=CATEGORY][@moodCode=EVN]/component[1]/typeCode=COMP][substanceAdministration/for[k]/substanceAdministration/@classCode=SBADM][@moodCode=EVN]/consumable/@typeCode=CSM][1]/instanceOfKind/@classCode=INST]/kind OfProduct/@classCode=MMAT][@determinerCode=KIND]/ingredient/@classCode=ACT][r]/quant ity/denominator/@value=1]/numerator/@value</pre> |
| <p>e</p> <p>G.k.2.3.r.3b</p> | <p>含量 (単位)</p> | <p>50AN</p> | <p>Physical Quantity (PQ)</p> | <p>unit=Coded Simple Value (CS)</p> | <pre>/MCCL_IN200100UV01/@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/PORR_IN049016UV/r/controlActProcess/@classCode=CACT][@moo dCode=EVN]/subject/@typeCode=SUBJ][1]/investigationEvent/@classCode=INVTG][@moodCo de=EVN]/component/@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment /@classCode=INVTG][@moodCode=EVN]/subject[1]/typeCode=SBJ][1]/primaryRole/@classC ode=INVSBJ]/subjectOr2/@typeCode=SBJ]/organizer/code/@code=4][@codeSystem=2.16.840.1 113883.3.989.2.1.1.20][1]/organizer/@classCode=CATEGORY][@moodCode=EVN]/component[1]/typeCode=COMP][substanceAdministration/for[k]/substanceAdministration/@classCode=SBADM][@moodCode=EVN]/consumable/@typeCode=CSM][1]/instanceOfKind/@classCode=INST]/kind OfProduct/@classCode=MMAT][@determinerCode=KIND]/ingredient/@classCode=ACT][r]/quant ity/denominator/@value=1]/numerator/@unit</pre> |

(別添 3)

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

| | | | | | | | |
|---|------------|------------------------|------|-----------------------------|------------------------------|-------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| e | G.k.3.2 | 承認/申請国 | 2A | Coded With Equivalents (CE) | code=Character String (ST) | 値 | /MCCI_IN200100UV01[ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PDRR_IN049016UV[controlActProcess/@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]/subjectOf2[@typeCode=SBJ]/organizer[@code=4][@codeSystem=2.16.840.1.113883.3.989.2.1.1.20][1]/organizer[@classCode=CATEGORY][@moodCode=EVN]/component[1].13883.3.989.2.1.1.20][1]/organizer[1]/approval[@classCode=CNTRCT][@moodCode=EVN]/product[@classCode=MMAT][@determinerCode=KIND]/asManufacturedProduct[1]/classCode=SBADM MANU]/subjectOf[1]/approval[@classCode=CNTRCT][@moodCode=EVN]/approval[@typeCode=AU]/territorialAuthority[@classCode=TERR]/territory[@classCode=NA][@determinerCode=INSTANCE]/code/@codeSystem=1.0.3.166.1.2.2][@code |
| e | G.k.3.3 | 承認の取得者/申請者の名称 | 60AN | Organization Name (ON) | name=Entity Name Part (ENXP) | 値 | /MCCI_IN200100UV01[ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PDRR_IN049016UV[controlActProcess/@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]/subjectOf2[@typeCode=SBJ]/organizer[@code=4][@codeSystem=2.16.840.1.113883.3.989.2.1.1.20][1]/organizer[1]/approval[@classCode=CNTRCT][@moodCode=EVN]/product[@classCode=MMAT][@determinerCode=KIND]/asManufacturedProduct[1]/classCode=SBADM MANU]/subjectOf[1]/approval[@typeCode=CNTRCT][@moodCode=EVN]/approval[@typeCode=AU]/territorialAuthority[@classCode=TERR]/territory[@classCode=EVN]/role/@typeCode=HLD][1]/role/@classCode=HLD]/playingOrganization/@classCode=ORG][@determinerCode=INSTANCE]/name/text() |
| h | G.k.4.r | 投与量及び関連情報 (必要に応じて繰り返す) | | | | 繰り返し ノード | /MCCI_IN200100UV01[ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PDRR_IN049016UV[controlActProcess/@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]/subjectOf2[@typeCode=SBJ]/organizer[@code=4][@codeSystem=2.16.840.1.113883.3.989.2.1.1.20][1]/organizer[1]/approval[@classCode=CNTRCT][@moodCode=EVN]/product[@classCode=MMAT][@determinerCode=KIND]/asManufacturedProduct[1]/classCode=SBADM MANU]/subjectOf[1]/approval[@typeCode=CNTRCT][@moodCode=EVN]/approval[@typeCode=AU]/territorialAuthority[@classCode=TERR]/territory[@classCode=EVN]/role/@typeCode=HLD][1]/role/@classCode=HLD]/playingOrganization/@classCode=ORG][@determinerCode=INSTANCE]/name/text() |
| e | G.k.4.r.1a | 投与量 (数) | 8N | Physical Quantity (PQ) | value=Real Number (REAL) | 値 | /MCCI_IN200100UV01[ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PDRR_IN049016UV[controlActProcess/@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]/subjectOf2[@typeCode=SBJ]/organizer[@code=4][@codeSystem=2.16.840.1.113883.3.989.2.1.1.20][1]/organizer[1]/approval[@classCode=CNTRCT][@moodCode=EVN]/product[@classCode=MMAT][@determinerCode=KIND]/asManufacturedProduct[1]/classCode=SBADM MANU]/subjectOf[1]/approval[@typeCode=CNTRCT][@moodCode=EVN]/approval[@typeCode=AU]/territorialAuthority[@classCode=TERR]/territory[@classCode=EVN]/role/@typeCode=HLD][1]/role/@classCode=HLD]/playingOrganization/@classCode=ORG][@determinerCode=INSTANCE]/name/text() |

| | | | | |
|----------|------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <p>e</p> | | <p>3.以下のデータ項目の1つの値のみが表示される場合</p> <ol style="list-style-type: none"> 1) G.k.4.r.2, G.k.4.r.3 2) G.k.4.r.4 3) G.k.4.r.5 4) G.k.4.r.6a, G.k.4.r.6b | <p>Periodic Interval of Time (PVL_TS)</p> | <p>値</p> <pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/PORR_IN049016UV[r]/controlActProcess/@classCode=CACT][@moo dCode=EVN]/subject/@typeCode=SUBJ[1]/investigationEvent/@classCode=INVTG][@moodCo de=EVN]/component/@typeCode=COMP[adverseEventAssessment[1]/adverseEventAssessment [@classCode=INVTG][@moodCode=EVN]/subject1/@typeCode=SBJ[1]/primaryRole[@classC ode=INVSBJ/subjectO2/@typeCode=SBJ]/organizer/@code=4][@codeSystem=2.16.840.1 .113883.3.989.2.1.1.20][1]/organizer/@classCode=CATEGORY][@moodCode=EVN]/component[1]/@typeCode=COMP[1]/substanceAdministration[id][k]/substanceAdministration/@classCode=SBADM][@moodCode=EVN]/outboundRelationship2/@typeCode=COMP[1]/substanceAdministration[r]/sub stanceAdministration/@classCode=SBADM][@moodCode=EVN]/effectiveTime/@xsi:type=PVL_T S]/period/@value </pre> |
| <p>e</p> | <p>G.k.4.r.3</p> | <p>1.以下のデータ項目の2つの値が表示される場合</p> <ol style="list-style-type: none"> 1) G.k.4.r.2, G.k.4.r.3 2) G.k.4.r.4 3) G.k.4.r.5 4) G.k.4.r.6a, G.k.4.r.6b <p>データ型 SXPTR を伴う最初の comp 項目</p> <p>Parenthetic Set Expression of Time (SXPTR_TS) [Periodic Interval of Time (PVL_TS)]</p> | <p>50AN</p> | <p>値</p> <pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/PORR_IN049016UV[r]/controlActProcess/@classCode=CACT][@moo dCode=EVN]/subject/@typeCode=SUBJ[1]/investigationEvent/@classCode=INVTG][@moodCo de=EVN]/component/@typeCode=COMP[adverseEventAssessment[1]/adverseEventAssessment [@classCode=INVTG][@moodCode=EVN]/subject1/@typeCode=SBJ[1]/primaryRole[@classC ode=INVSBJ/subjectO2/@typeCode=SBJ]/organizer/@code=4][@codeSystem=2.16.840.1 .113883.3.989.2.1.1.20][1]/organizer/@classCode=CATEGORY][@moodCode=EVN]/component[1]/@typeCode=COMP[1]/substanceAdministration[id][k]/substanceAdministration/@classCode=SBADM][@moodCode=EVN]/outboundRelationship2/@typeCode=COMP[1]/substanceAdministration[r]/sub stanceAdministration/@classCode=SBADM][@moodCode=EVN]/effectiveTime/@xsi:type=SXPTR_ TS]/comp/@xsi:type=PVL_TS]/period/@unit </pre> |

| | | | | |
|---|--|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | <p>2. 以下のデータ項目の2つを超える値が表示される場合:</p> <ol style="list-style-type: none"> 1) G.k.4.r.2、G.k.4.r.3 2) G.k.4.r.4 3) G.k.4.r.5 4) G.k.4.r.6a、G.k.4.r.6b <p>データ型 SXPР を伴う 2 番目の comp 項目</p> <p>Parenthetic Set Expression of Time (SXPР_TS) [Periodic Interval of Time (PIVL_TS)]</p> | 値 | <pre> /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UV/j/controlActProcess[@classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUBJ][1]/investigationEvent[@classCode=INVSTG][@moodCode=EVN]/component[@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment[@classCode=INVSTG][@moodCode=EVN]/subject1[@typeCode=SBJ][1]/primaryRole[@classCode=INVSBJ]/subjectOf2[@typeCode=SBJ][organizer/code[@code=4]][@codeSystem=2.16.840.1.13883.3.989.2.1.1.20][1]/organizer[@classCode=CATEGORY][@moodCode=EVN]/component[@typeCode=COMP][substanceAdministration/id[k]/substanceAdministration[@classCode=SBADM][@moodCode=EVN]/outboundRelationship2[@typeCode=COMP][substanceAdministration][r]/substanceAdministration[@classCode=SBADM][@moodCode=EVN]/effectiveTime[@xsi:type=SXPR_TS]/comp[@xsi:type=PIVL_TS][operator=A]/period/@unit </pre> |
| e | | <p>3. 以下のデータ項目の1つの値のみが表示される場合</p> <ol style="list-style-type: none"> 1) G.k.4.r.2、G.k.4.r.3 2) G.k.4.r.4 3) G.k.4.r.5 4) G.k.4.r.6a、G.k.4.r.6b <p>Periodic Interval of Time (PIVL_TS)</p> | 値 | <pre> /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UV/j/controlActProcess[@classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUBJ][1]/investigationEvent[@classCode=INVSTG][@moodCode=EVN]/component[@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment[@classCode=INVSTG][@moodCode=EVN]/subject1[@typeCode=SBJ][1]/primaryRole[@classCode=INVSBJ]/subjectOf2[@typeCode=SBJ][organizer/code[@code=4]][@codeSystem=2.16.840.1.13883.3.989.2.1.1.20][1]/organizer[@classCode=CATEGORY][@moodCode=EVN]/component[@typeCode=COMP][substanceAdministration/id[k]/substanceAdministration[@classCode=SBADM][@moodCode=EVN]/outboundRelationship2[@typeCode=COMP][substanceAdministration][r]/substanceAdministration[@classCode=SBADM][@moodCode=EVN]/effectiveTime[@xsi:type=PIVL_TS]/period/@unit </pre> |

period/unit=Coded Simple Value (CS)

