

(別添3)



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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

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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。本文書の情報はすべて ICH ICSR 実装ガイドと一致しており、技術的ポイントの詳細について概要を示す。

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

II. 技術的情報

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

ICH 及び HL7 におけるデータ型を下表に示す。

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

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

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

| h:ヘッダ e:エンティ ティ | 項目番号 | 要素名 | ICH データ型 | HL7データ型 | HL7データ型 (下位構成要素) | 分類 | Xpath |
|-----------------------|---------|---|-------------|---------------------------------|----------------------------------|---------|--|
| h | N.1 | ICH ICSR 伝送識別子 (バッチラッパー) 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 |
| e | N.1.2 | 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 | 100AN | Instance Identifier (II) | extension=Character String (ST) | 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]*/codeSystemVersion |
| 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[@determinerCode=INSTANCE]/id[@root=2.16.840.1.113883.3.989.2.1.3.13]*/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[@determinerCode=INSTANCE]/id[@root=2.16.840.1.113883.3.989.2.1.3.14]*/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]*/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]*/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]*/extension |
| e | N.2.r.4 | メッセージ作成の日付 | 日付/時間 | Point in Time (TS) | | 値 | /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UV[id/@root=2.16.840.1.113883.3.989.2.1.3.12]*/extension |
| h | C.1 | 症例安全性報告の識別 | | | | | |

(別添 3)

| | 送信者ごとに固有の (症例) 安全性報告識別子 | 100AN | Instance Identifier (I) | extension=Character String (ST) | 値 |
|---|-------------------------|--------|------------------------------------|---------------------------------|---|
| e | C.1.1 | | Point in Time (TS) | | /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@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]/id[@root=2.16.840.1.1.13883.3.989.2.1.3.1][1]/@extension |
| e | C.1.2 | 日付/時間 | Point in Time (TS) | | /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UV/r/controlActProcess[@classCode=CACT][@moodCode=EVN]/effectiveTime/@value |
| e | C.1.3 | 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]/subjectOf2[@typeCode=SUBJ][investigationCharacteristic/@code=1][@codeSystem=2.16.840.1.1.13883.3.989.2.1.1.23][1]/investigationCharacteristic[@classCode=OBS][@moodCode=EVN]/value[@xsi:type=CE][@codeSystem=2.16.840.1.1.13883.3.989.2.1.1.2][@code |
| e | C.1.4 | 日付/時間 | Interval of Point in Time (VL<TS>) | low=Interval Boundary (VXB) | /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@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][investigationCharacteristic/@code=1][@codeSystem=2.16.840.1.1.13883.3.989.2.1.1.23][1]/investigationCharacteristic[@classCode=OBS][@moodCode=EVN]/value[@xsi:type=CE][@codeSystem=2.16.840.1.1.13883.3.989.2.1.1.2][@codeSystem Version |
| e | C.1.5 | 日付/時間 | Point in Time (TS) | | /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@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]/availabilityTime/@value |
| h | C.1.6 | | | | |
| e | C.1.6.1 | 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]/component[@typeCode=COMP][observationEvent/@code=1][@codeSystem=2.16.840.1.1.13883.3.989.2.1.1.19][1]/observationEvent[@classCode=OBS][@moodCode=EVN]/value[@xsi:type=BL]/@value |
| h | C.1.6.1.r | | | | /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UV/r/controlActProcess[@classCode=CACT][@moodCode=EVN]/reference[@typeCode=REFR][document/@code=1][@codeSystem=2.16.840.1.1.13883.3.989.2.1.1.27] |
| e | C.1.6.1.r.1 | 2000AN | 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]/reference[@typeCode=REFR][document/@code=1][@codeSystem=2.16.840.1.1.13883.3.989.2.1.1.27][1]/document[@classCode=DOC][@moodCode=EVN]/title/text() |

| | | | | | | |
|---|-------------|--------------------------------|-------|-----------------------------|------------|---|
| e | C.1.6.1.r.2 | 含まれる資料 | N/A | Encapsulated Data (ED) | 値 | <pre> /MCCL_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hi7-org:v3 MCCL_IN200100UV01.xsd']/PORR_IN049016UV01/controlActProcess[@classCode='CACT'][@moo dCode='EVN']/subject[@typeCode='SUBJ']/investigationEvent[@classCode='INVTG'][@moodCo de='EVN']/reference[@typeCode='REFR']/documentCode[@code='1'][@codeSystem='2.16.840.1.11 3883.3.989.2.1.1.27']/document[@classCode='DOC'][@moodCode='EVN']/text/text() </pre> |
| 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 | <pre> /MCCL_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hi7-org:v3 MCCL_IN200100UV01.xsd']/PORR_IN049016UV01/controlActProcess[@classCode='CACT'][@moo dCode='EVN']/subject[@typeCode='SUBJ']/investigationEvent[@classCode='INVTG'][@moodCo de='EVN']/component[@typeCode='COMP']/observationEvent/code[@code='23'][@codeSystem='2. 16.840.1.113883.3.989.2.1.1.19']/observationEvent[@classCode='OBS'][@moodCode='EVN']/val ue[@xsi:type='BL']/@value </pre> |
| e | | | | | NullFlavor | <pre> /MCCL_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hi7-org:v3 MCCL_IN200100UV01.xsd']/PORR_IN049016UV01/controlActProcess[@classCode='CACT'][@moo dCode='EVN']/subject[@typeCode='SUBJ']/investigationEvent[@classCode='INVTG'][@moodCo de='EVN']/component[@typeCode='COMP']/observationEvent/code[@code='23'][@codeSystem='2. 16.840.1.113883.3.989.2.1.1.19']/observationEvent[@classCode='OBS'][@moodCode='EVN']/val ue[@xsi:type='BL']/@nullFlavor </pre> |
| h | C.1.8 | 世界的に固有の症例識別子 | | | | |
| e | C.1.8.1 | 世界的に固有の症例識別子 | 100AN | Instance Identifier (I) | 値 | <pre> /MCCL_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hi7-org:v3 MCCL_IN200100UV01.xsd']/PORR_IN049016UV01/controlActProcess[@classCode='CACT'][@moo dCode='EVN']/subject[@typeCode='SUBJ']/investigationEvent[@classCode='INVTG'][@moodCo de='EVN']/id/@root='2.16.840.1.113883.3.989.2.1.3.2']/1/@extension </pre> |
| e | C.1.8.2 | 本症例の第一送信者 | 1N | Coded With Equivalents (CE) | 値 | <pre> /MCCL_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hi7-org:v3 MCCL_IN200100UV01.xsd']/PORR_IN049016UV01/controlActProcess[@classCode='CACT'][@moo dCode='EVN']/subject[@typeCode='SUBJ']/investigationEvent[@classCode='INVTG'][@moodCo de='EVN']/outboundRelationship[@typeCode='SPRT']/relatedInvestigation/code[@code='1'][@code System='2.16.840.1.113883.3.989.2.1.1.22']/relatedInvestigation[@classCode='INVTG'][@moo dCode='EVN']/subjectOf2[@typeCode='SUBJ']/controlActEvent[@classCode='CACT'][@moodCo de='EVN']/author[@typeCode='AUT']/assignedEntity[@classCode='ASSIGNED']/code/@codeSystem m='2.16.840.1.113883.3.989.2.1.1.3']/@code </pre> |
| | | 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 | | | | <pre> /MCCL_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hi7-org:v3 MCCL_IN200100UV01.xsd']/PORR_IN049016UV01/controlActProcess[@classCode='CACT'][@moo dCode='EVN']/subject[@typeCode='SUBJ']/investigationEvent[@classCode='INVTG'][@moodCo de='EVN']/outboundRelationship[@typeCode='SPRT']/relatedInvestigation/code[@code='1'][@code System='2.16.840.1.113883.3.989.2.1.1.22']/relatedInvestigation[@classCode='INVTG'][@moo dCode='EVN']/subjectOf2[@typeCode='SUBJ']/controlActEvent[@classCode='CACT'][@moodCo de='EVN']/author[@typeCode='AUT']/assignedEntity[@classCode='ASSIGNED']/code/@codeSystem m='2.16.840.1.113883.3.989.2.1.1.3']/@codeSystemVersion </pre> |
| h | C.1.9 | その他の症例識別子 | | | | |
| e | C.1.9.1 | 過去の伝送で記載されたその他の症例識別子はあるか? | ブール型 | Boolean (BL) | 値 | <pre> /MCCL_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hi7-org:v3 MCCL_IN200100UV01.xsd']/PORR_IN049016UV01/controlActProcess[@classCode='CACT'][@moo dCode='EVN']/subject[@typeCode='SUBJ']/investigationEvent[@classCode='INVTG'][@moodCo de='EVN']/subjectOf2[@typeCode='SUBJ']/investigationCharacteristic/code[@code='2'][@codeSyste m='2.16.840.1.113883.3.989.2.1.1.23']/investigationCharacteristic[@classCode='OBS'][@moodCo de='EVN']/value[@xsi:type='BL']/@value </pre> |