| | | | | | | |
|---------------------------|------------------|--------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <p>e</p> <p>G.k.4.r.4</p> | <p>医薬品の投与開始日</p> | <p>日付/時間</p> | <p>1.以下のデータ項目の2つを超える値が表示される場合： 1) G.k.4.r.2、 G.k.4.r.3 2) G.k.4.r.4 3) G.k.4.r.5 4) G.k.4.r.6a、 G.k.4.r.6b データ型 SXPRT を伴う最初の comp 項目 Parenthetic Set Expression of Time (SXPRT_TS) [Intervale of Point in Time (IVL_TS)]</p> | <p>low=Interval Boundary (VXB)</p> | <p>値</p> | <pre> /MCC1_IN200100UV01[@ITSVersion='XML_1.0']/@xsi:schemaLocation=urn:hl7-org:v3 MCC1_IN200100UV01.xsd]/PORR_IN049016UV[f]/controlActProcess/@classCode=CACAT][@moodCode=EVN]/subject/@typeCode='SUBJ']]/investigationEvent/@classCode=INVESTG][@moodCode=EVN]/component/@typeCode='COMP']]/adverseEventAssessment[1]/adverseEventAssessment/@classCode=INVESTG][@moodCode=EVN]/subject1/@typeCode='SBJ']]/primaryRole/@classCode=INVSBJ/subjectOr2/@typeCode='SBJ']]/organizer/code/@code='4']/@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']]/organizer/@classCode='CATEGORY']]/@moodCode='EVN']/component[1]/@typeCode='COMP']]/substanceAdministration[id][k]/substanceAdministration/@classCode='SBADM']]/@moodCode='EVN']/outboundRelationship2/@typeCode='COMP']]/substanceAdministration[id][k]/substanceAdministration/@classCode='SBADM']]/@xsi:type='IVL_TS']/low/@value </pre> |
| <p>e</p> | | | | <p>NullFlavor</p> | <pre> /MCC1_IN200100UV01[@ITSVersion='XML_1.0']/@xsi:schemaLocation=urn:hl7-org:v3 MCC1_IN200100UV01.xsd]/PORR_IN049016UV[f]/controlActProcess/@classCode=CACAT][@moodCode=EVN]/subject/@typeCode='SUBJ']]/investigationEvent/@classCode=INVESTG][@moodCode=EVN]/component/@typeCode='COMP']]/adverseEventAssessment[1]/adverseEventAssessment/@classCode=INVESTG][@moodCode=EVN]/subject1/@typeCode='SBJ']]/primaryRole/@classCode=INVSBJ/subjectOr2/@typeCode='SBJ']]/organizer/code/@code='4']/@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']]/organizer/@classCode='CATEGORY']]/@moodCode='EVN']/component[1]/@typeCode='COMP']]/substanceAdministration[id][k]/substanceAdministration/@classCode='SBADM']]/@moodCode='EVN']/outboundRelationship2/@typeCode='COMP']]/substanceAdministration[id][k]/substanceAdministration/@classCode='SBADM']]/@xsi:type='IVL_TS']/low/@nullFlavor </pre> | |

| | | |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <p>2.以下のデータ項目の2つを超える値が表示される場合:</p> <ol style="list-style-type: none"> 1) G.k.4.r.2、 G.k.4.r.3 2) G.k.4.r.4 3) G.k.4.r.5 4) G.k.4.r.6a、 G.k.4.r.6b <p>データ型 SXPР を伴う 2 番目の comp 項目</p> <p>Parenthetic Set Expression of Time (SXPР_TS) [Intervale of Point in Time (IVL_TS)]</p> | <p>値</p> | <pre> /MCCJ_IN200100UV01[@ITSVersion="XML_1.0"]/@xsi:schemaLocation='urn:hl7-org:v3 MCCJ_IN200100UV01.xsd'/PORR_IN049016UV/rf/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="SB.J"]/primaryRole/@classCode="INVSBJ"/subjectOf2[@typeCode="SB.J"]/organizer/code[@code="4"]/@codeSystem="2.16.840.1.113883.3.988.2.1.1.20"[1]/organizer/@classCode="CATEGORY"/@moodCode="EVN"/component[@typeCode="COMP"]/substanceAdministration/d[k]/substanceAdministration[@classCode="SBADM"]/@moodCode="EVN"/youtboundRelationship2[@typeCode="COMP"]/substanceAdministration/@classCode="SBADM"/@operator="A"/low/@value </pre> |
| <p>値</p> | <p>NullFlavor</p> | <pre> /MCCJ_IN200100UV01[@ITSVersion="XML_1.0"]/@xsi:schemaLocation='urn:hl7-org:v3 MCCJ_IN200100UV01.xsd'/PORR_IN049016UV/rf/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="SB.J"]/primaryRole/@classCode="INVSBJ"/subjectOf2[@typeCode="SB.J"]/organizer/code[@code="4"]/@codeSystem="2.16.840.1.113883.3.988.2.1.1.20"[1]/organizer/@classCode="CATEGORY"/@moodCode="EVN"/component[@typeCode="COMP"]/substanceAdministration/d[k]/substanceAdministration[@classCode="SBADM"]/@moodCode="EVN"/youtboundRelationship2[@typeCode="COMP"]/substanceAdministration/@classCode="SBADM"/@operator="A"/low/@nullFlavor </pre> |

| | | | | |
|----------|------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <p>e</p> | | <p>3.以下のデータ項目の1つの値のみが表 示される場合 1) G.k.4.r.2、 G.k.4.r.3 2) G.k.4.r.4 3) G.k.4.r.5 4) G.k.4.r.6a、 G.k.4.r.6b Interval of Point in Time (IVL_TS)</p> | <p>low=Interval Boundary (VXB)</p> | <p>値</p> <pre>/MCCI_IN200100UV01[@ITSVersion='XML_1.0']/@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd)/PDRR_IN049016UVJ1/controlActProcess/@classCode=CACTI/@moodCode=EVN/subject/@typeCode=SUBJ/1/investigationEvent/@classCode=INVSTG/1/@moodCode=EVN/component/@typeCode=COMP/1/adverseEventAssessment/1/adverseEventAssessment/@classCode=INVSTG/1/@moodCode=EVN/subject1/@typeCode=SBJ/1/primaryRole/@classCode=INVSBJ/subjectOr2/@typeCode=SBJ/organizer/code/@code=4/1/@codeSystem=2.16.840.1.113883.3.989.2.1.1.20/1/1/organizer/@classCode=CATEGORY/1/@moodCode=EVN/component/@typeCode=COMP/1/substanceAdministration/@classCode=SBADM/1/@moodCode=EVN/outboundRelationship2/@typeCode=COMP/1/substanceAdministration/1/subjectAdministration/@classCode=SBADM/1/@moodCode=EVN/effectiveTime/@xsi:type=IVL_TS/low/@value</pre> |
| <p>e</p> | | <p>1.以下のデータ項目の2つを超える値が表示される場合： 1) G.k.4.r.2、 G.k.4.r.3 2) G.k.4.r.4 3) G.k.4.r.5 4) G.k.4.r.6a、 G.k.4.r.6b データ型 SXPР を伴う最初の comp 項目 Parenthetic Set Expression of Time (SXPР_TS) [Intervale of Point in Time (IVL_TS)]</p> | <p>NullFlavor</p> | <p>値</p> <pre>/MCCI_IN200100UV01[@ITSVersion='XML_1.0']/@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd)/PDRR_IN049016UVJ1/controlActProcess/@classCode=CACTI/@moodCode=EVN/subject/@typeCode=SUBJ/1/investigationEvent/@classCode=INVSTG/1/@moodCode=EVN/component/@typeCode=COMP/1/adverseEventAssessment/1/adverseEventAssessment/@classCode=INVSTG/1/@moodCode=EVN/subject1/@typeCode=SBJ/1/primaryRole/@classCode=INVSBJ/subjectOr2/@typeCode=SBJ/organizer/code/@code=4/1/@codeSystem=2.16.840.1.113883.3.989.2.1.1.20/1/1/organizer/@classCode=CATEGORY/1/@moodCode=EVN/component/@typeCode=COMP/1/substanceAdministration/@classCode=SBADM/1/@moodCode=EVN/outboundRelationship2/@typeCode=COMP/1/substanceAdministration/1/subjectAdministration/@classCode=SBADM/1/@moodCode=EVN/effectiveTime/@xsi:type=IVL_TS/low/@nullFlavor</pre> |
| <p>e</p> | <p>G.k.4.r.5 医薬品の投与終了日 日付/時間</p> | <p>高=Interval Boundary (VXB)</p> | <p>値</p> <pre>/MCCI_IN200100UV01[@ITSVersion='XML_1.0']/@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd)/PDRR_IN049016UVJ1/controlActProcess/@classCode=CACTI/@moodCode=EVN/subject/@typeCode=SUBJ/1/investigationEvent/@classCode=INVSTG/1/@moodCode=EVN/component/@typeCode=COMP/1/adverseEventAssessment/1/adverseEventAssessment/@classCode=INVSTG/1/@moodCode=EVN/subject1/@typeCode=SBJ/1/primaryRole/@classCode=INVSBJ/subjectOr2/@typeCode=SBJ/organizer/code/@code=4/1/@codeSystem=2.16.840.1.113883.3.989.2.1.1.20/1/1/organizer/@classCode=CATEGORY/1/@moodCode=EVN/component/@typeCode=COMP/1/substanceAdministration/@classCode=SBADM/1/@moodCode=EVN/outboundRelationship2/@typeCode=COMP/1/substanceAdministration/1/subjectAdministration/@xsi:type=IVL_TS/high/@value</pre> | |

(別添 3)

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

| | | | | | | |
|---|------------|-------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------|-------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| e | | | <p>3.以下のデータ項目の1つの値のみが表 示される場合</p> <p>1) G.k.4.r.2, G.k.4.r.3</p> <p>2) G.k.4.r.4</p> <p>3) G.k.4.r.5</p> <p>4) G.k.4.r.6a, G.k.4.r.6b</p> <p>Interval of Point in Time (IVL_TS)</p> | <p>high=Interval Boundary (VXB)</p> | <p>値</p> | <pre>/MCCL_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCL_IN200100UV01.xsd']/PORR_IN049016UV/r/controlActProcess/@classCode=CACTT][@moo dCode=EVN]/subject/@typeCode=SUBJ][investigationEvent/@classCode=INVTG][@moodCo de=EVN]/component/@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessme nt/@classCode=INVTG][@moodCode=EVN]/subject1/@typeCode=SBJ][1]/primaryRole/@classC ode=INVSBJ/subjectOf2/@typeCode=SBJ][organizer/code/@code=4][@codeSystem=2.16.840.1 .113883.3.988.2.1.1.20][1]/organizer/@classCode=CATEGORY][@moodCode=EVN]/component[1]/@typeCode=COMP][substanceAdministration[id][k]/substanceAdministration/@classCode=SBADM][@moodCode=EVN]/outboundRelationship2/@typeCode=COMP][substanceAdministration]/sub stanceAdministration/@classCode=SBADM][@xsi:type=IVL_TS]/high/@value</pre> |
| e | | | <p>1.以下のデータ項目 の2つを超える値が 表示される場合:</p> <p>1) G.k.4.r.2, G.k.4.r.3</p> <p>2) G.k.4.r.4</p> <p>3) G.k.4.r.5</p> <p>4) G.k.4.r.6a, G.k.4.r.6b</p> <p>データ型 SXPР を伴 う最初の comp 項目</p> <p>Parenthetic Set Expression of Time (SXPР_TS) [Intervale of Point in Time (IVL_TS)]</p> | <p>width/value=Real Number (REAL)</p> | <p>NullFlavor</p> | <pre>/MCCL_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCL_IN200100UV01.xsd']/PORR_IN049016UV/r/controlActProcess/@classCode=CACTT][@moo dCode=EVN]/subject/@typeCode=SUBJ][1]/investigationEvent/@classCode=INVTG][@moodCo de=EVN]/component/@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessme nt/@classCode=INVTG][@moodCode=EVN]/subject1/@typeCode=SBJ][1]/primaryRole/@classC ode=INVSBJ/subjectOf2/@typeCode=SBJ][organizer/code/@code=4][@codeSystem=2.16.840.1 .113883.3.988.2.1.1.20][1]/organizer/@classCode=CATEGORY][@moodCode=EVN]/component[1]/@typeCode=COMP][substanceAdministration[id][k]/substanceAdministration/@classCode=SBADM][@moodCode=EVN]/outboundRelationship2/@typeCode=COMP][substanceAdministration]/sub stanceAdministration/@classCode=SBADM][@xsi:type=IVL_TS]/high/@nullFlavor</pre> |
| e | G.k.4.r.6a | 医薬品投与期間 (数) | 5N | | <p>値</p> | <pre>/MCCL_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCL_IN200100UV01.xsd']/PORR_IN049016UV/r/controlActProcess/@classCode=CACTT][@moo dCode=EVN]/subject/@typeCode=SUBJ][1]/investigationEvent/@classCode=INVTG][@moodCo de=EVN]/component/@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessme nt/@classCode=INVTG][@moodCode=EVN]/subject1/@typeCode=SBJ][1]/primaryRole/@classC ode=INVSBJ/subjectOf2/@typeCode=SBJ][organizer/code/@code=4][@codeSystem=2.16.840.1 .113883.3.988.2.1.1.20][1]/organizer/@classCode=CATEGORY][@moodCode=EVN]/component[1]/@typeCode=COMP][substanceAdministration[id][k]/substanceAdministration/@classCode=SBADM][@moodCode=EVN]/outboundRelationship2/@typeCode=COMP][substanceAdministration]/sub stanceAdministration/@classCode=SBADM][@xsi:type=IVL_TS]/width/@value</pre> |

| | | |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <p>2. 以下のデータ項目の2つを超える値が表示される場合:</p> <ol style="list-style-type: none"> 1) G.k.4.r.2, G.k.4.r.3 2) G.k.4.r.4 3) G.k.4.r.5 4) G.k.4.r.6a, G.k.4.r.6b <p>データ型 SXPР を伴う 2 番目の comp 項目</p> <p>Parenthetic Set Expression of Time (SXPР_TS) [Intervale of Point in Time (IVL_TS)]</p> | <p>値</p> | <pre> /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UV[r]/controlActProcess[@classCode=CACT][@mo dCode=EVN]/subject[@typeCode=SUBJ][adverseEvent][@classCode=INVESTG][@moodCo de=EVN]/component[@typeCode=COMP][adverseEventAssessment][adverseEventAssessment [@classCode=INVESTG][@moodCode=EVN]/subject[@typeCode=SBJ][primaryRole[@classC ode=INVSBJ]/subjectOf2[@typeCode=SBJ][organizer/code[@code=4]][@codeSystem=2.16.840.1 13883.3.989.2.1.1.20][1]/organizer[@classCode=CATEGORY][@moodCode=EVN]/component[@typeCode=COMP][substanceAdministration/r][k]/substanceAdministration[@classCode=SBADM][@moodCode=EVN]/outboundRelationship2[@typeCode=COMP][substanceAdministration/r]/sub stanceAdministration[@classCode=SBADM][@moodCode=EVN]/effectiveTime[@xsi:type=SXPР_ TS]/comp[@xsi:type=IVL_TS][@operator=A]/width/@value </pre> |
| <p>3. 以下のデータ項目の1つの値のみが表示される場合</p> <ol style="list-style-type: none"> 1) G.k.4.r.2, G.k.4.r.3 2) G.k.4.r.4 3) G.k.4.r.5 4) G.k.4.r.6a, G.k.4.r.6b <p>Interval of Point in Time (IVL_TS)</p> | <p>値</p> <p>width/value=Real Number (REAL)</p> | <pre> /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UV[r]/investigationEvent[@classCode=CACT][@mo 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]/subjectOf2[@typeCode=SBJ][organizer/code[@code=4]][@codeSystem=2.16.840.1 13883.3.989.2.1.1.20][1]/organizer[@classCode=CATEGORY][@moodCode=EVN]/component[@typeCode=COMP][substanceAdministration/r][k]/substanceAdministration[@classCode=SBADM][@moodCode=EVN]/outboundRelationship2[@typeCode=COMP][substanceAdministration/r]/sub stanceAdministration[@classCode=SBADM][@moodCode=EVN]/effectiveTime[@xsi:type=IVL_ TS]/width/@value </pre> |

e

| | | | | |
|------------------------------------------------|-------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <p>e</p> <p>G.k.4.r.6b</p> <p>医薬品投与期間 (単位)</p> | <p>50AN</p> | <p>1.以下のデータ項目の2つを超える値が表示される場合:</p> <p>1) G.k.4.r.2, G.k.4.r.3</p> <p>2) G.k.4.r.4</p> <p>3) G.k.4.r.5</p> <p>4) G.k.4.r.6a, G.k.4.r.6b</p> <p>データ型 SXPB を伴う最初の comp 項目</p> <p>Parenthetic Set Expression of Time (SXPB_TS)[Interval of Point in Time (IVL_TS)]</p> | <p>width/unit=Coded Simple Value (CS)</p> <p>値</p> | <pre> /MCCI_IN200100UV01[@ITSVersion=XMML_1.0][@xsi:schemaLocation=urn:hl7-org:v3:MCCI_IN200100UV01.xsd]/PORR_IN049076UV/r/controlActProcess/@classCode=CACT][@moodCode=EVN]/subject/@typeCode=SUBJ][1]/investigationEvent/@classCode=INVTG][@moodCode=EVN]/component/@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment/@classCode=INVTG][@moodCode=EVN]/subject1/@typeCode=SBJ][1]/primaryRole/@classCode=INVSBJ][subjectOf2/@typeCode=SBJ][organizer/code/@code=4][@codeSystem=2.16.840.1.113883.3.989.2.1.1.20][1]/organizer/@classCode=CATEGORY][@moodCode=EVN]/component/@typeCode=COMP][substanceAdministration/d[k]/substanceAdministration/@classCode=SBADM][@xsi:type=IVL_TS][width/@unit]</pre> |
| | | | <p>値</p> | <pre> /MCCI_IN200100UV01[@ITSVersion=XMML_1.0][@xsi:schemaLocation=urn:hl7-org:v3:MCCI_IN200100UV01.xsd]/PORR_IN049076UV/r/controlActProcess/@classCode=CACT][@moodCode=EVN]/subject/@typeCode=SUBJ][1]/investigationEvent/@classCode=INVTG][@moodCode=EVN]/component/@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment/@classCode=INVTG][@moodCode=EVN]/subject1/@typeCode=SBJ][1]/primaryRole/@classCode=INVSBJ][subjectOf2/@typeCode=SBJ][organizer/code/@code=4][@codeSystem=2.16.840.1.113883.3.989.2.1.1.20][1]/organizer/@classCode=CATEGORY][@moodCode=EVN]/component/@typeCode=COMP][substanceAdministration/d[k]/substanceAdministration/@classCode=SBADM][@xsi:type=IVL_TS][width/@unit]</pre> |

(別添 3)

| | | | | | |
|----------|--------------------|----------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------|----------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <p>e</p> | | <p>3. 以下の子-タ項目の1つの値のみが表示される場合</p> <p>1) G.k.4.r.2, G.k.4.r.3 2) G.k.4.r.4 3) G.k.4.r.5 4) G.k.4.r.6a, G.k.4.r.6b</p> | <p>Interval of Point in Time (IVL_TS)</p> | <p>値</p> <p>width/unit=Coded Simple Value (CS)</p> | <pre> /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UVJ/controlActProcess[@classCode=CACT][@mo dCode=EVN]/subject[@typeCode=SUBJ][1]/investigationEvent[@classCode=INVESTG][@mo dCode=EVN]/component[@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment [@classCode=INVESTG][@moodCode=EVN]/subject[1][@typeCode=SBJ][1]/primaryRole[1].classC ode=INVSBJ]/subjectOf2[@typeCode=SBJ][organizer/code[@code=4]][@codeSystem=2.16.840.1 13883.3.989.2.1.1.20][1]/organizer[@classCode=CATEGORY][@moodCode=EVN]/component[@typeCode=COMP][substanceAdministration[id]/substanceAdministration[@classCode=SBADM][@moodCode=EVN]/outboundRelationship2[@typeCode=COMP][substanceAdministration][r/sub stanceAdministration[@classCode=SBADM][@moodCode=EVN]/effectiveTime[@xsi:type=IVL_TS]/width/@unit </pre> |
| <p>e</p> | <p>G.k.4.r.7</p> | <p>バッチ/ロット番号</p> | <p>35AN</p> | <p>値</p> | <pre> /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UVJ/controlActProcess[@classCode=CACT][@mo dCode=EVN]/subject[@typeCode=SUBJ][1]/investigationEvent[@classCode=INVESTG][@mo dCode=EVN]/component[@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment [@classCode=INVESTG][@moodCode=EVN]/subject[1][@typeCode=SBJ][1]/primaryRole[1].classC ode=INVSBJ]/subjectOf2[@typeCode=SBJ][organizer/code[@code=4]][@codeSystem=2.16.840.1 13883.3.989.2.1.1.20][1]/organizer[@classCode=CATEGORY][@moodCode=EVN]/component[@typeCode=COMP][substanceAdministration[id]/substanceAdministration[@classCode=SBADM][@moodCode=EVN]/outboundRelationship2[@typeCode=COMP][substanceAdministration][r/sub stanceAdministration[@classCode=SBADM][@moodCode=EVN]/consumable[@typeCode=CSM][1]/instanceOfKind[@classCode=INST]/productInstance[@classCode=MMA1][@determine rCode=INSTANCE]/lotNumber/text() </pre> |
| <p>e</p> | <p>G.k.4.r.8</p> | <p>投与量を表す記述情報</p> | <p>2000AN</p> | <p>値</p> | <pre> /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UVJ/controlActProcess[@classCode=CACT][@mo dCode=EVN]/subject[@typeCode=SUBJ][1]/investigationEvent[@classCode=INVESTG][@mo dCode=EVN]/component[@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment [@classCode=INVESTG][@moodCode=EVN]/subject[1][@typeCode=SBJ][1]/primaryRole[1].classC ode=INVSBJ]/subjectOf2[@typeCode=SBJ][organizer/code[@code=4]][@codeSystem=2.16.840.1 13883.3.989.2.1.1.20][1]/organizer[@classCode=CATEGORY][@moodCode=EVN]/component[@typeCode=COMP][substanceAdministration[id]/substanceAdministration[@classCode=SBADM][@moodCode=EVN]/outboundRelationship2[@typeCode=COMP][substanceAdministration][r/sub stanceAdministration[@classCode=SBADM][@moodCode=EVN]/text/text() </pre> |
| <p>h</p> | <p>G.k.4.r.9</p> | <p>医薬品精形</p> | | <p>値</p> | <pre> /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UVJ/controlActProcess[@classCode=CACT][@mo dCode=EVN]/subject[@typeCode=SUBJ][1]/investigationEvent[@classCode=INVESTG][@mo dCode=EVN]/component[@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment [@classCode=INVESTG][@moodCode=EVN]/subject[1][@typeCode=SBJ][1]/primaryRole[1].classC ode=INVSBJ]/subjectOf2[@typeCode=SBJ][organizer/code[@code=4]][@codeSystem=2.16.840.1 13883.3.989.2.1.1.20][1]/organizer[@classCode=CATEGORY][@moodCode=EVN]/component[@typeCode=COMP][substanceAdministration[id]/substanceAdministration[@classCode=SBADM][@moodCode=EVN]/outboundRelationship2[@typeCode=COMP][substanceAdministration][r/sub stanceAdministration[@classCode=SBADM][@moodCode=EVN]/consumable[@typeCode=CSM][1]/instanceOfKind[@classCode=INST]/kindOfProduct[@classCode=MMA1][@determinerCode=KI ND]/formCode[@codeSystem=TTBD-DoseForm]/originalText/text() </pre> |
| <p>e</p> | <p>G.k.4.r.9.1</p> | <p>医薬品剤形 (自由記載)</p> | <p>60AN</p> | <p>値</p> | <pre> /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UVJ/controlActProcess[@classCode=CACT][@mo dCode=EVN]/subject[@typeCode=SUBJ][1]/investigationEvent[@classCode=INVESTG][@mo dCode=EVN]/component[@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment [@classCode=INVESTG][@moodCode=EVN]/subject[1][@typeCode=SBJ][1]/primaryRole[1].classC ode=INVSBJ]/subjectOf2[@typeCode=SBJ][organizer/code[@code=4]][@codeSystem=2.16.840.1 13883.3.989.2.1.1.20][1]/organizer[@classCode=CATEGORY][@moodCode=EVN]/component[@typeCode=COMP][substanceAdministration[id]/substanceAdministration[@classCode=SBADM][@moodCode=EVN]/outboundRelationship2[@typeCode=COMP][substanceAdministration][r/sub stanceAdministration[@classCode=SBADM][@moodCode=EVN]/consumable[@typeCode=CSM][1]/instanceOfKind[@classCode=INST]/kindOfProduct[@classCode=MMA1][@determinerCode=KI ND]/formCode[@codeSystem=TTBD-DoseForm]/originalText/text() </pre> |