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| e | | | | | | | | | /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:h7-org:v3 MCCL_IN200100UV01.xsd]/PARR_IN049016UV/r/controlActProcess[@classCode=CACTT][@moodCode=EVN]/subject[@typeCode=SUBJ][1]/investigationEvent[1][@moodCode=INVSTG][@moodCode=EVN]/subjectOf2[@typeCode=SUBJ][investigationCharacteristic/@code=2][@codeSystem=2.16.840.1.113883.3.989.2.1.1.23][1]/investigationCharacteristic[@classCode=OBS][@moodCode=EVN][value[@xsi:type=BL]]/@nullFlavor |
| h | C.1.9.1.r | 症例識別子の情報源 (必要に応じて繰り返す) | | | | | 繰り返しのノード | | /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:h7-org:v3 MCCL_IN200100UV01.xsd]/PARR_IN049016UV/r/controlActProcess[@classCode=CACTT][@moodCode=EVN]/subjectOf1[@typeCode=SUBJ][1]/investigationEvent[1][@moodCode=EVN]/subjectOf1[@typeCode=SUBJ][controlActEventId] |
| e | C.1.9.1.r.1 | 症例識別子の情報源 | 100AN | Instance Identifier (I) | | assigningAuthorityName=Character String (ST) | 値 | | /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:h7-org:v3 MCCL_IN200100UV01.xsd]/PARR_IN049016UV/r/controlActProcess[@classCode=CACTT][@moodCode=EVN]/subjectOf1[@typeCode=SUBJ][1]/investigationEvent[1][@moodCode=EVN]/subjectOf1[@typeCode=SUBJ][controlActEventId][r/controlActEventId/@root=2.16.840.1.113883.3.989.2.1.3.3][1]/assigningAuthorityName |
| e | C.1.9.1.r.2 | 症例識別子 | 100AN | Instance Identifier (I) | | extension=Character String (ST) | 値 | | /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:h7-org:v3 MCCL_IN200100UV01.xsd]/PARR_IN049016UV/r/controlActProcess[@classCode=CACTT][@moodCode=EVN]/subjectOf1[@typeCode=SUBJ][1]/investigationEvent[1][@moodCode=INVSTG][@moodCode=EVN]/subjectOf1[@typeCode=SUBJ][controlActEventId][r/controlActEventId/@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 (I) | | extension=Character String (ST) | 値 | | /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:h7-org:v3 MCCL_IN200100UV01.xsd]/PARR_IN049016UV/r/controlActProcess[@classCode=CACTT][@moodCode=EVN]/subjectOf1[@typeCode=SUBJ][1]/investigationEvent[1][@moodCode=INVSTG][@moodCode=EVN]/subjectOf1[@typeCode=SUBJ][1]/investigationEvent[1][@moodCode=SPRT][relatedInvestigation/@code=nullFlavor='NA'][1]/relatedInvestigation[@classCode=INVSTG][@moodCode=EVN]/subjectOf2[@typeCode=SUBJ][1]/controlActEvent[1][@classCode=CACTT][@moodCode=EVN][id][@root=2.16.840.1.113883.3.989.2.1.3.2][1]/extension |
| h | C.1.11 | 報告破棄/修正 | | | | | | | |
| e | C.1.11.1 | 報告破棄/修正 | 1N | Coded With Equivalents (CE) | | code=Character String (ST) | 値 | | /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:h7-org:v3 MCCL_IN200100UV01.xsd]/PARR_IN049016UV/r/controlActProcess[@classCode=CACTT][@moodCode=EVN]/subjectOf1[@typeCode=SUBJ][1]/investigationEvent[1][@moodCode=INVSTG][@moodCode=EVN]/subjectOf2[@typeCode=SUBJ][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][@codeVersion |
| e | C.1.11.2 | 報告破棄/修正理由 ICH コードリストのバージョン | 2000AN | Coded With Equivalents (CE) | | originalText = Encapsulated Data (ED) | 値 | | /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:h7-org:v3 MCCL_IN200100UV01.xsd]/PARR_IN049016UV/r/controlActProcess[@classCode=CACTT][@moodCode=EVN]/subjectOf2[@typeCode=SUBJ][1]/investigationEvent[1][@moodCode=INVSTG][@moodCode=EVN]/subjectOf2[@typeCode=SUBJ][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() |

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|---|-----------|--------------------|------|------------------|--------------------------------|------------|---|
| h | C.2.r | 第一次情報源 (必要に応じ繰り返す) | | | | 繰り返しノード | <pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/PORR_IN049016UV/r/controlActProcess[@classCode=CACTT][@moodCode=EVN]/subject[@typeCode=SUBJ][@typeCode=SPRT][relatedInvestigation/code/@code=2][@code=EVN]/outboundRelationship[@typeCode=SPRT][relatedInvestigation/code/@code=2][@codeSystem=2.16.840.1.113883.3.989.2.1.1.22][relatedInvestigation/@classCode=INVSIG][@moodCode=EVN]/subjectO12[@typeCode=SUBJ]/controlActEvent[@classCode=CACTT][@moodCode=EVN]/author[@typeCode=AUT]/assignedEntity[@classCode=ASSIGNED]/assignedPerson[@classCode=PSN][@determinerCode=INSTANCE]/name/prefix[1]/text() </pre> |
| h | C.2.r.1 | 報告者の氏名 | | | | | <pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/PORR_IN049016UV/r/controlActProcess[@classCode=CACTT][@moodCode=EVN]/subject[@typeCode=SUBJ][@typeCode=SPRT][relatedInvestigation/code/@code=2][@codeSystem=2.16.840.1.113883.3.989.2.1.1.22][relatedInvestigation/@classCode=INVSIG][@moodCode=EVN]/subjectO12[@typeCode=SUBJ]/controlActEvent[@classCode=CACTT][@moodCode=EVN]/author[@typeCode=AUT]/assignedEntity[@classCode=ASSIGNED]/assignedPerson[@classCode=PSN][@determinerCode=INSTANCE]/name/prefix[1]/text() </pre> |
| e | C.2.r.1.1 | 報告者の職名 | 50AN | Person Name (PN) | prefix=Entity Name Part (ENXP) | 値 | <pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/PORR_IN049016UV/r/controlActProcess[@classCode=CACTT][@moodCode=EVN]/subject[@typeCode=SUBJ][@typeCode=SPRT][relatedInvestigation/code/@code=2][@codeSystem=2.16.840.1.113883.3.989.2.1.1.22][relatedInvestigation/@classCode=INVSIG][@moodCode=EVN]/subjectO12[@typeCode=SUBJ]/controlActEvent[@classCode=CACTT][@moodCode=EVN]/author[@typeCode=AUT]/assignedEntity[@classCode=ASSIGNED]/assignedPerson[@classCode=PSN][@determinerCode=INSTANCE]/name/prefix[1]/text() </pre> |
| e | C.2.r.1.2 | 報告者の名前 | 60AN | Person Name (PN) | given=Entity Name Part (ENXP) | NullFlavor | <pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/PORR_IN049016UV/r/controlActProcess[@classCode=CACTT][@moodCode=EVN]/subject[@typeCode=SUBJ][@typeCode=SPRT][relatedInvestigation/code/@code=2][@codeSystem=2.16.840.1.113883.3.989.2.1.1.22][relatedInvestigation/@classCode=INVSIG][@moodCode=EVN]/subjectO12[@typeCode=SUBJ]/controlActEvent[@classCode=CACTT][@moodCode=EVN]/author[@typeCode=AUT]/assignedEntity[@classCode=ASSIGNED]/assignedPerson[@classCode=PSN][@determinerCode=INSTANCE]/name/given[1]/text() </pre> |
| e | C.2.r.1.3 | 報告者の中間名 | 60AN | Person Name (PN) | given=Entity Name Part (ENXP) | 値 | <pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/PORR_IN049016UV/r/controlActProcess[@classCode=CACTT][@moodCode=EVN]/subject[@typeCode=SUBJ][@typeCode=SPRT][relatedInvestigation/code/@code=2][@codeSystem=2.16.840.1.113883.3.989.2.1.1.22][relatedInvestigation/@classCode=INVSIG][@moodCode=EVN]/subjectO12[@typeCode=SUBJ]/controlActEvent[@classCode=CACTT][@moodCode=EVN]/author[@typeCode=AUT]/assignedEntity[@classCode=ASSIGNED]/assignedPerson[@classCode=PSN][@determinerCode=INSTANCE]/name/given[2]/text() </pre> |

(別添 3)

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|---|-----------|--------------|------|------------------------|--------------------------------|------------|---|
| e | | | | | | NullFlavor | /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UV1/controlActProcess[@classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUB][1]/investigationEvent[@classCode=INVTG][@moodCode=EVN]/outboundRelationship[@typeCode=SPRT][relatedInvestigation/codel@code=2][@codeSystem=2.16.840.1.113883.3.989.2.1.1.22][r/relatedInvestigation][@classCode=INVTG][@moodCode=EVN]/subjectO12[@typeCode=SUB][controlActEvent[@classCode=CACT][@moodCode=EVN]/author[@typeCode=AUT]/assignedEntity[@classCode=ASSIGNED]/assignedPerson[@classCode=PSN][@determinerCode=INSTANCE]/name/given2][@nullFlavor |
| e | C.2.r.1.4 | 報告者の姓 | 60AN | Person Name (PN) | family=Entity Name Part (ENXP) | 値 | /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UV1/controlActProcess[@classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUB][1]/investigationEvent[@classCode=INVTG][@moodCode=EVN]/outboundRelationship[@typeCode=SPRT][relatedInvestigation/codel@code=2][@codeSystem=2.16.840.1.113883.3.989.2.1.1.22][r/relatedInvestigation][@classCode=INVTG][@moodCode=EVN]/subjectO12[@typeCode=SUB][controlActEvent[@classCode=CACT][@moodCode=EVN]/author[@typeCode=AUT]/assignedEntity[@classCode=ASSIGNED]/assignedPerson[@classCode=PSN][@determinerCode=INSTANCE]/name/family1][text() |
| e | | | | | | NullFlavor | /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UV1/controlActProcess[@classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUB][1]/investigationEvent[@classCode=INVTG][@moodCode=EVN]/outboundRelationship[@typeCode=SPRT][relatedInvestigation/codel@code=2][@codeSystem=2.16.840.1.113883.3.989.2.1.1.22][r/relatedInvestigation][@classCode=INVTG][@moodCode=EVN]/subjectO12[@typeCode=SUB][controlActEvent[@classCode=CACT][@moodCode=EVN]/author[@typeCode=AUT]/assignedEntity[@classCode=ASSIGNED]/assignedPerson[@classCode=PSN][@determinerCode=INSTANCE]/name/family1][@nullFlavor |
| h | C.2.r.2 | 報告者の住所及び電話番号 | | | | | |
| e | C.2.r.2.1 | 報告者の組織 | 60AN | Organization Name (ON) | name=Entity Name Part (ENXP) | 値 | /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UV1/controlActProcess[@classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUB][1]/investigationEvent[@classCode=INVTG][@moodCode=EVN]/outboundRelationship[@typeCode=SPRT][relatedInvestigation/codel@code=2][@codeSystem=2.16.840.1.113883.3.989.2.1.1.22][r/relatedInvestigation][@classCode=INVTG][@moodCode=EVN]/subjectO12[@typeCode=SUB][controlActEvent[@classCode=CACT][@moodCode=EVN]/author[@typeCode=AUT]/assignedEntity[@classCode=ASSIGNED]/representedOrganization[@classCode=ORG][@determinerCode=INSTANCE]/assignedEntity[@classCode=ASSIGNED]/representedOrganization[@classCode=ORG][@determinerCode=ORGT][@determinerCode=INSTANCE]/name/text() |
| e | | | | | | NullFlavor | /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UV1/controlActProcess[@classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUB][1]/investigationEvent[@classCode=INVTG][@moodCode=EVN]/outboundRelationship[@typeCode=SPRT][relatedInvestigation/codel@code=2][@codeSystem=2.16.840.1.113883.3.989.2.1.1.22][r/relatedInvestigation][@classCode=INVTG][@moodCode=EVN]/subjectO12[@typeCode=SUB][controlActEvent[@classCode=CACT][@moodCode=EVN]/author[@typeCode=AUT]/assignedEntity[@classCode=ASSIGNED]/representedOrganization[@classCode=ORG][@determinerCode=INSTANCE]/assignedEntity[@classCode=ASSIGNED]/representedOrganization[@classCode=ORGT][@determinerCode=INSTANCE]/name/@nullFlavor |

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

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|---|-----------|----------------|------|---------------------------------|--------------------------------|------------|---|
| e | C.2.r.2.5 | 報告者の住所 (都道府県等) | 40AN | Postal Address (AD) | state=Address Part (ADXP) | 値 | <pre> /MCCJ_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCJ_IN200100UV01.xsd]/PORR_IN049016UV/r/controlAct/process/@classCode=CACT][@mood dCode=EVN]/subject/@typeCode=SUBJ][1]/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]/subjectOI2/@typeCode=SUBJ][controlActEvent/@classCode=CACT][@moodCode= EVN]/author/@typeCode=AUT][assignedEntity/@classCode=ASSIGNED][addr1/@state1/@nullFI avor </pre> |
| e | | | | | | NullFlavor | <pre> /MCCJ_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCJ_IN200100UV01.xsd]/PORR_IN049016UV/r/controlAct/process/@classCode=CACT][@mood dCode=EVN]/subject/@typeCode=SUBJ][1]/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]/subjectOI2/@typeCode=SUBJ][controlActEvent/@classCode=CACT][@moodCode= EVN]/author/@typeCode=AUT][assignedEntity/@classCode=ASSIGNED][addr1/@state1/@nullFI avor </pre> |
| e | C.2.r.2.6 | 報告者の住所 (郵便番号) | 15AN | Postal Address (AD) | postalCode=Address Part (ADXP) | 値 | <pre> /MCCJ_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCJ_IN200100UV01.xsd]/PORR_IN049016UV/r/controlAct/process/@classCode=CACT][@mood dCode=EVN]/subject/@typeCode=SUBJ][1]/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]/subjectOI2/@typeCode=SUBJ][controlActEvent/@classCode=CACT][@moodCode= EVN]/author/@typeCode=AUT][assignedEntity/@classCode=ASSIGNED][addr1/@postalCode1]/te xt() </pre> |
| e | | | | | | NullFlavor | <pre> /MCCJ_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCJ_IN200100UV01.xsd]/PORR_IN049016UV/r/controlAct/process/@classCode=CACT][@mood dCode=EVN]/subject/@typeCode=SUBJ][1]/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]/subjectOI2/@typeCode=SUBJ][controlActEvent/@classCode=CACT][@moodCode= EVN]/author/@typeCode=AUT][assignedEntity/@classCode=ASSIGNED][addr1/@postalCode1]/ @nullFlavor </pre> |
| e | C.2.r.2.7 | 報告者の電話番号 | 33AN | Telecommunication Address (TEL) | | 値 | <pre> substring(MCCJ_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCJ_IN200100UV01.xsd]/PORR_IN049016UV/r/controlAct/process/@classCode=CACT][@mood dCode=EVN]/subject/@typeCode=SUBJ][1]/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]/subjectOI2/@typeCode=SUBJ][controlActEvent/@classCode=CACT][@moodCode= EVN]/author/@typeCode=AUT][assignedEntity/@classCode=ASSIGNED][telecomStarts-with/@v alue,tei:)]][1]@value,5) </pre> |
| e | | | | | | NullFlavor | <pre> /MCCJ_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCJ_IN200100UV01.xsd]/PORR_IN049016UV/r/controlAct/process/@classCode=CACT][@mood dCode=EVN]/subject/@typeCode=SUBJ][1]/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]/subjectOI2/@typeCode=SUBJ][controlActEvent/@classCode=CACT][@moodCode= EVN]/author/@typeCode=AUT][assignedEntity/@classCode=ASSIGNED][telecomStarts-with/@v alue,tei:)]][1]@nullFlavor </pre> |

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| e | C.2.r.3 | 報告者の国コード | 2A | Concept Descriptor (CD) | code=Character String (ST) | 値 | /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UV/r/controlActProcess[@classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUBJ][r/investigationEvent[@classCode=INVTG][@moodCode=EVN]/outboundRelationship[@typeCode=SPRT][relatedInvestigation/code/@code=2][@codeSystem=2.16.840.1.113883.3.989.2.1.1.22][r/relatedInvestigation/@classCode=INVTG][@moodCode=EVN]/subjectOr2[@typeCode=SUBJ]/controlActEvent[@classCode=CACT][@moodCode=EVN]/author[@typeCode=AUT]/assignedEntity[@classCode=ASSIGNED]/assignedPerson[@classCode=PSN][@determinerCode=INSTANCE]/asLocatedEntity[@classCode=LOCE][r/location/@classCode=COUNTRY][@determinerCode=INSTANCE]/code[@codeSystem=1.0.3166.1.2.2][@code |
|---|---------|-----------------------------|----|-----------------------------|----------------------------|---|--|
| e | | | | | NullFlavor | | /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UV/r/controlActProcess[@classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUBJ][r/investigationEvent[@classCode=INVTG][@moodCode=EVN]/outboundRelationship[@typeCode=SPRT][relatedInvestigation/code/@code=2][@codeSystem=2.16.840.1.113883.3.989.2.1.1.22][r/relatedInvestigation/@classCode=INVTG][@moodCode=EVN]/subjectOr2[@typeCode=SUBJ]/controlActEvent[@classCode=CACT][@moodCode=EVN]/author[@typeCode=AUT]/assignedEntity[@classCode=ASSIGNED]/assignedPerson[@classCode=PSN][@determinerCode=INSTANCE]/asLocatedEntity[@classCode=LOCE][r/location/@classCode=COUNTRY][@determinerCode=INSTANCE]/code[@codeSystem=1.0.3166.1.2.2][@nullFlavor |
| e | C.2.r.4 | 資格 | 1N | Coded With Equivalents (CE) | code=Character String (ST) | 値 | /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UV/r/controlActProcess[@classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUBJ][r/investigationEvent[@classCode=INVTG][@moodCode=EVN]/outboundRelationship[@typeCode=SPRT][relatedInvestigation/code/@code=2][@codeSystem=2.16.840.1.113883.3.989.2.1.1.22][r/relatedInvestigation/@classCode=INVTG][@moodCode=EVN]/subjectOr2[@typeCode=SUBJ]/controlActEvent[@classCode=CACT][@moodCode=EVN]/author[@typeCode=AUT]/assignedEntity[@classCode=ASSIGNED]/assignedPerson[@classCode=PSN][@determinerCode=INSTANCE]/asQualifiedEntity[@classCode=QUAL][r/code/@codeSystem=2.16.840.1.113883.3.989.2.1.1.6][@code |
| e | | 資格に関する 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_IN049016UV/r/controlActProcess[@classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUBJ][r/investigationEvent[@classCode=INVTG][@moodCode=EVN]/outboundRelationship[@typeCode=SPRT][relatedInvestigation/code/@code=2][@codeSystem=2.16.840.1.113883.3.989.2.1.1.22][r/relatedInvestigation/@classCode=INVTG][@moodCode=EVN]/subjectOr2[@typeCode=SUBJ]/controlActEvent[@classCode=CACT][@moodCode=EVN]/author[@typeCode=AUT]/assignedEntity[@classCode=ASSIGNED]/assignedPerson[@classCode=PSN][@determinerCode=INSTANCE]/asQualifiedEntity[@classCode=QUAL][r/code/@codeSystem=2.16.840.1.113883.3.989.2.1.1.6][@codeSystem/Version |
| 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][r/investigationEvent[@classCode=INVTG][@moodCode=EVN]/outboundRelationship[@typeCode=SPRT][relatedInvestigation/code/@code=2][@codeSystem=2.16.840.1.113883.3.989.2.1.1.22][r/relatedInvestigation/@classCode=INVTG][@moodCode=EVN]/subjectOr2[@typeCode=SUBJ]/controlActEvent[@classCode=CACT][@moodCode=EVN]/author[@typeCode=AUT]/assignedEntity[@classCode=ASSIGNED]/assignedPerson[@classCode=PSN][@determinerCode=INSTANCE]/asQualifiedEntity[@classCode=QUAL][r/code/@codeSystem=2.16.840.1.113883.3.989.2.1.1.6][@nullFlavor |