(別添 3)

| | | | | | | | |
|---|--------------|--------------------------|----------------------|--------------------------------|---------------------------------------------|------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| e | G.k.4.r.9.2a | 医薬品剤形の ID パージョン 日付／番号 | M5 ガイド ラインを参 照 | Coded With Equivalents (CE) | codeSystemVersion= Character String (ST) | NullFlavor | /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UV/r/controlAcqProcess/@classCode=CACTT[@moo dCode=EVN]/subject/@typeCode=SUBJ[1]/investigationEvent/@classCode=INVESTG[@moodCo de=EVN]/component/@typeCode=COMP[1]/adverseEventAssessment[1]/adverseEventAssessment /@classCode=INVESTG[@moodCode=EVN]/subject1/@typeCode=SBJ[1]/primaryRole/@classC ode=INVSBJ[subjectOr2/@typeCode=SBJ]/organizer/@code=4[@codeSystem=2,16,840,1 113883.3,989.2,1,1,20][1]/organizer/@classCode=CATEGORY[1]/moodCode=EVN]/component[@typeCode=COMP]/substanceAdministration[id][k]/substanceAdministration/@classCode=SBADM [1]/moodCode=EVN]/outboundRelationship2/@typeCode=COMP[1]/substanceAdministration[1]/sub stanceAdministration/@classCode=SBADM[1]/moodCode=EVN]/consumable/@typeCode=CSTM[1] 1]/instanceOfKind/@classCode=INST[1]/kindOfProduct/@classCode=MMAT[1]/determinerCode=KI ND]/formCode/@codeSystem=TBD-DoseForm]/originalText/@nullFlavor |
| e | G.k.4.r.9.2b | 医薬品剤形の ID | M5 ガイド ラインを参 照 | Coded With Equivalents (CE) | code=Character String (ST) | 値 | /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UV/r/controlAcqProcess/@classCode=CACTT[@moo dCode=EVN]/subject/@typeCode=SUBJ[1]/investigationEvent/@classCode=INVESTG[@moodCo de=EVN]/component/@typeCode=COMP[1]/adverseEventAssessment[1]/adverseEventAssessment /@classCode=INVESTG[@moodCode=EVN]/subject1/@typeCode=SBJ[1]/primaryRole/@classC ode=INVSBJ[subjectOr2/@typeCode=SBJ]/organizer/@code=4[@codeSystem=2,16,840,1 113883.3,989.2,1,1,20][1]/organizer/@classCode=CATEGORY[1]/moodCode=EVN]/component[@typeCode=COMP]/substanceAdministration[id][k]/substanceAdministration/@classCode=SBADM [1]/moodCode=EVN]/outboundRelationship2/@typeCode=COMP[1]/substanceAdministration[1]/sub stanceAdministration/@classCode=SBADM[1]/moodCode=EVN]/consumable/@typeCode=CSTM[1] 1]/instanceOfKind/@classCode=INST[1]/kindOfProduct/@classCode=MMAT[1]/determinerCode=KI ND]/formCode/@codeSystem=TBD-DoseForm]/@codeSystemVersion |
| h | G.k.4.r.10 | 投与経路 | | | | 値 | /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UV/r/controlAcqProcess/@classCode=CACTT[@moo dCode=EVN]/subject/@typeCode=SUBJ[1]/investigationEvent/@classCode=INVESTG[@moodCo de=EVN]/component/@typeCode=COMP[1]/adverseEventAssessment[1]/adverseEventAssessment /@classCode=INVESTG[@moodCode=EVN]/subject1/@typeCode=SBJ[1]/primaryRole/@classC ode=INVSBJ[subjectOr2/@typeCode=SBJ]/organizer/@code=4[@codeSystem=2,16,840,1 113883.3,989.2,1,1,20][1]/organizer/@classCode=CATEGORY[1]/moodCode=EVN]/component[@typeCode=COMP]/substanceAdministration[id][k]/substanceAdministration/@classCode=SBADM [1]/moodCode=EVN]/outboundRelationship2/@typeCode=COMP[1]/substanceAdministration[1]/sub stanceAdministration/@classCode=SBADM[1]/moodCode=EVN]/consumable/@typeCode=CSTM[1] 1]/instanceOfKind/@classCode=INST[1]/kindOfProduct/@classCode=MMAT[1]/determinerCode=KI ND]/formCode/@codeSystem=TBD-DoseForm]/@code |
| e | G.k.4.r.10.1 | 投与経路 (自由記載) | 60AN | Coded With Equivalents (CE) | originalText=Encapsu lated Data (ED) | 値 | /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UV/r/controlAcqProcess/@classCode=CACTT[@moo dCode=EVN]/subject/@typeCode=SUBJ[1]/investigationEvent/@classCode=INVESTG[@moodCo de=EVN]/component/@typeCode=COMP[1]/adverseEventAssessment[1]/adverseEventAssessment /@classCode=INVESTG[@moodCode=EVN]/subject1/@typeCode=SBJ[1]/primaryRole/@classC ode=INVSBJ[subjectOr2/@typeCode=SBJ]/organizer/@code=4[@codeSystem=2,16,840,1 113883.3,989.2,1,1,20][1]/organizer/@classCode=CATEGORY[1]/moodCode=EVN]/component[@typeCode=COMP]/substanceAdministration[id][k]/substanceAdministration/@classCode=SBADM [1]/moodCode=EVN]/outboundRelationship2/@typeCode=COMP[1]/substanceAdministration[1]/sub stanceAdministration/@classCode=SBADM[1]/moodCode=EVN]/consumable/@typeCode=CSTM[1] 1]/instanceOfKind/@classCode=INST[1]/kindOfProduct/@classCode=MMAT[1]/determinerCode=KI ND]/formCode/@codeSystem=TBD-DoseForm]/@code |

(別添 3)

| | | | | | | | |
|---|---------------|----------------------|--------------------|-----------------------------|------------------------------------------|------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| e | G.k.4.r.10.2a | 投与経路の ID パージョン日付ノ番号 | M5 ガイドラインを参照 | Coded With Equivalents (CE) | code=SystemVersion=Character String (ST) | NullFlavor | <pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/PORR_IN049016UV/rj/controlActProcess[@classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUBJ][1]/investigationEvent[@classCode=INVESTG][@moodCode=EVN]/component[@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment[@classCode=INVESTG][@moodCode=EVN]/subject1[@typeCode=SBJ][1]/primaryRole[@classCode=INVSBJ]/subjectOf2[@typeCode=SBJ][organizer/code[@code=4]][@codeSystem=2.16.840.1.113883.3.989.2.1.1.20][1]/organizer[@classCode=CATEGORY][@moodCode=EVN]/component[1][@typeCode=COMP][substanceAdministration[id][k]/substanceAdministration[@classCode=SBADM][@moodCode=EVN]/outboundRelationship2[@typeCode=COMP][substanceAdministration][r]/substanceAdministration[@classCode=SBADM][@moodCode=EVN]/routeCode[@codeSystem=2.16.840.1.113883.3.989.2.1.1.14]/originalText/@nullFlavor </pre> |
| e | G.k.4.r.10.2b | 投与経路の ID | M5 ガイドライン (3N) を参照 | Coded With Equivalents (CE) | code=Character String (ST) | 値 | <pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/PORR_IN049016UV/rj/controlActProcess[@classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUBJ][1]/investigationEvent[@classCode=INVESTG][@moodCode=EVN]/component[@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment[@classCode=INVESTG][@moodCode=EVN]/subject1[@typeCode=SBJ][1]/primaryRole[@classCode=INVSBJ]/subjectOf2[@typeCode=SBJ][organizer/code[@code=4]][@codeSystem=2.16.840.1.113883.3.989.2.1.1.20][1]/organizer[@classCode=CATEGORY][@moodCode=EVN]/component[1][@typeCode=COMP][substanceAdministration[id][k]/substanceAdministration[@classCode=SBADM][@moodCode=EVN]/outboundRelationship2[@typeCode=COMP][substanceAdministration][r]/substanceAdministration[@classCode=SBADM][@moodCode=EVN]/routeCode[@codeSystem=2.16.840.1.113883.3.989.2.1.1.14]/@codeSystemVersion </pre> |
| h | G.k.4.r.11 | 親への投与経路 (親子ノ胎児報告の場合) | | | | | <pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/PORR_IN049016UV/rj/controlActProcess[@classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUBJ][1]/investigationEvent[@classCode=INVESTG][@moodCode=EVN]/component[@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment[@classCode=INVESTG][@moodCode=EVN]/subject1[@typeCode=SBJ][1]/primaryRole[@classCode=INVSBJ]/subjectOf2[@typeCode=SBJ][organizer/code[@code=4]][@codeSystem=2.16.840.1.113883.3.989.2.1.1.20][1]/organizer[@classCode=CATEGORY][@moodCode=EVN]/component[1][@typeCode=COMP][substanceAdministration[id][k]/substanceAdministration[@classCode=SBADM][@moodCode=EVN]/outboundRelationship2[@typeCode=COMP][substanceAdministration][r]/substanceAdministration[@classCode=SBADM][@moodCode=EVN]/routeCode[@codeSystem=2.16.840.1.113883.3.989.2.1.1.14]/@code </pre> |
| e | G.k.4.r.11.1 | 親への投与経路 (自由記載) | 60AN | Coded With Equivalents (CE) | originalText=Encapsulated Data (ED) | 値 | <pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/PORR_IN049016UV/rj/controlActProcess[@classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUBJ][1]/investigationEvent[@classCode=INVESTG][@moodCode=EVN]/component[@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment[@classCode=INVESTG][@moodCode=EVN]/subject1[@typeCode=SBJ][1]/primaryRole[@classCode=INVSBJ]/subjectOf2[@typeCode=SBJ][organizer/code[@code=4]][@codeSystem=2.16.840.1.113883.3.989.2.1.1.20][1]/organizer[@classCode=CATEGORY][@moodCode=EVN]/component[1][@typeCode=COMP][substanceAdministration[id][k]/substanceAdministration[@classCode=SBADM][@moodCode=EVN]/outboundRelationship2[@typeCode=COMP][substanceAdministration][r]/substanceAdministration[@classCode=SBADM][@moodCode=EVN]/routeCode[@codeSystem=2.16.840.1.113883.3.989.2.1.1.14]/@codeSystemVersion </pre> |