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|---|---------|-----------------------------|-------|-----------------------------|---|--|
| e | C.2.r.5 | 規制目的上の第一次情報源 | 1N | Real Number (REAL) | 値 | <pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/PORR_IN049016UV01/controlActProcess/@classCode=CACTT[@moodCo dCode=EVN]/subject/@typeCode=SUBJ[1]/investigationEvent/@classCode=INVTG[1]@moodCo de=EVN/outboundRelationship/@typeCode=SPRT[relatedInvestigation/code/@code=2]@code System=2.16.840.1.113883.3.989.2.1.1.7]]/priorityNumber/@value </pre> |
| h | C.3 | 症例安全性報告の送信者に関する情報 | | | | |
| e | C.3.1 | 送信者の種類 | 1N | Coded With Equivalents (CE) | 値 | <pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/PORR_IN049016UV01/controlActProcess/@classCode=CACTT[@moodCo dCode=EVN]/subject/@typeCode=SUBJ[1]/investigationEvent/@classCode=INVTG[1]@moodCo de=EVN]/subjectOr1/@typeCode=SUBJ[1]/controlActEvent/author/assignedEntity/code/@codeSyste m=2.16.840.1.113883.3.989.2.1.1.7]]/controlActEvent/@classCode=CACTT[@moodCode=EVN] /author/@typeCode=AUT[assignedEntity/@classCode=ASSIGNED]/code/@codeSystem=2.16.84 0.1.113883.3.989.2.1.1.7]]@code </pre> |
| e | C.3.2 | 送信者の種類に関する ICH コードリストのバージョン | 100AN | Organization Name (ON) | 値 | <pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/PORR_IN049016UV01/controlActProcess/@classCode=CACTT[@moodCo dCode=EVN]/subject/@typeCode=SUBJ[1]/investigationEvent/@classCode=INVTG[1]@moodCo de=EVN]/subjectOr1/@typeCode=SUBJ[1]/controlActEvent/author/assignedEntity/code/@codeSyste m=2.16.840.1.113883.3.989.2.1.1.7]]/controlActEvent/@classCode=CACTT[@moodCode=EVN] /author/@typeCode=AUT[assignedEntity/@classCode=ASSIGNED]/code/@codeSystem=2.16.8 40.1.113883.3.989.2.1.1.7]]/codeSystemVersion </pre> |
| h | C.3.3 | 報告送信の責任者 | | | | |
| e | C.3.3.1 | 送信者の部署 | 60AN | Organization Name (ON) | 値 | <pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/PORR_IN049016UV01/controlActProcess/@classCode=CACTT[@moodCo dCode=EVN]/subject/@typeCode=SUBJ[1]/investigationEvent/@classCode=INVTG[1]@moodCo de=EVN]/subjectOr1/@typeCode=SUBJ[1]/controlActEvent/author/assignedEntity/code/@codeSyste m=2.16.840.1.113883.3.989.2.1.1.7]]/controlActEvent/@classCode=CACTT[@moodCode=EVN] /author/@typeCode=AUT[assignedEntity/@classCode=ASSIGNED]/representedOrganization/@cl assCode=ORG[1]/determinerCode=INSTANCE[assignedEntity/@classCode=ASSIGNED]/pres entedOrganization/@classCode=ORG[1]/determinerCode=INSTANCE[name/text] </pre> |
| e | C.3.3.2 | 送信者の職名 | 50AN | Person Name (PN) | 値 | <pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/PORR_IN049016UV01/controlActProcess/@classCode=CACTT[@moodCo dCode=EVN]/subject/@typeCode=SUBJ[1]/investigationEvent/@classCode=INVTG[1]@moodCo de=EVN]/subjectOr1/@typeCode=SUBJ[1]/controlActEvent/author/assignedEntity/code/@codeSyste m=2.16.840.1.113883.3.989.2.1.1.7]]/controlActEvent/@classCode=CACTT[@moodCode=EVN] /author/@typeCode=AUT[assignedEntity/@classCode=ASSIGNED]/name/prefix[1]/text </pre> |

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|---|---------|-----------------------------------|-------|---------------------|---------------------------------------|---|---|
| e | C.3.3.3 | 送信者の名前 | 60AN | Person Name (PN) | given=Entity Name Part (ENXP) | 値 | <pre> /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:h7-org:v3 MCCI_IN200100UV01.xsd]/PARR_IN049016UVU1/controlActProcess[@classCode=CACT][@moodCo dCode=EVN]/subjectOf[@typeCode=SUBJ][1]/investigationEvent[@classCode=INVTG][@moodCo de=EVN]/subjectOf1[@typeCode=SUBJ][1]/controlActEvent/author/assignedEntity/code[@codeSyste m=2.16.840.1.1.13883.3.989.2.1.1.7][1]/controlActEvent[@classCode=CACT][@moodCode=EVN] /author[@typeCode=AUT]/assignedEntity[@classCode=ASSIGNED]/assignedPerson[@classCode =PSN][@determinerCode=INSTANCE]/name/given[1]/text() </pre> |
| e | C.3.3.4 | 送信者の中間名 | 60AN | Person Name (PN) | given=Entity Name Part (ENXP) | 値 | <pre> /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:h7-org:v3 MCCI_IN200100UV01.xsd]/PARR_IN049016UVU1/controlActProcess[@classCode=CACT][@moodCo dCode=EVN]/subjectOf[@typeCode=SUBJ][1]/investigationEvent[@classCode=INVTG][@moodCo de=EVN]/subjectOf1[@typeCode=SUBJ][1]/controlActEvent/author/assignedEntity/code[@codeSyste m=2.16.840.1.1.13883.3.989.2.1.1.7][1]/controlActEvent[@classCode=CACT][@moodCode=EVN] /author[@typeCode=AUT]/assignedEntity[@classCode=ASSIGNED]/assignedPerson[@classCode =PSN][@determinerCode=INSTANCE]/name/given[2]/text() </pre> |
| e | C.3.3.5 | 送信者の姓 | 60AN | Person Name (PN) | family=Entity Name Part (ENXP) | 値 | <pre> /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:h7-org:v3 MCCI_IN200100UV01.xsd]/PARR_IN049016UVU1/controlActProcess[@classCode=CACT][@moodCo dCode=EVN]/subjectOf[@typeCode=SUBJ][1]/investigationEvent[@classCode=INVTG][@moodCo de=EVN]/subjectOf1[@typeCode=SUBJ][1]/controlActEvent/author/assignedEntity/code[@codeSyste m=2.16.840.1.1.13883.3.989.2.1.1.7][1]/controlActEvent[@classCode=CACT][@moodCode=EVN] /author[@typeCode=AUT]/assignedEntity[@classCode=ASSIGNED]/assignedPerson[@classCode =PSN][@determinerCode=INSTANCE]/name/family[1]/text() </pre> |
| h | C.3.4 | 送信者の住所、FAX 番号、電 話番号及び電子メールアドレス | | | | | |
| e | C.3.4.1 | 送信者の住所 (番地) | 100AN | Postal Address (AD) | streetAddressLine=Address Part (ADXP) | 値 | <pre> /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:h7-org:v3 MCCI_IN200100UV01.xsd]/PARR_IN049016UVU1/controlActProcess[@classCode=CACT][@moodCo dCode=EVN]/subjectOf[@typeCode=SUBJ][1]/investigationEvent[@classCode=INVTG][@moodCo de=EVN]/subjectOf1[@typeCode=SUBJ][1]/controlActEvent/author/assignedEntity/code[@codeSyste m=2.16.840.1.1.13883.3.989.2.1.1.7][1]/controlActEvent[@classCode=CACT][@moodCode=EVN] /author[@typeCode=AUT]/assignedEntity[@classCode=ASSIGNED]/addr[1]/streetAddressLine[1]/t ext() </pre> |
| e | C.3.4.2 | 送信者の住所 (市町村等) | 35AN | Postal Address (AD) | city=Address Part (ADXP) | 値 | <pre> /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:h7-org:v3 MCCI_IN200100UV01.xsd]/PARR_IN049016UVU1/controlActProcess[@classCode=CACT][@moodCo dCode=EVN]/subjectOf[@typeCode=SUBJ][1]/investigationEvent[@classCode=INVTG][@moodCo de=EVN]/subjectOf1[@typeCode=SUBJ][1]/controlActEvent/author/assignedEntity/code[@codeSyste m=2.16.840.1.1.13883.3.989.2.1.1.7][1]/controlActEvent[@classCode=CACT][@moodCode=EVN] /author[@typeCode=AUT]/assignedEntity[@classCode=ASSIGNED]/addr[1]/city[1]/text() </pre> |
| e | C.3.4.3 | 送信者の住所 (都道府県等) | 40AN | Postal Address (AD) | state=Address Part (ADXP) | 値 | <pre> /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:h7-org:v3 MCCI_IN200100UV01.xsd]/PARR_IN049016UVU1/controlActProcess[@classCode=CACT][@moodCo dCode=EVN]/subjectOf[@typeCode=SUBJ][1]/investigationEvent[@classCode=INVTG][@moodCo de=EVN]/subjectOf1[@typeCode=SUBJ][1]/controlActEvent/author/assignedEntity/code[@codeSyste m=2.16.840.1.1.13883.3.989.2.1.1.7][1]/controlActEvent[@classCode=CACT][@moodCode=EVN] /author[@typeCode=AUT]/assignedEntity[@classCode=ASSIGNED]/addr[1]/state[1]/text() </pre> |

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|---|---------|------------------------|-------|---------------------------------|--------------------------------|-------------|---|
| 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:h7-org:v3 MCCL_IN200100UV01.xsd]/PORR_IN049016UV/r/controlAct/process/@classCode=CACTT][@moo dCode=EVN]/subject/@typeCode=SUBJ][1]/investigationEvent/@classCode=INVSSTG][@moodCo de=EVN]/subjectOff/@typeCode=SUBJ][controlActEvent/author/assignedEntity/code/@codeSyste m=2.16.840.1.113883.3.989.2.1.1.7][1]/controlActEvent/@classCode=CACTT][@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:h7-org:v3 MCCL_IN200100UV01.xsd]/PORR_IN049016UV/r/controlAct/process/@classCode=CACTT][@moo dCode=EVN]/subject/@typeCode=SUBJ][1]/investigationEvent/@classCode=INVSSTG][@moodCo de=EVN]/subjectOff/@typeCode=SUBJ][controlActEvent/author/assignedEntity/code/@codeSyste m=2.16.840.1.113883.3.989.2.1.1.7][1]/controlActEvent/@classCode=CACTT][@moodCode=EVN] /author/@typeCode=AUT]/assignedEntity/@classCode=ASSIGNED]/assignedPerson/@classCode =PSN][@determinerCode=INSTANCE]/lastOccatedEntity/@classCode=LOC][1]/location/@classC ode=COUNTRY][@determinerCode=INSTANCE]/code/@codeSystem=1.0.3166.1.2.2][@code </pre> |
| e | C.3.4.6 | 送信者の電話番号 | 33AN | Telecommunication Address (TEL) | | 値 | <pre> substring(MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:h7-org:v3 MCCL_IN200100UV01.xsd]/PORR_IN049016UV/r/controlAct/process/@classCode=CACTT][@moo dCode=EVN]/subject/@typeCode=SUBJ][1]/investigationEvent/@classCode=INVSSTG][@moodCo de=EVN]/subjectOff/@typeCode=SUBJ][controlActEvent/author/assignedEntity/code/@codeSyste m=2.16.840.1.113883.3.989.2.1.1.7][1]/controlActEvent/@classCode=CACTT][@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:h7-org:v3 MCCL_IN200100UV01.xsd]/PORR_IN049016UV/r/controlAct/process/@classCode=CACTT][@moo dCode=EVN]/subject/@typeCode=SUBJ][1]/investigationEvent/@classCode=INVSSTG][@moodCo de=EVN]/subjectOff/@typeCode=SUBJ][controlActEvent/author/assignedEntity/code/@codeSyste m=2.16.840.1.113883.3.989.2.1.1.7][1]/controlActEvent/@classCode=CACTT][@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:h7-org:v3 MCCL_IN200100UV01.xsd]/PORR_IN049016UV/r/controlAct/process/@classCode=CACTT][@moo dCode=EVN]/subject/@typeCode=SUBJ][1]/investigationEvent/@classCode=INVSSTG][@moodCo de=EVN]/subjectOff/@typeCode=SUBJ][controlActEvent/author/assignedEntity/code/@codeSyste m=2.16.840.1.113883.3.989.2.1.1.7][1]/controlActEvent/@classCode=CACTT][@moodCode=EVN] /author/@typeCode=AUT]/assignedEntity/@classCode=ASSIGNED]/telecom[starts-with(@value, 'mailto:')]][1]/@value, 8) </pre> |
| h | C.4.r | 引用文献 (必要に応じて繰り返し ず) | | | | 繰り返し ノード | <pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:h7-org:v3 MCCL_IN200100UV01.xsd]/PORR_IN049016UV/r/controlAct/process/@classCode=CACTT][@moo dCode=EVN]/subject/@typeCode=SUBJ][1]/investigationEvent/@classCode=INVSSTG][@moodCo de=EVN]/reference/@typeCode=REFR][documentCode/@code=2][@codeSystem=2.16.840.1.11 3883.3.989.2.1.1.27]]/document/@classCode=DOC][@moodCode=EVN]/bibliographicDesignati on/text/text() </pre> |
| e | C.4.r.1 | 引用文献 | 500AN | Encapsulated Data (ED) | | 値 | <pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:h7-org:v3 MCCL_IN200100UV01.xsd]/PORR_IN049016UV/r/controlAct/process/@classCode=CACTT][@moo dCode=EVN]/subject/@typeCode=SUBJ][1]/investigationEvent/@classCode=INVSSTG][@moodCo de=EVN]/reference/@typeCode=REFR][documentCode/@code=2][@codeSystem=2.16.840.1.11 3883.3.989.2.1.1.27]]/document/@classCode=EVN]/bibliographicDesignati on/text/text() </pre> |

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|---|-----------|-------------------------|------|--------------------------|---------------------------------|-------------|---|
| e | | | | | | NullFlavor | /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=INVTG][@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]/biographicDesignationText[@nullFlavor |
| e | C.4.r.2 | 含まれる資料 | N/A | Encapsulated Data (ED) | | 値 | /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UV01/controlActProcess[@classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUBJ][@investigationEvent[@classCode=INVTG][@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]/text() |
| h | C.5 | 試験の識別 | | | | | |
| h | C.5.1.r | 試験の登録情報 (必要に応じ 繰り返す) | | | | 繰り返し ノード | /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UV01/controlActProcess[@classCode=CACT][@moodCode=EVN]/component[@typeCode=COMP][@adverseEventAssessment[@typeCode=EVN]/subjectOf1[@typeCode=EVN]/subject1[@typeCode=SBJ][@primaryRole/@classCode=INVTG][@moodCode=EVN]/researchStudy[@classCode=CLNTRL][@moodCode=EVN]/authorization[@typeCode=AUTH] |
| e | C.5.1.r.1 | 試験の登録番号 | 50AN | Instance Identifier (II) | extension=Character String (ST) | 値 | /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UV01/controlActProcess[@classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUBJ][@investigationEvent[@classCode=INVTG][@moodCode=EVN]/component[@typeCode=COMP][@adverseEventAssessment[@typeCode=EVN]/subjectOf1[@typeCode=EVN]/subject1[@typeCode=SBJ][@primaryRole/@classCode=INVTG][@moodCode=EVN]/researchStudy[@classCode=CLNTRL][@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 | | | | | | NullFlavor | /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UV01/controlActProcess[@classCode=CACT][@moodCode=EVN]/component[@typeCode=COMP][@adverseEventAssessment[@typeCode=EVN]/subjectOf1[@typeCode=EVN]/subject1[@typeCode=SBJ][@primaryRole/@classCode=INVTG][@moodCode=EVN]/researchStudy[@classCode=CLNTRL][@moodCode=EVN]/authorization[@typeCode=AUTH][@studyRegistration[@classCode=ACT][@moodCode=EVN]/id[@root=2.16.840.1.113883.3.989.2.1.3.6][@nullFlavor |
| e | C.5.1.r.2 | 試験の登録国 | 2A | Concept Descriptor (CD) | code=Character String (ST) | 値 | /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UV01/controlActProcess[@classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUBJ][@investigationEvent[@classCode=INVTG][@moodCode=EVN]/component[@typeCode=COMP][@adverseEventAssessment[@typeCode=EVN]/subjectOf1[@typeCode=EVN]/subject1[@typeCode=SBJ][@primaryRole/@classCode=INVTG][@moodCode=EVN]/researchStudy[@classCode=CLNTRL][@moodCode=EVN]/authorization[@typeCode=AUTH][@territorialAuthority[@classCode=TERR][@governingPlace/@classCode=COUNTRY][@determinerCode=INSTANCE]/code/@codeSystem=1.0.3166.1.2.2][@code |

(別添 3)

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|---|-------|---------------------------|--------|-----------------------------|---------------------------------|--|
| e | | | | | NullFlavor | <pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/PDRR_IN049016UV/r/controlActProcess/@classCode=CACTI[@moodCo dCode=EVN]/subject/@typeCode=SUBJ[1]/investigationEvent/@classCode=INVTG[1]@moodCo de=EVN/component/@typeCode=COMP[1]adverseEventAssessment[1]/adverseEventAssessment [@classCode=INVTG][@moodCode=EVN]/subject1/@typeCode=SBJ[1]/primaryRole/@classCo de=INVSBJ[1]/subjectOf1/@typeCode=EVN[1]/researchStudy/@classCode=CLNTRL[1]@moodCo de=EVN/authorization/@typeCode=AUT[1]/studyRegistration/@classCode=ACT[1]@moodCode =EVN/author/@typeCode=AUT[1]/territorialAuthority/@classCode=TERR[1]governingPlace/@class Code=COUNTRY[1]@code/@determinerCode=INSTANCE[1]code/@codesSystem=1.0.3.166.1.2.2][@nullFla vor </pre> |
| e | C.5.2 | 試験名 | 2000AN | Character String (ST) | 値 | <pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/PDRR_IN049016UV/r/controlActProcess/@classCode=CACTI[@moo dCode=EVN]/subject/@typeCode=SUBJ[1]/investigationEvent/@classCode=INVTG[1]@moodCo de=EVN/component/@typeCode=COMP[1]adverseEventAssessment[1]/adverseEventAssessment [@classCode=INVTG][@moodCode=EVN]/subject1/@typeCode=SBJ[1]/primaryRole/@classCo de=INVSBJ[1]/subjectOf1/@typeCode=EVN[1]/researchStudy/@classCode=CLNTRL[1]@moodCo de=EVN/authorization/@typeCode=AUT[1]/studyRegistration/@classCode=ACT[1]@moodCode =EVN/author/@typeCode=AUT[1]/territorialAuthority/@classCode=TERR[1]governingPlace/@class Code=COUNTRY[1]@code/@determinerCode=INSTANCE[1]code/@codesSystem=1.0.3.166.1.2.2][@nullFla vor </pre> |
| e | C.5.3 | 試験依頼者 (スポンサー) の 試験番号 | 50AN | Instance Identifier (II) | extension=Character String (ST) | <pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/PDRR_IN049016UV/r/controlActProcess/@classCode=CACTI[@moo dCode=EVN]/subject/@typeCode=SUBJ[1]/investigationEvent/@classCode=INVTG[1]@moodCo de=EVN/component/@typeCode=COMP[1]adverseEventAssessment[1]/adverseEventAssessment [@classCode=INVTG][@moodCode=EVN]/subject1/@typeCode=SBJ[1]/primaryRole/@classCo de=INVSBJ[1]/subjectOf1/@typeCode=EVN[1]/researchStudy/@classCode=CLNTRL[1]@moodCo de=EVN/authorization/@typeCode=AUT[1]/studyRegistration/@classCode=ACT[1]@moodCode =EVN/author/@typeCode=AUT[1]/territorialAuthority/@classCode=TERR[1]governingPlace/@class Code=COUNTRY[1]@code/@determinerCode=INSTANCE[1]code/@codesSystem=1.0.3.166.1.2.2][@nullFla vor </pre> |
| e | C.5.4 | 副作用 / 有害事象が観察さ れた試験の種類 | 1N | Coded With Equivalents (CE) | code=Character String (ST) | <pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/PDRR_IN049016UV/r/controlActProcess/@classCode=CACTI[@moo dCode=EVN]/subject/@typeCode=SUBJ[1]/investigationEvent/@classCode=INVTG[1]@moodCo de=EVN/component/@typeCode=COMP[1]adverseEventAssessment[1]/adverseEventAssessment [@classCode=INVTG][@moodCode=EVN]/subject1/@typeCode=SBJ[1]/primaryRole/@classCo de=INVSBJ[1]/subjectOf1/@typeCode=EVN[1]/researchStudy/@classCode=CLNTRL[1]@moodCo de=EVN/authorization/@typeCode=AUT[1]/studyRegistration/@classCode=ACT[1]@moodCode =EVN/author/@typeCode=AUT[1]/territorialAuthority/@classCode=TERR[1]governingPlace/@class Code=COUNTRY[1]@code/@determinerCode=INSTANCE[1]code/@codesSystem=1.0.3.166.1.2.2][@nullFla vor </pre> |