(別添3)

| | | | | | | |
|---|---------------|-----------------------------|---------------------------|----------------------------------------------|-----------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| e | G.k.4.r.11.2a | 親への投与経路の ID パー ジョン日付/番号 | M5 ガイド ラインを参 照 | Coded With Equivalents (CE) | NullFlavor | <pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/PORR_IN049016UV/r/controlActProcess/@classCode=CACTT][@moo dCode=EVN]/subject/@typeCode=SUBJ][1]/investigationEvent/@classCode=INVTG][@moodCo de=EVN]/component/@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment [@classCode=INVTG][@moodCode=EVN]/subject1/@typeCode=SBJ][1]/primaryRole/@classC ode=INVSBJ][subjectOr2/@typeCode=SBJ][organizer/code/@code=4][@codeSystem=2.16.840.1 .113883.3.989.2.1.1.20][1]/organizer/@classCode=CATEGORY][@moodCode=EVN]/component[@typeCode=COMP][substanceAdministration[id]/k/substanceAdministration/@classCode=SBADM][@moodCode=EVN]/outboundRelationship2/@typeCode=COMP][substanceAdministration]/sub stanceAdministration/@classCode=SBADM][@moodCode=EVN]/inboundRelationship/@typeCode =REFR][observation/code/@code=28][@codeSystem=2.16.840.1.113883.3.989.2.1.1.19][1]/obse rvation/@classCode=OBS][@moodCode=EVN]/value/@xsi:type=CE][@codeSystem=2.16.840.1. 113883.3.989.2.1.1.14][1]/originalText/@nullFlavor </pre> |
| e | G.k.4.r.11.2b | 親への投与経路の ID | M5 ガイド ラインを参 照 (3N) | code=SystemVersion= Character String (ST) | 値 | <pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/PORR_IN049016UV/r/controlActProcess/@classCode=CACTT][@moo dCode=EVN]/subject/@typeCode=SUBJ][1]/investigationEvent/@classCode=INVTG][@moodCo de=EVN]/component/@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment [@classCode=INVTG][@moodCode=EVN]/subject1/@typeCode=SBJ][1]/primaryRole/@classC ode=INVSBJ][subjectOr2/@typeCode=SBJ][organizer/code/@code=4][@codeSystem=2.16.840.1 .113883.3.989.2.1.1.20][1]/organizer/@classCode=CATEGORY][@moodCode=EVN]/component[@typeCode=COMP][substanceAdministration[id]/k/substanceAdministration/@classCode=SBADM][@moodCode=EVN]/outboundRelationship2/@typeCode=COMP][substanceAdministration]/sub stanceAdministration/@classCode=SBADM][@moodCode=EVN]/inboundRelationship/@typeCode =REFR][observation/code/@code=28][@codeSystem=2.16.840.1.113883.3.989.2.1.1.19][1]/obse rvation/@classCode=OBS][@moodCode=EVN]/value/@xsi:type=CE][@codeSystem=2.16.840.1. 113883.3.989.2.1.1.14][1]/@codeSystemVersion </pre> |
| e | G.k.5a | 副作用/有害事象発現まで の累積総投与量 (数) | 10N | Physical Quantity (PQ) | value=Real Number (REAL) | <pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/PORR_IN049016UV/r/controlActProcess/@classCode=CACTT][@moo dCode=EVN]/subject/@typeCode=SUBJ][1]/investigationEvent/@classCode=INVTG][@moodCo de=EVN]/component/@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment [@classCode=INVTG][@moodCode=EVN]/subject1/@typeCode=SBJ][1]/primaryRole/@classC ode=INVSBJ][subjectOr2/@typeCode=SBJ][organizer/code/@code=4][@codeSystem=2.16.840.1 .113883.3.989.2.1.1.20][1]/organizer/@classCode=CATEGORY][@moodCode=EVN]/component[@typeCode=COMP][substanceAdministration[id]/k/substanceAdministration/@classCode=SBADM][@moodCode=EVN]/outboundRelationship2/@typeCode=COMP][substanceAdministration]/sub stanceAdministration/@classCode=SBADM][@moodCode=EVN]/inboundRelationship/@typeCode =REFR][observation/code/@code=28][@codeSystem=2.16.840.1.113883.3.989.2.1.1.19][1]/obse rvation/@classCode=OBS][@moodCode=EVN]/value/@xsi:type=CE][@codeSystem=2.16.840.1. 113883.3.989.2.1.1.14][1]/@code </pre> |

(別添 3)

| | | | | | | | |
|---|---------|-------------------------|------|------------------------|------------------------------|---------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| e | G.k.6b | 副作用／有害事象発現までの累積総投与量（単位） | 50AN | Physical Quantity (PQ) | unit=Coded Simple Value (CS) | 値 | /MCC1_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3:MCC1_IN200100UV01.xsd']/PORR_IN049016UVJ/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='EVN']/organizer[@code='4'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[1]@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']/observation[@code='14'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']/observation[@code='14'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']/observation[@code='OBS'][@moodCode='EVN']/value[@xsi:type='PQ']/value |
| e | G.k.6a | 曝露時の妊娠期間（数） | 3N | Physical Quantity (PQ) | value=Real Number (REAL) | 値 | /MCC1_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3:MCC1_IN200100UV01.xsd']/PORR_IN049016UVJ/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='EVN']/organizer[@code='4'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[1]@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']/observation[@code='16'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']/observation[@code='16'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']/observation[@code='OBS'][@moodCode='EVN']/value[@xsi:type='PQ']/value |
| e | G.k.6b | 曝露時の妊娠期間（単位） | 50AN | Physical Quantity (PQ) | unit=Coded Simple Value (CS) | 値 | /MCC1_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3:MCC1_IN200100UV01.xsd']/PORR_IN049016UVJ/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='EVN']/organizer[@code='4'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[1]@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']/observation[@code='16'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']/observation[@code='16'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']/observation[@code='OBS'][@moodCode='EVN']/value[@xsi:type='PQ']/value |
| h | G.k.7.r | 医薬品使用理由（必要に応じ繰り返し返す） | | | | 繰り返し返す ノード | /MCC1_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3:MCC1_IN200100UV01.xsd']/PORR_IN049016UVJ/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='EVN']/organizer[@code='4'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[1]@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']/observation[@code='16'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']/observation[@code='16'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']/observation[@code='OBS'][@moodCode='EVN']/value[@xsi:type='PQ']/value |

(別添 3)

| | |
|------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <p>e</p> <p>G.k.7.r.1</p> <p>第一次情報源により報告された使用理由</p> <p>250AN</p> <p>Coded With Equivalents (CE)</p> <p>originalText=Encapsulated Data (ED)</p> <p>値</p> | <pre> /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UV/r/controlActProcess[@classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUBJ][@investigationEvent][@classCode=INVTG][@moodCode=EVN]/component[@typeCode=COMP][adverseEventAssessment][@adverseEventAssessment[@classCode=INVTG][@moodCode=EVN]/subject1[@typeCode=SBJ][@primaryRole][@classCode=INVSBJ]/subjectO2[@typeCode=SBJ][organizer/code][@code=4][@codeSystem=2.16.840.1.113883.3.989.2.1.1.20][@organizer/@classCode=CATEGORY][@moodCode=EVN]/component[@typeCode=COMP][substanceAdministration/id][substanceAdministration[@classCode=SBADM][@moodCode=EVN]/inboundRelationship[@typeCode=RSN][observation/code][@code=19][@codeSystem=2.16.840.1.113883.3.989.2.1.1.19][@observation/@classCode=OBS][@moodCode=EVN]/performer[@typeCode=PRF]/assignedEntity[@classCode=ASSIGNED]/code[@code=3][@codeSystem=2.16.840.1.113883.3.989.2.1.1.21][@value/@xsi:type=CE][@codeSystem=2.16.840.1.113883.6.163][@originalText/text() </pre> |
| <p>e</p> <p>NullFlavor</p> | <pre> /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UV/r/controlActProcess[@classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUBJ][@investigationEvent][@classCode=INVTG][@moodCode=EVN]/component[@typeCode=COMP][adverseEventAssessment][@adverseEventAssessment[@classCode=INVTG][@moodCode=EVN]/subject1[@typeCode=SBJ][@primaryRole][@classCode=INVSBJ]/subjectO2[@typeCode=SBJ][organizer/code][@code=4][@codeSystem=2.16.840.1.113883.3.989.2.1.1.20][@organizer/@classCode=CATEGORY][@moodCode=EVN]/component[@typeCode=COMP][substanceAdministration/id][substanceAdministration[@classCode=SBADM][@moodCode=EVN]/inboundRelationship[@typeCode=RSN][observation/code][@code=19][@codeSystem=2.16.840.1.113883.3.989.2.1.1.19][@observation/@classCode=OBS][@moodCode=EVN]/performer[@typeCode=PRF]/assignedEntity[@classCode=ASSIGNED]/code[@code=3][@codeSystem=2.16.840.1.113883.3.989.2.1.1.21][@value/@xsi:type=CE][@codeSystem=2.16.840.1.113883.6.163][@originalText/@nullFlavor </pre> |
| <p>e</p> <p>G.k.7.r.2a</p> <p>使用理由の MedDRA パージョン</p> <p>4AN</p> <p>Coded With Equivalents (CE)</p> <p>codeSystemVersion=Character String (ST)</p> <p>値</p> | <pre> /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UV/r/controlActProcess[@classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUBJ][@investigationEvent][@classCode=INVTG][@moodCode=EVN]/component[@typeCode=COMP][adverseEventAssessment][@adverseEventAssessment[@classCode=INVTG][@moodCode=EVN]/subject1[@typeCode=SBJ][@primaryRole][@classCode=INVSBJ]/subjectO2[@typeCode=SBJ][organizer/code][@code=4][@codeSystem=2.16.840.1.113883.3.989.2.1.1.20][@organizer/@classCode=CATEGORY][@moodCode=EVN]/component[@typeCode=COMP][substanceAdministration/id][substanceAdministration[@classCode=SBADM][@moodCode=EVN]/inboundRelationship[@typeCode=RSN][observation/code][@code=19][@codeSystem=2.16.840.1.113883.3.989.2.1.1.19][@observation/@classCode=OBS][@moodCode=EVN]/performer[@typeCode=PRF]/assignedEntity[@classCode=ASSIGNED]/code[@code=3][@codeSystem=2.16.840.1.113883.3.989.2.1.1.21][@value/@xsi:type=CE][@codeSystem=2.16.840.1.113883.6.163][@originalText/@codeSystemVersion </pre> |

(別添 3)

| | | | | | | |
|---|---------------|---------------------------------|------|-----------------------------|-------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| e | G.k.9.i.2.r.1 | 評価の情報源 | 60AN | Coded With Equivalents (CE) | originalText=Encapsulated Data (ED) | <pre> /MCC1_IN200100UV01[@ITSVersion=XML_1.0' MCC1_IN200100UV01.xsd]/PORR_IN049016UV1/controlActProcess[@classCode=CACT][@moodCode=EVN]/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode=INVTG][@moodCode=EVN]/component[@typeCode='COMP']/adverseEventAssessment[1]/adverseEventAssessment[@classCode=INVTG][@moodCode=EVN]/component[@typeCode='COMP']/causalityAssessment[ni/code[@code='39']][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']][causalityAssessment[@classCode=OBS][@moodCode=EVN][subject1[@typeCode='SUBJ']/adverseEffectReference[@classCode=OBS][@moodCode=EVN]/id[@root=UUIID of i-th reaction][subject2[@typeCode='SUBJ']/productUseReference[@classCode=SBADM][@moodCode=EVN]/id[@root=UUIID of k-th drug][author[@typeCode=AUT][1]/assignedEntity[@classCode=ASSIGNED]/code/originalText/text() </pre> |
| e | G.k.9.i.2.r.2 | 評価方法 | 60AN | Coded With Equivalents (CE) | originalText=Encapsulated Data (ED) | <pre> /MCC1_IN200100UV01[@ITSVersion=XML_1.0' MCC1_IN200100UV01.xsd]/PORR_IN049016UV1/controlActProcess[@classCode=CACT][@moodCode=EVN]/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode=INVTG][@moodCode=EVN]/component[@typeCode='COMP']/adverseEventAssessment[1]/adverseEventAssessment[@classCode=INVTG][@moodCode=EVN]/component[@typeCode='COMP']/causalityAssessment[ni/code[@code='39']][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']][causalityAssessment[@classCode=OBS][@moodCode=EVN][subject1[@typeCode='SUBJ']/adverseEffectReference[@classCode=OBS][@moodCode=EVN]/id[@root=UUIID of i-th reaction][subject2[@typeCode='SUBJ']/productUseReference[@classCode=SBADM][@moodCode=EVN]/id[@root=UUIID of k-th drug]/methodCode[1]/originalText/text() </pre> |
| e | G.k.9.i.2.r.3 | 評価結果 | 60AN | Character String (ST) | | <pre> /MCC1_IN200100UV01[@ITSVersion=XML_1.0' MCC1_IN200100UV01.xsd]/PORR_IN049016UV1/controlActProcess[@classCode=CACT][@moodCode=EVN]/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode=INVTG][@moodCode=EVN]/component[@typeCode='COMP']/adverseEventAssessment[1]/adverseEventAssessment[@classCode=INVTG][@moodCode=EVN]/component[@typeCode='COMP']/causalityAssessment[ni/code[@code='39']][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']][causalityAssessment[@classCode=OBS][@moodCode=EVN][subject1[@typeCode='SUBJ']/adverseEffectReference[@classCode=OBS][@moodCode=EVN]/id[@root=UUIID of i-th reaction][subject2[@typeCode='SUBJ']/productUseReference[@classCode=SBADM][@moodCode=EVN]/id[@root=UUIID of k-th drug]/value[@xsi:type=ST]/text() </pre> |
| e | G.k.9.i.3.1a | 医薬品の投与開始から副作用／有害事象発現までの時間間隔 (数) | 5N | Physical Quantity (PQ) | value=Real Number (REAL) | <pre> /MCC1_IN200100UV01[@ITSVersion=XML_1.0' MCC1_IN200100UV01.xsd]/PORR_IN049016UV1/controlActProcess[@classCode=CACT][@moodCode=EVN]/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode=INVTG][@moodCode=EVN]/component[@typeCode='COMP']/adverseEventAssessment[1]/adverseEventAssessment[@classCode=INVTG][@moodCode=EVN]/subjectO2[@typeCode='SUBJ']/organizer[@classCode='CATEGORY']][@moodCode=EVN][code[@code=4][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][component[@typeCode=COMP][substanceAdministration[id][K]/substanceAdministration[@classCode=SBADM][@moodCode=EVN]/outboundRelationship1[@typeCode=SAS][aciReference[@classCode=OBS][@moodCode=EVN]/id[@root=UUIID of i-th reaction][pauseQuantity/@value </pre> |