(別添3)

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|---|---------|---------------------------------|------|--------------------------|---------------------------------|------------|--|
| h | D | 患者特性 | | | | | <pre>/MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PDRR_IN049016UV01/controlActProcess[@classCode=CACCT][@moo dCode=EVN]/subject/@typeCode="SUBJ" investigationEvent[@classCode=INVSTG][@moodCo de=EVN]/component/@typeCode="COMP" adverseEventAssessment[@classCode=ASSESSM T][@classCode=INVSTG][@moodCode=EVN]/subject1/@typeCode="SBJ" primaryRole[@classC ode=INVSBJ]/subject1/@typeCode="SBJ" researchStudy[@classCode=CLNTRL][@moodCo de=EVN]/code[@codeSystem="2.16.840.1.113883.3.989.2.1.1.8"]/@codeSystemVersion</pre> |
| e | D.1 | 患者 (名前又はイニシャル) | 60AN | Entity Name (EN) | name=Entity Name Part (ENXP) | 値 | <pre>/MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PDRR_IN049016UV01/controlActProcess[@classCode=CACCT][@moo dCode=EVN]/subject/@typeCode="SUBJ" investigationEvent[@classCode=INVSTG][@moodCo de=EVN]/component/@typeCode="COMP" adverseEventAssessment[@classCode=ASSESSM T][@classCode=INVSTG][@moodCode=EVN]/subject1/@typeCode="SBJ" primaryRole[@classC ode=INVSBJ]/player1/@classCode="PSN" @determinerCode="INSTANCE"/name[1]/text()</pre> |
| e | | | | | | NullFlavor | <pre>/MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PDRR_IN049016UV01/controlActProcess[@classCode=CACCT][@moo dCode=EVN]/subject/@typeCode="SUBJ" investigationEvent[@classCode=INVSTG][@moodCo de=EVN]/component/@typeCode="COMP" adverseEventAssessment[@classCode=ASSESSM T][@classCode=INVSTG][@moodCode=EVN]/subject1/@typeCode="SBJ" primaryRole[@classC ode=INVSBJ]/player1/@classCode="PSN" @determinerCode="INSTANCE"/name[1]/text()</pre> |
| h | D.1.1 | 患者の診療記録番号及びその情報源 (記載が許可されている場合) | | | | | |
| e | D.1.1.1 | 患者の診療記録番号及びその情報源 (開業医診療記録番号) | 20AN | Instance Identifier (II) | extension=Character String (ST) | 値 | <pre>/MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PDRR_IN049016UV01/controlActProcess[@classCode=CACCT][@moo dCode=EVN]/subject/@typeCode="SUBJ" investigationEvent[@classCode=INVSTG][@moodCo de=EVN]/component/@typeCode="COMP" adverseEventAssessment[@classCode=ASSESSM T][@classCode=INVSTG][@moodCode=EVN]/subject1/@typeCode="SBJ" primaryRole[@classC ode=INVSBJ]/player1/@classCode="PSN" @determinerCode="INSTANCE"/asIdentifierEntity/@cl assCode="IDENT" code[@code="1"]/@codeSystem="2.16.840.1.113883.3.989.2.1.1.4" [1]/id/@root=" 2.16.840.1.113883.3.989.2.1.3.7" [1] @extension</pre> |
| e | | | | | | NullFlavor | <pre>/MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PDRR_IN049016UV01/controlActProcess[@classCode=CACCT][@moo dCode=EVN]/subject/@typeCode="SUBJ" investigationEvent[@classCode=INVSTG][@moodCo de=EVN]/component/@typeCode="COMP" adverseEventAssessment[@classCode=ASSESSM T][@classCode=INVSTG][@moodCode=EVN]/subject1/@typeCode="SBJ" primaryRole[@classC ode=INVSBJ]/player1/@classCode="PSN" @determinerCode="INSTANCE"/asIdentifierEntity/@cl assCode="IDENT" code[@code="1"]/@codeSystem="2.16.840.1.113883.3.989.2.1.1.4" [1]/id/@root=" 2.16.840.1.113883.3.989.2.1.3.7" [1] @extension</pre> |
| e | D.1.1.2 | 患者の診療記録番号及びその情報源 (専門医診療記録番号) | 20AN | Instance Identifier (II) | extension=Character String (ST) | 値 | <pre>/MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PDRR_IN049016UV01/controlActProcess[@classCode=CACCT][@moo dCode=EVN]/subject/@typeCode="SUBJ" investigationEvent[@classCode=INVSTG][@moodCo de=EVN]/component/@typeCode="COMP" adverseEventAssessment[@classCode=ASSESSM T][@classCode=INVSTG][@moodCode=EVN]/subject1/@typeCode="SBJ" primaryRole[@classC ode=INVSBJ]/player1/@classCode="PSN" @determinerCode="INSTANCE"/asIdentifierEntity/@cl assCode="IDENT" code[@code="2"]/@codeSystem="2.16.840.1.113883.3.989.2.1.1.4" [1]/id/@root=" 2.16.840.1.113883.3.989.2.1.3.8" [1] @extension</pre> |

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| e | | | | | NullFlavor | /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PDRR_IN049016UV01/controlAcqProcess[@classCode=CACTT][@moodCode=EVN]/subject[@typeCode=SUBJ][1]/investigationEvent[@classCode=INVSSTG][@moodCode=EVN]/component[@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment[@classCode=INVSSTG][@moodCode=EVN]/subject[1]/primaryRole[@classCode=INVSBJ][player1][@classCode=PSNT][@determinerCode=INSTANCE]/asIdentifiedEntity[@classCode=IDENT][code[@code=2]][@codeSystem=2.16.840.1.113883.3.989.2.1.1.4][1]/id[@root=2.16.840.1.113883.3.989.2.1.3.8][1]]/@nullFlavor | |
| e | D.1.1.3 | 患者の診療記録番号及びその情報源 (病院診療記録番号) | 20AN | Instance Identifier (II) | extension=Character String (ST) | 値 | /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PDRR_IN049016UV01/controlAcqProcess[@classCode=CACTT][@moodCode=EVN]/subject[@typeCode=SUBJ][1]/investigationEvent[@classCode=INVSSTG][@moodCode=EVN]/component[@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment[@classCode=INVSSTG][@moodCode=EVN]/subject[1]/primaryRole[@classCode=INVSBJ][player1][@classCode=PSNT][@determinerCode=INSTANCE]/asIdentifiedEntity[@classCode=IDENT][code[@code=3]][@codeSystem=2.16.840.1.113883.3.989.2.1.1.4][1]/id[@root=2.16.840.1.113883.3.989.2.1.3.9][1]]/@extension |
| e | | | | | NullFlavor | /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PDRR_IN049016UV01/controlAcqProcess[@classCode=CACTT][@moodCode=EVN]/subject[@typeCode=SUBJ][1]/investigationEvent[@classCode=INVSSTG][@moodCode=EVN]/component[@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment[@classCode=INVSSTG][@moodCode=EVN]/subject[1]/primaryRole[@classCode=INVSBJ][player1][@classCode=PSNT][@determinerCode=INSTANCE]/asIdentifiedEntity[@classCode=IDENT][code[@code=3]][@codeSystem=2.16.840.1.113883.3.989.2.1.1.4][1]/id[@root=2.16.840.1.113883.3.989.2.1.3.9][1]]/@nullFlavor | |
| e | D.1.1.4 | 患者の診療記録番号及びその情報源 (試験の中での患者識別番号) | 20AN | Instance Identifier (II) | extension=Character String (ST) | 値 | /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PDRR_IN049016UV01/controlAcqProcess[@classCode=CACTT][@moodCode=EVN]/subject[@typeCode=SUBJ][1]/investigationEvent[@classCode=INVSSTG][@moodCode=EVN]/component[@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment[@classCode=INVSSTG][@moodCode=EVN]/subject[1]/primaryRole[@classCode=INVSBJ][player1][@classCode=PSNT][@determinerCode=INSTANCE]/asIdentifiedEntity[@classCode=IDENT][code[@code=4]][@codeSystem=2.16.840.1.113883.3.989.2.1.1.4][1]/id[@root=2.16.840.1.113883.3.989.2.1.3.10][1]]/@extension |
| e | | | | | NullFlavor | /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PDRR_IN049016UV01/controlAcqProcess[@classCode=CACTT][@moodCode=EVN]/subject[@typeCode=SUBJ][1]/investigationEvent[@classCode=INVSSTG][@moodCode=EVN]/component[@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment[@classCode=INVSSTG][@moodCode=EVN]/subject[1]/primaryRole[@classCode=INVSBJ][player1][@classCode=PSNT][@determinerCode=INSTANCE]/asIdentifiedEntity[@classCode=IDENT][code[@code=4]][@codeSystem=2.16.840.1.113883.3.989.2.1.1.4][1]/id[@root=2.16.840.1.113883.3.989.2.1.3.10][1]]/@nullFlavor | |
| h | D.2 | 年齢情報 | | | | | |
| e | D.2.1 | 生年月日 | 日付/時間 | Point in Time (TS) | | 値 | /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PDRR_IN049016UV01/controlAcqProcess[@classCode=CACTT][@moodCode=EVN]/subject[@typeCode=SUBJ][1]/investigationEvent[@classCode=INVSSTG][@moodCode=EVN]/component[@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment[@classCode=INVSSTG][@moodCode=EVN]/subject[1]/primaryRole[@classCode=INVSBJ][player1][@classCode=PSNT][@determinerCode=INSTANCE]/asIdentifiedEntity[@classCode=IDENT][code[@code=4]][@codeSystem=2.16.840.1.113883.3.989.2.1.1.4][1]/id[@root=2.16.840.1.113883.3.989.2.1.3.10][1]]/@nullFlavor |