| | | | | |
|------------------------------|----------------------------------------------------|----------------------------------------------------------------------|----------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <p>e</p> <p>G.k.9.1.3.1b</p> | <p>医薬品の投与開始から副作用／有害事象発現までの時間間隔（単位）</p> <p>50AN</p> | <p>Physical Quantity (PQ)</p> <p>unit=Coded Simple Value (CS)</p> | <p>値</p> | <pre> /MCCI_IN200100UV01[@ITSVersion='XML_1.0']/@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd/PORR_IN049016UV01/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='SB']/primaryRole/@classCode='INVSBJ']/subjectOf2[@typeCode='SB']/organizer[@classCode='CATEGORY']/@moodCode='EVN']/code/@code=4[@codeSystem=2.16.840.1.113883.3.989.2.1.1.20][1]/component/@typeCode='COMP']/substanceAdministration[id][k]/substanceAdministration[@classCode='SBADM']/@moodCode='EVN']/id/@root='UUIID of i-h reaction'[/pauseQuantity/@unit </pre> |
| <p>e</p> <p>G.k.9.1.3.2a</p> | <p>医薬品の最終投与から副作用／有害事象発現までの時間間隔（数）</p> <p>5N</p> | <p>Physical Quantity (PQ)</p> <p>value=Real Number (REAL)</p> | <p>値</p> | <pre> /MCCI_IN200100UV01[@ITSVersion='XML_1.0']/@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd/PORR_IN049016UV01/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='SB']/primaryRole/@classCode='INVSBJ']/subjectOf2[@typeCode='SB']/organizer[@classCode='CATEGORY']/@moodCode='EVN']/code/@code=4[@codeSystem=2.16.840.1.113883.3.989.2.1.1.20][1]/component/@typeCode='COMP']/substanceAdministration[id][k]/substanceAdministration[@classCode='SBADM']/@moodCode='EVN']/id/@root='UUIID of i-h reaction'[/pauseQuantity/@value </pre> |
| <p>e</p> <p>G.k.9.1.3.2b</p> | <p>医薬品の最終投与から副作用／有害事象発現までの時間間隔（単位）</p> <p>50AN</p> | <p>Physical Quantity (PQ)</p> <p>unit=Coded Simple Value (CS)</p> | <p>値</p> | <pre> /MCCI_IN200100UV01[@ITSVersion='XML_1.0']/@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd/PORR_IN049016UV01/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='SB']/primaryRole/@classCode='INVSBJ']/subjectOf2[@typeCode='SB']/organizer[@classCode='CATEGORY']/@moodCode='EVN']/code/@code=4[@codeSystem=2.16.840.1.113883.3.989.2.1.1.20][1]/component/@typeCode='COMP']/substanceAdministration[id][k]/substanceAdministration[@classCode='SBADM']/@moodCode='EVN']/id/@root='UUIID of i-h reaction'[/pauseQuantity/@unit </pre> |
| <p>e</p> <p>G.k.9.1.4</p> | <p>再投与で副作用は再発したか？</p> <p>1N</p> | <p>Coded With Equivalents (CE)</p> <p>code=Character String (ST)</p> | <p>値</p> | <pre> /MCCI_IN200100UV01[@ITSVersion='XML_1.0']/@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd/PORR_IN049016UV01/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='SB']/primaryRole/@classCode='INVSBJ']/subjectOf2[@typeCode='SB']/organizer[@classCode='CATEGORY']/@moodCode='EVN']/code/@code=4[@codeSystem=2.16.840.1.113883.3.989.2.1.1.20][1]/component/@typeCode='COMP']/substanceAdministration[id][k]/substanceAdministration[@classCode='SBADM']/@moodCode='EVN']/id/@root='UUIID of i-h reaction'[/actReference/@classCode='EVN']/id/@root='UUIID of i-h reaction'[/value] </pre> |

| | | | | | | |
|---|----------|--------------------------------------|----------|-----------------------------|-------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| e | G.k.11 | 医薬品に関するその他の情報 (自由記載) | 2000AN | Character String (ST) | 値 | /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PDRR_IN049016UVU1/controlActProcess[@classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUBJ][1]/investigationEvent[@classCode=INVESTG][@moodCode=EVN]/component[@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment[@classCode=INVESTG][@moodCode=EVN]/subject[1]/primaryRole[@classCode=INVSBJ][@typeCode=EVN]/component[1]/organizer[@typeCode=SBJ][1]/organizer[@classCode=CATEGORY][@moodCode=EVN]/component[1]/substanceAdministration[id]/substanceAdministration[@classCode=SBADM][@moodCode=EVN]/outboundRelationship2[@typeCode=REFR][observation/code[@code=2][@codeSystem=2.16.840.1.113883.3.989.2.1.1.19][1]]/observation/code[@code=2][@codeSystem=2.16.840.1.113883.3.989.2.1.1.19][1]]/text |
| h | H | 症例概要及びその他の情報の記述 | | | | |
| e | H.1 | 臨床経過、治療処置、転帰及びその他の関連情報を含む症例の記述情報 | 100000AN | Encapsulated Data (ED) | 値 | /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PDRR_IN049016UVU1/controlActProcess[@classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUBJ][1]/investigationEvent[@classCode=INVESTG][@moodCode=EVN]/text |
| e | H.2 | 報告者の意見 | 20000AN | Encapsulated Data (ED) | 値 | /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PDRR_IN049016UVU1/controlActProcess[@classCode=CACT][@moodCode=EVN]/component[@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment[@classCode=INVESTG][@moodCode=EVN]/component[1]/typeCode=COMP][observationEvent/code[@code=10][@codeSystem=2.16.840.1.113883.3.989.2.1.1.19][author/@typeCode=AUT]/asSignedEntity[@classCode=ASSIGNED]/code[@code=3][@codeSystem=2.16.840.1.113883.3.989.2.1.1.21][1]]/observationEvent[@classCode=OBS][@moodCode=EVN]/value[@xsi:type=ED]/text |
| h | H.3.r | 送信者による診断名 (必要に応じて繰り返し返す) | | | 繰り返し ノード | /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PDRR_IN049016UVU1/controlActProcess[@classCode=CACT][@moodCode=EVN]/component[@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment[@classCode=INVESTG][@moodCode=EVN]/component[1]/typeCode=COMP][observationEvent/code[@code=15][@codeSystem=2.16.840.1.113883.3.989.2.1.1.19][author/@typeCode=AUT]/asSignedEntity[@classCode=ASSIGNED]/code[@code=4][@codeSystem=2.16.840.1.113883.3.989.2.1.1.21][1]] |
| e | H.3.r.1a | 送信者による診断名/症候群及び/又は副作用/有害事象の再分類のバージョン | 4AN | Coded With Equivalents (CE) | 値 | /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PDRR_IN049016UVU1/controlActProcess[@classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUBJ][1]/investigationEvent[@classCode=INVESTG][@moodCode=EVN]/component[@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment[@classCode=INVESTG][@moodCode=EVN]/component[1]/typeCode=COMP][observationEvent/code[@code=15][@codeSystem=2.16.840.1.113883.3.989.2.1.1.19][author/@typeCode=AUT]/asSignedEntity[@classCode=ASSIGNED]/code[@code=11][@codeSystem=2.16.840.1.113883.3.989.2.1.1.21][1]]/observationEvent[@classCode=OBS][@moodCode=EVN]/value[@xsi:type=CE][@codeSystem=2.16.840.1.113883.6.163]/@codeSystemVersion |

| | | | | | | | |
|---|----------|--------------------------------------------|----------|-----------------------------|----------------------------------|-----------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| e | H.3.r.1b | 送達者による診断名/症候群及び/又は副作用/有害事象の再分類 (MedDRAコード) | 8N | Coded With Equivalents (OE) | code=Character String (ST) | 値 | <pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UV/r/controlActProcess/@classCode=CACT][@moodCode=EVN]/subject/@typeCode=SUB/J[1]/investigationEvent/@classCode=INVTG][@moodCode=EVN]/component/@typeCode=COMP/adverseEventAssessment[1]/adverseEventAssessment/@classCode=INVTG][@moodCode=EVN]/component1/@typeCode=COMP/jobObservationEvent[code=@code=15][@codeSystem=2.16.840.1.113883.3.989.2.1.1.19][author/@typeCode=AUT]/assignedEntity/@classCode=ASSIGNED/code=@code=1][@codeSystem=2.16.840.1.113883.3.989.2.1.1.21][r/jobObservationEvent/@classCode=OBS][@moodCode=EVN]/value[@xsi:type=CE][@codeSystem=2.16.840.1.113883.6.163]/@code </pre> |
| e | H.4 | 送達者の意見 | 20000AN | Encapsulated Data (ED) | | 値 | <pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UV/r/controlActProcess/@classCode=CACT][@moodCode=EVN]/subject/@typeCode=SUB/J[1]/investigationEvent/@classCode=INVTG][@moodCode=EVN]/component/@typeCode=COMP/adverseEventAssessment[1]/adverseEventAssessment/@classCode=INVTG][@moodCode=EVN]/component1/@typeCode=COMP/jobObservationEvent[code=@code=10][@codeSystem=2.16.840.1.113883.3.989.2.1.1.19][author/@typeCode=AUT]/assignedEntity/@classCode=ASSIGNED/code=@code=1][@codeSystem=2.16.840.1.113883.3.989.2.1.1.21][r/jobObservationEvent/@classCode=OBS][@moodCode=EVN]/value[@xsi:type=ED]/text </pre> |
| h | H.5.r | 母国語で記載された症例概要及び報告者の意見 (必要に応じて繰り返し返す) | | | | 繰り返し返すノード | <pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UV/r/controlActProcess/@classCode=CACT][@moodCode=EVN]/subject/@typeCode=SUB/J[1]/investigationEvent/@classCode=INVTG][@moodCode=EVN]/component/@typeCode=COMP/jobObservationEvent[code=@code=36][@codeSystem=2.16.840.1.113883.3.989.2.1.1.19][author/@typeCode=AUT]/assignedEntity/@classCode=ASSIGNED/code=@code=2][@codeSystem=2.16.840.1.113883.3.989.2.1.1.21]] </pre> |
| e | H.5.r.1a | 症例概要及び報告者の意見に関する記述情報 | 100000AN | Encapsulated Data (ED) | | 値 | <pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UV/r/controlActProcess/@classCode=CACT][@moodCode=EVN]/subject/@typeCode=SUB/J[1]/investigationEvent/@classCode=INVTG][@moodCode=EVN]/component/@typeCode=COMP/jobObservationEvent[code=@code=36][@codeSystem=2.16.840.1.113883.3.989.2.1.1.19][author/@typeCode=AUT]/assignedEntity/@classCode=ASSIGNED/code=@code=2][@codeSystem=2.16.840.1.113883.3.989.2.1.1.21][r/jobObservationEvent/@classCode=OBS][@moodCode=EVN]/value[@xsi:type=ED]/text() </pre> |
| e | H.5.r.1b | 症例概要及び報告者の意見の記載言語 | 3A | Encapsulated Data (ED) | language=Coded Simple Value (CS) | 値 | <pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UV/r/controlActProcess/@classCode=CACT][@moodCode=EVN]/subject/@typeCode=SUB/J[1]/investigationEvent/@classCode=INVTG][@moodCode=EVN]/component/@typeCode=COMP/jobObservationEvent[code=@code=36][@codeSystem=2.16.840.1.113883.3.989.2.1.1.19][author/@typeCode=AUT]/assignedEntity/@classCode=ASSIGNED/code=@code=2][@codeSystem=2.16.840.1.113883.3.989.2.1.1.21][r/jobObservationEvent/@classCode=OBS][@moodCode=EVN]/value[@xsi:type=ED]/@language </pre> |

| h:ヘッダ e:エン ティティ | フィールド 番号 | フィールド名 | ICSRメッ セージにおけ るフィールド 番号 | ICHデー タ型 | HL7デー タ型 | HL7デー タ型 (下位構成要素) | 分類 | Xpath |
|-----------------------|-------------|----------------------|----------------------------------|-------------|-----------------------------|------------------------------------|----|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| h | ACK.M/A | ICH ICSR バッチ確認 成書 | | | | | | |
| e | ACK.M.1 | 確認応答バッチ番号 | | 100AN | Instance Identifier (II) | extension=Character String (ST) | 値 | /MCCI_IN200101UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200101UV01.xsd]/id/@root=2.16.840.1.113883.3.989.2.1.3.20]/@extension |
| e | ACK.M.2 | 確認応答バッチ送信 者識別子 | N.1.4 | 60AN | Instance Identifier (II) | extension=Character String (ST) | 値 | /MCCI_IN200101UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200101UV01.xsd]/sender[@typeCode=SND]/device[@classCode=DEV][@determiner Code=INSTANCE]/id/@root=2.16.840.1.113883.3.989.2.1.3.17]/@extension |
| e | ACK.M.3 | 確認応答バッチ受信 者識別子 | N.1.3 | 60AN | Instance Identifier (II) | extension=Character String (ST) | 値 | /MCCI_IN200101UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200101UV01.xsd]/receiver[@typeCode=RCV]/device[@classCode=DEV][@determiner Code=INSTANCE]/id/@root=2.16.840.1.113883.3.989.2.1.3.18]/@extension |
| e | ACK.M.4 | バッチ伝送の確認応 答日 | | 日付/時 間 | Point in Time (TS) | | 値 | /MCCI_IN200101UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200101UV01.xsd]/creationTime/@value |
| e | ACK.A.1 | ICSR バッチ番号 | N.1.2 | 100AN | Instance Identifier (II) | extension=Character String (ST) | 値 | /MCCI_IN200101UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200101UV01.xsd]/acknowledgement[@typeCode]/targetBatch/id/@root=2.16.840.1.113 883.3.989.2.1.3.22]/@extension |
| e | ACK.A.2 | 確認応答地域メッ セージ番号 | | 100AN | Instance Identifier (II) | extension=Character String (ST) | 値 | /MCCI_IN200101UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200101UV01.xsd]/attentionLine[keyWordText/@code=2][@codeSystem=2.16.840.1.11 3883.3.989.2.1.1.24]]/value[@xsi:type=II]/@root=2.16.840.1.113883.3.989.2.1.3.21]/@extens ion |
| e | ACK.A.3 | ICSR バッチ伝送日 | N.1.5 | 日付/時 間 | Point in Time (TS) | | 値 | /MCCI_IN200101UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200101UV01.xsd]/attentionLine[keyWordText/@code=3][@codeSystem=2.16.840.1.11 3883.3.989.2.1.1.24]]/value[@xsi:type=TS]/@value |

(別添 3)

| | | | | | | | |
|---|-----------|---------------------|------------------|---------|--------------------------|----------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| e | ACK.A.4 | 伝送確認応答コード | | 2A | Coded Value (CS) | 値 | /MCCI_IN200101UV01[ITSVersion=XMML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200101UV01.xsd]/acknowledgement[@typeCode] |
| e | ACK.A.5 | バッチバリデーションエラー | | 250AN | Encapsulated Data (ED) | 値 | /MCCI_IN200101UV01[ITSVersion=XMML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200101UV01.xsd]/acknowledgementDetail[1]/text/text() |
| h | ACK.B.r | ICH ICSR メッセージ 確認応答 | | | | 繰り返し ノード | /MCCI_IN200101UV01[ITSVersion=XMML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200101UV01.xsd]/MCCI_IN000002UV01 |
| e | ACK.B.r.1 | ICSR メッセージ番号 | N.2.r.1 C.1.1 | 100AN | Instance Identifier (II) | 値 | /MCCI_IN200101UV01[ITSVersion=XMML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200101UV01.xsd]/MCCI_IN000002UV01[r]/acknowledgement[@typeCode][1]/targetMessage/id[@root=2.16.840.1.113883.3.989.2.1.3.1]/@extension |
| e | ACK.B.r.2 | 地域報告番号 | | 100AN | Instance Identifier (II) | 値 | /MCCI_IN200101UV01[ITSVersion=XMML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200101UV01.xsd]/MCCI_IN000002UV01[r]/id[@root=2.16.840.1.113883.3.989.2.1.3.19]/@extension |
| e | ACK.B.r.3 | ICSR メッセージ確認 応答受信者 | N.2.r.2 | 60AN | Instance Identifier (II) | 値 | /MCCI_IN200101UV01[ITSVersion=XMML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200101UV01.xsd]/MCCI_IN000002UV01[r]/receiver[@typeCode=RCV]/device[classCode=DEV][@determinerCode=INSTANCE]/id[@root=2.16.840.1.113883.3.989.2.1.3.16]/@extension |
| e | ACK.B.r.4 | ICSR メッセージ確認 応答送信者 | N.2.r.3 | 60AN | Instance Identifier (II) | 値 | /MCCI_IN200101UV01[ITSVersion=XMML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200101UV01.xsd]/MCCI_IN000002UV01[r]/sender[@typeCode=SEND]/device[classCode=DEV][@determinerCode=INSTANCE]/id[@root=2.16.840.1.113883.3.989.2.1.3.15]/@extension |
| e | ACK.B.r.5 | ICSR メッセージ作成 成日 | N.2.r.4 C.1.2 | 日付 / 時間 | Point in Time (TS) | 値 | /MCCI_IN200101UV01[ITSVersion=XMML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200101UV01.xsd]/MCCI_IN000002UV01[r]/attentionLine[keyWordText[@code=1]][@codeSystem=2.16.840.1.113883.3.989.2.1.1.24][1]/value[@xsi:type=TS]/@value |
| e | ACK.B.r.6 | ICSR メッセージの 確認応答コード | | 2A | Coded Value (CS) | 値 | /MCCI_IN200101UV01[ITSVersion=XMML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200101UV01.xsd]/MCCI_IN000002UV01[r]/acknowledgement[1]/@typeCode |

(別添 3)

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

2. 複数の XML 表現に関する XML 断片

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

2.1 開始日、終了日及び持続期間

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

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

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

2.1.2. E.i.4「発現日」(又は E.i.5「終了日」) 及び E.i.6「持続期間」に入力する

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

```

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

```

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

```

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

```



```

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

```

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

```

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

```

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

```

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

```

```

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

```

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

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

IVL_TSの例：

```

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

```

PIVL_TSのもう1つの例：

```

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

```

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

```

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

```

```

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

```

2.2. F 検査結果

2.2.1. F.r.3.2 値及び限定子

2.2.1.1. 値 (例: "10 mg/dL")

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

```

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

```

2.2.1.2. 値より大きい (例: "> 10 mg/dL")

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

```

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

```

2.2.1.3. 値より小さい (例: "< 10 mg/dL")

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

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

2.2.1.4. 値以上 (例: ">= 10 mg/dL")

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

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

2.2.1.5. 値以下 (例: "<= 10 mg/dL")

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

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

2.2.2 F.r.3.2 及び F.r.3.3

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

```

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

```

2.2.3. F.r.3.1

```

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

```

2.2.4. F.r.3.4

```

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

```

2.3. G.k.4 投与量の例

2.3.1. 1日当たり 1/回

```

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

```

```
</outboundRelationship2>
```

2.3.2. 1日当たり1錠/回

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

2.3.3. 1日1回、1/4錠/回

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

```

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

```

2.3.4. 週1回、6錠/回

```

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

```

2.3.5. 1日2回、1錠/回

例1

```

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

```

```

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

```

例2

```

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

```

2.3.6. 1日4回、7.5 mg/回

例1

```

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

```



```

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

```

例2

```

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

```

2.3.7. 1日1回、15 mL/回

```

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

```

2.3.8. 2日に1回、1錠/回

```

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

```

```

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

```

2.3.9. 頓用、1錠/回、開始日、終了日

```

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

```

2.3.10. 頓用、20 mg/回

```

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

```

2.3.11. 周期的、500 mg/回、開始日、終了日

```

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

```

2.3.12. 周期的、500 mg/回

```

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

```

2.3.13. 総投与量 20,000 mg、開始日、終了日

```

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

```

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

HL7 telecom データ型の構文 –

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

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

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

例 –

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

これは標準のHL7のnull flavorではないことに留意する。

2.6. トライメスターを使用した妊娠期間 (D.2.2.1b)

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

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

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

</ingredient>

2.8. 各副作用に関する因果関係情報の例

```

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

```

III. 参照インスタンスについての注意事項

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

例：

```

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

```

IV. 参考

ICSR メッセージにおける E2B (R3) データ項目構造

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

| 該当通知 | 旧頁 | 旧 | 新頁 | 新 |
|----------------------------------------|------|--------------------------------------------------------------------------------------------|------|--------------------------------------------------------------------------------------------|
| 別添 1 個別症例安全性報告 (ICSR) の電子的伝送に係る実装ガイド | 108 | 複数の用語が報告され (例: 診断名を徴候及び症状とともに報告)、報告者から副作用 / 有害事象ごとの明確な終了日が記載されなければ、このデータ項目に最初の症状の終了日を入力する。 | 108 | 複数の用語が報告され (例: 診断名を徴候及び症状とともに報告)、報告者から副作用 / 有害事象ごとの明確な終了日が記載されなければ、このデータ項目に最後の症状の終了日を入力する。 |
| 別添2 付録I (B) E2B (R2) 及びE2B (R3) 互換性の推奨 | 表紙 | バージョン 2.00 2012年11月14日 | 表紙 | バージョン 2.01 2014年11月11日 |
| 別添2 付録I (B) E2B (R2) 及びE2B (R3) 互換性の推奨 | フッター | 2012年11月14日 | フッター | 2014年11月11日 |
| 別添2 付録I (B) E2B (R2) 及びE2B (R3) 互換性の推奨 | — | — | 1 | *文書の履歴の表を追加 |
| 別添2 付録I (B) E2B (R2) 及びE2B (R3) 互換性の推奨 | 1-3 | — | 2-4 | *目次の更新 |
| 別添2 付録I (B) E2B (R2) 及びE2B (R3) 互換性の推奨 | 15 | 5.2.1 同一セットのコード | 16 | 5.2.1 コード化値 |
| 別添2 付録I (B) E2B (R2) 及びE2B (R3) 互換性の推奨 | 15 | 以下のデータ項目についてはE2B (R2) とE2B (R3) で同一セットのコードを使用することが求められている。 | 16 | A. 以下のデータ項目についてはE2B (R2) とE2B (R3) で同一セットのコードを使用することが求められている。 |
| 別添2 付録I (B) E2B (R2) 及びE2B (R3) 互換性の推奨 | 15 | 表 D.9.3のコードリスト 3種類の値 | 16 | 表 D.9.3のコードリスト 3種類の値 (*) |
| 別添2 付録I (B) E2B (R2) 及びE2B (R3) 互換性の推奨 | 15 | — | — | *表から最終観察時の副作用 / 有害事象の転帰 (B.2.i.8 及びE.i.7) を削除 |