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| e | | | | | NullFlavor | /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UV/r/controlActProcess/@classCode=CACTT][@moodCode=EVN]/subject/@typeCode=SUBJ][1]/investigationEvent/@classCode=INVTSG][@moodCode=EVN]/component/@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment/@classCode=INVTSG][@moodCode=EVN]/subject1/@typeCode=SBJ][1]/primaryRole/@classCode=INVSBJ]/player1/@classCode=PSN][@determinerCode=INSTANCE]/birthTime/@nullFlavor |
| h | D.2.2 | 副作用／有害事象発現時の年齢 | | | | |
| e | D.2.2a | 副作用／有害事象発現時の年齢 (数) | 5N | Physical Quantity (PQ) | 値 | value=Real Number (REAL) |
| e | D.2.2b | 副作用／有害事象発現時の年齢 (単位) | 50AN | Physical Quantity (PQ) | 値 | unit=Coded Simple Value (CS) |
| 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) | 値 | value=Real Number (REAL) |
| 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) | 値 | unit=Coded Simple Value (CS) |
| e | D.2.3 | 患者の年齢群 (報告者の意項による) | 1N | Coded With Equivalents (CE) | 値 | code=Character String (ST) |

(別添 3)

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| 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 リストのバージョン | 6N | Physical Quantity (PQ) | 値 | /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:h7-org:v3 MCCI_IN200100UV01.xsd]/PDRR_IN049016UV/r/controlAct/process/@classCode=CACTT[@moodCode=EVN]/subject/@typeCode=SUBJ[1]/investigationEvent/@classCode=INVSSTG[1]@moodCode=EVN/component/@typeCode=COMP[1]adverseEventAssessment[1]adverseEventAssessment[@classCode=INVSSTG][@moodCode=EVN]/subject[1]@typeCode=SBJ[1]/primaryRole/@classCode=INVSBJ[1]subjectO2[1]@typeCode=SBJ[1]observation/code/@code=4[1]@codeSystem=2.16.84.0.1.113883.3.989.2.1.1.19[1]observation/@classCode=OBS[1]@moodCode=EVN/value/@xsi:type=CE[1]@codeSystem=2.16.84.0.1.113883.3.989.2.1.1.9[1]@codeSystem/Version |
| e | D.3 | 体重 (kg) | 6N | Physical Quantity (PQ) | 値 | /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:h7-org:v3 MCCI_IN200100UV01.xsd]/PDRR_IN049016UV/r/controlAct/process/@classCode=CACTT[@moodCode=EVN]/subject/@typeCode=SUBJ[1]/investigationEvent/@classCode=INVSSTG[1]@moodCode=EVN/component/@typeCode=COMP[1]adverseEventAssessment[1]adverseEventAssessment[@classCode=INVSSTG][@moodCode=EVN]/subject[1]@typeCode=SBJ[1]/primaryRole/@classCode=INVSBJ[1]subjectO2[1]@typeCode=SBJ[1]observation/code/@code=7[1]@codeSystem=2.16.84.0.1.113883.3.989.2.1.1.19[1]observation/@classCode=OBS[1]@moodCode=EVN/value/@xsi:type=PQ[1]@unit=kg[1]@value |
| e | D.4 | 身長 (cm) | 3N | Physical Quantity (PQ) | 値 | /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:h7-org:v3 MCCI_IN200100UV01.xsd]/PDRR_IN049016UV/r/controlAct/process/@classCode=CACTT[@moodCode=EVN]/subject/@typeCode=SUBJ[1]/investigationEvent/@classCode=INVSSTG[1]@moodCode=EVN/component/@typeCode=COMP[1]adverseEventAssessment[1]adverseEventAssessment[@classCode=INVSSTG][@moodCode=EVN]/subject[1]@typeCode=SBJ[1]/primaryRole/@classCode=INVSBJ[1]subjectO2[1]@typeCode=SBJ[1]observation/code/@code=1[1]@codeSystem=2.16.84.0.1.113883.3.989.2.1.1.19[1]observation/@classCode=OBS[1]@moodCode=EVN/value/@xsi:type=PQ[1]@unit=cm[1]@value |
| e | D.5 | 性別 | 1N | Coded With Equivalents (CE) | 値 | /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:h7-org:v3 MCCI_IN200100UV01.xsd]/PDRR_IN049016UV/r/controlAct/process/@classCode=CACTT[@moodCode=EVN]/subject/@typeCode=SUBJ[1]/investigationEvent/@classCode=INVSSTG[1]@moodCode=EVN/component/@typeCode=COMP[1]adverseEventAssessment[1]adverseEventAssessment[@classCode=INVSSTG][@moodCode=EVN]/subject[1]@typeCode=SBJ[1]/primaryRole/@classCode=INVSBJ[1]player1/@classCode=PSN[1]@determinerCode=INSTANCE/administrativeGenderCode/@codeSystem=1.0.5218[1]@code |
| e | | | | Null flavor | Null flavor | /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:h7-org:v3 MCCI_IN200100UV01.xsd]/PDRR_IN049016UV/r/controlAct/process/@classCode=CACTT[@moodCode=EVN]/subject/@typeCode=SUBJ[1]/investigationEvent/@classCode=INVSSTG[1]@moodCode=EVN/component/@typeCode=COMP[1]adverseEventAssessment[1]adverseEventAssessment[@classCode=INVSSTG][@moodCode=EVN]/subject[1]@typeCode=SBJ[1]/primaryRole/@classCode=INVSBJ[1]player1/@classCode=PSN[1]@determinerCode=INSTANCE/administrativeGenderCode/@codeSystem=1.0.5218[1]@nullFlavor |
| e | D.6 | 最終月経日 | 日付/時間 | Point in Time (TS) | 値 | /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:h7-org:v3 MCCI_IN200100UV01.xsd]/PDRR_IN049016UV/r/controlAct/process/@classCode=CACTT[@moodCode=EVN]/subject/@typeCode=SUBJ[1]/investigationEvent/@classCode=INVSSTG[1]@moodCode=EVN/component/@typeCode=COMP[1]adverseEventAssessment[1]adverseEventAssessment[@classCode=INVSSTG][@moodCode=EVN]/subject[1]@typeCode=SBJ[1]/primaryRole/@classCode=INVSBJ[1]subjectO2[1]@typeCode=SBJ[1]observation/code/@code=22[1]@codeSystem=2.16.84.0.1.113883.3.989.2.1.1.19[1]observation/@classCode=OBS[1]@moodCode=EVN/value/@xsi:type=TS[1]@value |

(別添3)

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| e | | | | | | | NullFlavor | /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UV1[controlActProcess/@classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUBJ][investigationEvent/@classCode=INVTG][@moodCode=EVN]/component[@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment[@classCode=INVTG][@moodCode=EVN]/subject[1]/primaryRole/@classCode=INVSBJ/subjectOr2[@typeCode=SBJ][observation/code=22][@codeSystem=2.16.840.1.113883.3.989.2.1.1.20][observation/@classCode=OBS][@moodCode=EVN]/value[@xsi:type=TS][@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]/PORR_IN049016UV1[controlActProcess/@classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUBJ][investigationEvent/@classCode=INVTG][@moodCode=EVN]/component[@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment[@classCode=INVTG][@moodCode=EVN]/subject[1]/primaryRole/@classCode=INVSBJ/subjectOr2[@typeCode=SBJ][organizer/code=1][@codeSystem=2.16.840.1.113883.3.989.2.1.1.20][organizer/@classCode=CATEGORY][@moodCode=EVN]/component[@typeCode=COMP][observation/code/@codeSystem=2.16.840.1.113883.6.163] |
| e | D.7.1.r.1a | 関連する治療歴及び随伴症状の MedDRA パージョン | 4AN | Concept Descriptor (CD) | codeSystemVersion=Character String (ST) | 値 | | /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UV1[controlActProcess/@classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUBJ][investigationEvent/@classCode=INVTG][@moodCode=EVN]/component[@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment[@classCode=INVTG][@moodCode=EVN]/subject[1]/primaryRole/@classCode=INVSBJ/subjectOr2[@typeCode=SBJ][organizer/code=1][@codeSystem=2.16.840.1.113883.3.989.2.1.1.20][organizer/@classCode=CATEGORY][@moodCode=EVN]/component[@typeCode=COMP][observation/code/@codeSystem=2.16.840.1.113883.6.163][observation/@classCode=OBS][@moodCode=EVN]/code/@codeSystemVersion |
| e | D.7.1.r.1b | 関連する治療歴及び随伴症状 (疾病 / 手術処置 / その他) (MedDRA コード) | 8N | Concept Descriptor (CD) | code=Character String (ST) | 値 | | /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UV1[controlActProcess/@classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUBJ][investigationEvent/@classCode=INVTG][@moodCode=EVN]/component[@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment[@classCode=INVTG][@moodCode=EVN]/subject[1]/primaryRole/@classCode=INVSBJ/subjectOr2[@typeCode=SBJ][organizer/code=1][@codeSystem=2.16.840.1.113883.3.989.2.1.1.20][organizer/@classCode=CATEGORY][@moodCode=EVN]/component[@typeCode=COMP][observation/code/@codeSystem=2.16.840.1.113883.6.163][observation/@classCode=OBS][@moodCode=EVN]/code/@code |
| e | D.7.1.r.2 | 開始日 | 日付 / 時間 | Interval of Point in Time (VL<TS>) | low=Interval Boundary (IVXB) | 値 | | /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UV1[controlActProcess/@classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUBJ][investigationEvent/@classCode=INVTG][@moodCode=EVN]/component[@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment[@classCode=INVTG][@moodCode=EVN]/subject[1]/primaryRole/@classCode=INVSBJ/subjectOr2[@typeCode=SBJ][organizer/code=1][@codeSystem=2.16.840.1.113883.3.989.2.1.1.20][organizer/@classCode=CATEGORY][@moodCode=EVN]/component[@typeCode=COMP][observation/code/@codeSystem=2.16.840.1.113883.6.163][observation/@classCode=OBS][@moodCode=EVN]/effectiveTime[@xsi:type=IVL_TS][low/@value |

(別添3)