| 該当通知 | 旧頁 | 旧 | 新頁 | 新 |
|----------------------------------------|----|------------------------------------------------------------------------------------------------------------------------------------------------|----|----------------------------------------------------------------------------------------------------------------------------------|
| 別添2 付録I (B) E2B (R2) 及びE2B (R3) 互換性の推奨 | 15 | - | - | *表から医薬品に対して取られた処置 (B.4.k.16 及び G.k.8) を削除 |
| 別添2 付録I (B) E2B (R2) 及びE2B (R3) 互換性の推奨 | - | - | 16 | B. E2B(R2)と E2B(R3)で同じ用語を使用することが求められているが、コード値が異なる場合がある。 |
| 別添2 付録I (B) E2B (R2) 及びE2B (R3) 互換性の推奨 | - | - | 16 | *新しい表に最終観察時の副作用/有害事象の転帰 (B.2.i.8 及び E.i.7) を追加 |
| 別添2 付録I (B) E2B (R2) 及びE2B (R3) 互換性の推奨 | - | - | 16 | *新しい表に医薬品に対して取られた処置 (B.4.k.16 及び G.k.8) を追加 |
| 別添2 付録I (B) E2B (R2) 及びE2B (R3) 互換性の推奨 | 16 | A.1.13.1 報告破棄/修正理由の内容 | 17 | C.1.11.2 報告破棄/修正理由の内容 |
| 別添2 付録I (B) E2B (R2) 及びE2B (R3) 互換性の推奨 | 24 | 表 D.5 のコードリスト <ul style="list-style-type: none"> • 男性 • 女性 • 不明 • Null flavor : UNK、MSK、ASKU、NASK | 26 | 表 D.5 のコードリスト <ul style="list-style-type: none"> • 男性 • 女性 • Null flavor : UNK、MSK、ASKU、NASK |
| 別添2 付録I (B) E2B (R2) 及びE2B (R3) 互換性の推奨 | 26 | 表 B.2.i.2 の書式 8N / 250AN | 28 | 表 B.2.i.2 の書式 <u>8AN</u> / 250AN |
| 別添2 付録I (B) E2B (R2) 及びE2B (R3) 互換性の推奨 | 26 | 表 ACK: B.1.2 の書式 2N | 28 | 表 ACK: B.1.2 の書式 2AN |
| 別添2 付録I (B) E2B (R2) 及びE2B (R3) 互換性の推奨 | 27 | 表 Fr.2.2b の書式 4AN | 29 | 表 Fr.2.2b の書式 <u>8N</u> |

| 該当通知 | 旧頁 | 旧 | 新頁 | 新 |
|----------------------------------------|----|-------------------------------------------------------------|----|-----------------------------------------------------------------|
| 別添2 付録I (B) E2B (R2) 及びE2B (R3) 互換性の推奨 | 28 | E2B (R2) にダウングレードする場合、記述情報データ項目 (H) に E2B (R3) の項目値を入力すること。 | 30 | E2B (R2) にダウングレードする場合、記述情報データ項目 (B.5.1) に E2B (R3) の項目値を入力すること。 |
| 別添2 付録I (B) E2B (R2) 及びE2B (R3) 互換性の推奨 | — | — | 31 | M5 識別子は、ISO IDMP の用語と識別子に名前が変更された。 |
| 別添2 付録I (B) E2B (R2) 及びE2B (R3) 互換性の推奨 | 29 | 表 データ項目 D.8.r.3 | 31 | 表 データ項目 D.8.r.3a |
| 別添2 付録I (B) E2B (R2) 及びE2B (R3) 互換性の推奨 | 29 | 表 データ項目 G.k.2.1.2b | 31 | 表 データ項目 G.k.2.1.1b |
| 別添2 付録I (B) E2B (R2) 及びE2B (R3) 互換性の推奨 | 30 | 表 H.5.r.1a 及びH.5.r.1b の書式 100,000 AN | 32 | 表 H.5.r.1a 及びH.5.r.1b の書式 100000 AN |
| 別添2 付録I (B) E2B (R2) 及びE2B (R3) 互換性の推奨 | 33 | 表 C.2.r.1.2 のデータ項目長 60 | 35 | 表 C.2.r.1.2 のデータ項目長 60 (*) |
| 別添2 付録I (B) E2B (R2) 及びE2B (R3) 互換性の推奨 | 33 | 表 C.2.r.1.3 のデータ項目長 60 | 35 | 表 C.2.r.1.3 のデータ項目長 60 (*) |
| 別添2 付録I (B) E2B (R2) 及びE2B (R3) 互換性の推奨 | 33 | 表 C.2.r.1.4 のデータ項目長 60 | 35 | 表 C.2.r.1.4 のデータ項目長 60 (*) |
| 別添2 付録I (B) E2B (R2) 及びE2B (R3) 互換性の推奨 | 33 | 表 G.k.4.r.9.1 のデータ項目長 60 | 35 | 表 G.k.4.r.9.1 のデータ項目長 60 (*) |
| 別添2 付録I (B) E2B (R2) 及びE2B (R3) 互換性の推奨 | 34 | 表 B.4.k.19 のデータ項目長 1000 | 36 | 表 B.4.k.19 のデータ項目長 100 |
| 別添2 付録I (B) E2B (R2) 及びE2B (R3) 互換性の推奨 | 35 | B.2.i.0/E.i.1.1 副作用/有害事象 | 37 | B.2.i.0/E.i.1.1a 副作用/有害事象 |

| 該当通知 | 旧頁 | 旧 | 新頁 | 新 |
|----------------------------------------|----|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| (R3) 互換性の推奨 | | | | |
| 別添2 付録I (B) E2B (R2) 及びE2B (R3) 互換性の推奨 | 38 | 表 D.7.1.r.3 及びD.10.7.1.r.3に対応しているマスキング ASKU、NASK | 40 | 表 D.7.1.r.3 及びD.10.7.1.r.3に対応しているマスキング MSK、ASKU、NASK、UNK |
| 別添2 付録I (B) E2B (R2) 及びE2B (R3) 互換性の推奨 | 38 | データ項目「剖検は実施されたか？」(すなわち、 <u>B.1.9.3</u>)「継続(患者又は親の関連する治療歴及び随伴症状)」(すなわち、D.7.1.r.3 又はD.10.7.1.r.3)がE2B (R3) において null flavor (UNK) である場合、対応する E2B (R2) の項目値は「3」(不明)と示されること。 | 40 | データ項目「剖検は実施されたか？」(すなわち、 <u>D.9.3</u>)「継続(患者又は親の関連する治療歴及び随伴症状)」(すなわち、D.7.1.r.3 又はD.10.7.1.r.3)がE2B (R3) において null flavor (UNK) である場合、対応する E2B (R2) の項目値は「3」(不明)と示されること。 |
| 別添2 付録I (B) E2B (R2) 及びE2B (R3) 互換性の推奨 | 41 | E2B (R3) のデータ項目 C.1.8.2が「その他」に設定されている場合、E2B (R3) のデータ項目 <u>A.1.10.1</u> がE2B (R2) のデータ項目 <u>C.1.8.1</u> (その他の送信者の症例報告番号) にコピーされること。 | 43 | E2B (R3) のデータ項目 C.1.8.2が「その他」に設定されている場合、E2B (R3) のデータ項目 <u>C.1.8.1</u> がE2B (R2) のデータ項目 <u>A.1.10.2</u> (その他の送信者の症例報告番号) にコピーされること。 |
| 別添2 付録I (B) E2B (R2) 及びE2B (R3) 互換性の推奨 | 44 | 報告者によって重要とされた副作用／有害事象 (E.i.3.1) : true | 46 | 報告者によって重要とされた副作用／有害事象 (E.i.3.1) : 報告者により重要とされ、 <u>重篤</u> |
| 別添2 付録I (B) E2B (R2) 及びE2B (R3) 互換性の推奨 | 46 | 表 F.r.3.2の書式 値として (50AN) | 48 | 表 F.r.3.2の書式 値として (50N) |

| 該当通知 | 旧頁 | 旧 | 新頁 | 新 |
|----------------------------------------|----|---------------------------------------------------------------------------------------------------------------------------------------------------------------|----|-----------------------------------------------------------------------------------------------------------------|
| 別添2 付録I (B) E2B (R2) 及びE2B (R3) 互換性の推奨 | 46 | 表 データ項目 Fr.6 繰り返し可能 | 48 | 表 データ項目 Fr.3.4 |
| 別添2 付録I (B) E2B (R2) 及びE2B (R3) 互換性の推奨 | 46 | E2B (R2) の固有のデータ項目 B.3.2 は、E2B (R3) の追加のデータ項目 Fr.6 にコピーし、コメントも E2B (R3) のデータ項目 Fr.6 にコピーされること。 | 48 | E2B (R2) の固有のデータ項目 B.3.2 は、E2B (R3) のデータ項目 Fr.3.4 にコピーされること。 |
| 別添2 付録I (B) E2B (R2) 及びE2B (R3) 互換性の推奨 | 46 | E2B (R3) のデータ項目 Fr.3.2 (数値) に限定子が付されている (たとえば、「より大きい」) 場合、E2B (R2) のデータ項目 B.3.1.d にコピーされる情報は、限定子 (" $<$ "、" \leq "、" $>$ "又は" \geq ") とそれ に続く数値からなること。 | 48 | E2B (R3) のデータ項目 Fr.3.2 (数値) に限定子が付されている (たとえば、「より大きい」) 場合、E2B (R2) のデータ項目 B.3.1.d にコピーされる情報は、限定子とそれに続く数値からなること。 |
| 別添2 付録I (B) E2B (R2) 及びE2B (R3) 互換性の推奨 | 51 | 特定の副作用 / 有害事象に対して再発のフラグを設定すること (5.2.12 項を参照)。 | 53 | 特定の副作用 / 有害事象に対して再発のフラグを設定すること (5.2.11 項を参照)。 |
| 別添2 付録I (B) E2B (R2) 及びE2B (R3) 互換性の推奨 | 53 | 再投与による副作用の再発についてマトリックスの項目のとおり設定すること (5.2.12 項を参照)。 | 55 | 再投与による副作用の再発についてマトリックスの項目のとおり設定すること (5.2.11 項を参照)。 |
| 別添2 付録I (B) E2B (R2) 及びE2B (R3) 互換性の推奨 | 全体 | B.2.i.1.b | 全体 | B.2.i.1b |
| 別添2 付録I (B) E2B (R2) 及びE2B (R3) 互換性の推奨 | 全体 | B.1.9.2.b | 全体 | B.1.9.2b |

| 該当通知 | 旧頁 | 旧 | 新頁 | 新 |
|----------------------------------------|-------|--------------------------------------------------|------|------------------------------------------------|
| (R3) 互換性の推奨 | | | | |
| 別添2 付録I (B) E2B (R2) 及びE2B (R3) 互換性の推奨 | 全体 | B.1.9.4.b バージョン1.00 2012年11月14日 | 全体 | B.1.9.4b バージョン1.01 2014年11月10日 |
| 別添3 付録I (G) 技術的情報 | 表紙 | バージョン1.00 2012年11月14日 | 表紙 | バージョン1.01 2014年11月10日 |
| 別添3 付録I (G) 技術的情報 | フッター | 2012年11月14日 | フッター | 2014年11月10日 |
| 別添3 付録I (G) 技術的情報 | - | - | 1 | *文書の履歴の表を追加 |
| 別添3 付録I (G) 技術的情報 | 1-2 | - | 2-3 | *目次の更新 |
| 別添3 付録I (G) 技術的情報 | 48,49 | - | - | *F.r.3.2 の NullFlavor 取得のための Xpath を削除 |
| 別添3 付録I (G) 技術的情報 | 57 | B.4.k.4.r.3 の単位が合計の場合： Physical Quantity (PQ) | 60 | G.k.4.r.3 の単位が合計の場合： Physical Quantity (PQ) |
| 別添3 付録I (G) 技術的情報 | 58 | B.4.k.4.r.3 の単位が合計の場合： Physical Quantity (PQ) | 60 | G.k.4.r.3 の単位が合計の場合： Physical Quantity (PQ) |
| 別添3 付録I (G) 技術的情報 | - | - | 全体 | ICH コードリストのバージョンを取得するための Xpath の追加 |