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|---|-----------|-----|-------|------------------------------------|------------------------------|--|
| e | | | | | NullFlavor | <pre> MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UVTr/controlActProcess/@classCode=CACTT][@moo 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=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 </pre> |
| e | D.7.1.r.3 | 継続 | ブール型 | Boolean (BL) | 値 | <pre> MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UVTr/controlActProcess/@classCode=CACTT][@moo 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=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][@code=13][@codeSystem=2.16.840.1.113883.3.989.2.1.1.19][1]/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=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UVTr/controlActProcess/@classCode=CACTT][@moo 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=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]/value/@xsi:type=BL][1]/@value </pre> |
| e | D.7.1.r.4 | 終了日 | 日付/時間 | Interval of Point in Time (VL<TS>) | high=Interval Boundary (VXB) | <pre> MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UVTr/controlActProcess/@classCode=CACTT][@moo 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=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]/high/@value </pre> |
| e | | | | | NullFlavor | <pre> MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UVTr/controlActProcess/@classCode=CACTT][@moo 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=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]/high/@nullFlavor </pre> |

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

(別添3)

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|---|----------|----------------------------|-----------|-----------------------------|---|
| h | D.8.r | 関連する過去の医薬品使用歴 (必要に応じて繰り返す) | | 繰り返しのノード | <pre> MCCI_IN200100UV01[(@ITSVersion=XML_1.0)[@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UV[/(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]/subject1/@typeCode=SB.J[1]/primaryRole/@classCode=INVSBJ[subjectOf2/@typeCode=SB.J][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 (報告された薬理) | 250AN | Entity Name (EN) | <pre> MCCI_IN200100UV01[(@ITSVersion=XML_1.0)[@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UV[/(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]/subject1/@typeCode=SB.J[1]/primaryRole/@classCode=INVSBJ[subjectOf2/@typeCode=SB.J][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][substanceAdministration/@classCode=SBADM][@moodCode=EVN]/consumable/@typeCode=CSM[1]/instanceOfKind/@classCode=SBADM][fProduct/@classCode=MMAAT][@determinerCode=KIND]/name[1]/text) </pre> |
| e | | | | NullFlavor | <pre> MCCI_IN200100UV01[(@ITSVersion=XML_1.0)[@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UV[/(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]/subject1/@typeCode=SB.J[1]/primaryRole/@classCode=INVSBJ[subjectOf2/@typeCode=SB.J][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][substanceAdministration/@classCode=SBADM][@moodCode=EVN]/consumable/@typeCode=CSM[1]/instanceOfKind/@classCode=SBADM][fProduct/@classCode=MMAAT][@determinerCode=KIND]/name[1]/@nullFlavor </pre> |
| e | D.8.r.2a | MPID パージョン日付/番号 | M5 ガイドを参照 | Coded With Equivalents (CE) | <pre> MCCI_IN200100UV01[(@ITSVersion=XML_1.0)[@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UV[/(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]/subject1/@typeCode=SB.J[1]/primaryRole/@classCode=INVSBJ[subjectOf2/@typeCode=SB.J][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][substanceAdministration/@classCode=SBADM][@moodCode=EVN]/consumable/@typeCode=CSM[1]/instanceOfKind/@classCode=SBADM][fProduct/@classCode=MMAAT][@determinerCode=KIND]/code[1]/code/@codeSystem=TBD-MPID]/@codeSystemVersion </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) | <pre> MCCI_IN200100UV01[(@ITSVersion=XML_1.0)[@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UV[/(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]/subject1/@typeCode=SB.J[1]/primaryRole/@classCode=INVSBJ[subjectOf2/@typeCode=SB.J][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][substanceAdministration/@classCode=SBADM][@moodCode=EVN]/consumable/@typeCode=CSM[1]/instanceOfKind/@classCode=SBADM][fProduct/@classCode=MMAAT][@determinerCode=KIND]/code[1]/code/@codeSystem=TBD-MPID]/@codeSystemVersion </pre> |

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|---|----------|----------------------|---------------|--|--|---|
| e | D.8.r.3a | PHPID パージョン日付／番 号 | M5 ガイド を参照 | Coded With Equivalents (CE) | code=SystemVersion= Character String (ST) | /MCCI_IN200100UV01[@ITSVersion=XMML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UV[1]/controlActProcess[@classCode=CACT][@moodCo dCode=EVN]/subject[@typeCode=SUBJ][1]/investigationEvent[@classCode=INVTG][@moodCo de=EVN]/component[@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment [@classCode=INVTG][@moodCode=EVN]/subject[1][1]/primaryRole[@classC ode=INVSBJ]/subjectOr[2][@typeCode=SBJ][organizerCode=@code=2][@codeSystem=2.16.840.1 .113883.3.988.2.1.1.20][1]/organizer[@classCode=CATEGORY][@moodCode=EVN]/component[@typeCode=COMP][substanceAdministration[1]/substanceAdministration[@classCode=SBADM][@moodCode=EVN]/consumable[@typeCode=CSM][1]/instanceOfKind[@classCode=INST]/kindO fProduct[@classCode=MMAT][@determinerCode=KIND][code/@codeSystem=TBD-PPID]/@cod eSystemVersion |
| e | D.8.r.3b | 製剤識別子 (PhPID) | M5 ガイド を参照 | Coded With Equivalents (CE) | code=Character String (ST) | /MCCI_IN200100UV01[@ITSVersion=XMML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UV[1]/controlActProcess[@classCode=CACT][@moodCo dCode=EVN]/subject[@typeCode=SUBJ][1]/investigationEvent[@classCode=INVTG][@moodCo de=EVN]/component[@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment [@classCode=INVTG][@moodCode=EVN]/subject[1][1]/primaryRole[@classC ode=INVSBJ]/subjectOr[2][@typeCode=SBJ][organizerCode=@code=2][@codeSystem=2.16.840.1 .113883.3.988.2.1.1.20][1]/organizer[@classCode=CATEGORY][@moodCode=EVN]/component[@typeCode=COMP][substanceAdministration[1]/substanceAdministration[@classCode=SBADM][@moodCode=EVN]/consumable[@typeCode=CSM][1]/instanceOfKind[@classCode=INST]/kindO fProduct[@classCode=MMAT][@determinerCode=KIND][code/@codeSystem=TBD-PPID]/@cod e |
| e | D.8.r.4 | 開始日 | 日付／時間 | Interval of Point in Time (IVL<TS>) | low=Interval Boundary (VXB) | /MCCI_IN200100UV01[@ITSVersion=XMML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UV[1]/controlActProcess[@classCode=CACT][@moodCo dCode=EVN]/subject[@typeCode=SUBJ][1]/investigationEvent[@classCode=INVTG][@moodCo de=EVN]/component[@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment [@classCode=INVTG][@moodCode=EVN]/subject[1][1]/primaryRole[@classC ode=INVSBJ]/subjectOr[2][@typeCode=SBJ][organizerCode=@code=2][@codeSystem=2.16.840.1 .113883.3.988.2.1.1.20][1]/organizer[@classCode=CATEGORY][@moodCode=EVN]/component[@typeCode=COMP][substanceAdministration[1]/substanceAdministration[@classCode=SBADM][@moodCode=EVN]/effectiveTime[@xsi:type=IVL_TS]/low/@value |
| e | | | | | NullFlavor | /MCCI_IN200100UV01[@ITSVersion=XMML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UV[1]/controlActProcess[@classCode=CACT][@moodCo dCode=EVN]/subject[@typeCode=SUBJ][1]/investigationEvent[@classCode=INVTG][@moodCo de=EVN]/component[@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment [@classCode=INVTG][@moodCode=EVN]/subject[1][1]/primaryRole[@classC ode=INVSBJ]/subjectOr[2][@typeCode=SBJ][organizerCode=@code=2][@codeSystem=2.16.840.1 .113883.3.988.2.1.1.20][1]/organizer[@classCode=CATEGORY][@moodCode=EVN]/component[@typeCode=COMP][substanceAdministration[1]/substanceAdministration[@classCode=SBADM][@moodCode=EVN]/effectiveTime[@xsi:type=IVL_TS]/low/@value |
| e | D.8.r.5 | 終了日 | 日付／時間 | Interval of Point in Time (IVL<TS>) | high=Interval Boundary (VXB) | /MCCI_IN200100UV01[@ITSVersion=XMML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UV[1]/controlActProcess[@classCode=CACT][@moodCo dCode=EVN]/subject[@typeCode=SUBJ][1]/investigationEvent[@classCode=INVTG][@moodCo de=EVN]/component[@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment [@classCode=INVTG][@moodCode=EVN]/subject[1][1]/primaryRole[@classC ode=INVSBJ]/subjectOr[2][@typeCode=SBJ][organizerCode=@code=2][@codeSystem=2.16.840.1 .113883.3.988.2.1.1.20][1]/organizer[@classCode=CATEGORY][@moodCode=EVN]/component[@typeCode=COMP][substanceAdministration[1]/substanceAdministration[@classCode=SBADM][@moodCode=EVN]/effectiveTime[@xsi:type=IVL_TS]/high/@value |

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|---|------------|------------------|-----|--------------------------------|---|
| e | NullFlavor | | | | <pre> /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049076UV/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/@code=2][@codeSystem=2.16.840.1 .113883.3.989.2.1.1.19][1]/organizer/@classCode=CATEGORY][@moodCode=EVN]/component[@typeCode=COMP][substanceAdministration[1]/substanceAdministration[@classCode=SBADM][@moodCode=EVN]/effectiveTime[@xsi:type=IVL_TS]/high/@nullFlavor </pre> |
| e | D.8.r.6a | MedDRA パー ジョン | 4AN | Coded With Equivalents (CE) | <pre> /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049076UV/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/@code=2][@codeSystem=2.16.840.1 .113883.3.989.2.1.1.19][1]/organizer/@classCode=CATEGORY][@moodCode=EVN]/component[@typeCode=COMP][substanceAdministration[1]/substanceAdministration[@classCode=SBADM][@moodCode=EVN]/outboundRelationship2[@typeCode=RSN][observation/code/@code=19][@ codeSystem=2.16.840.1.113883.3.989.2.1.1.19][1]/observation[@classCode=OBS][@moodCode =EVN]/value[@xsi:type=CE][@codeSystem=2.16.840.1.113883.6.163][1][1]/@codeSystemVersion </pre> |
| e | D.8.r.6b | MedDRA コード | 8N | Coded With Equivalents (CE) | <pre> /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049076UV/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/@code=2][@codeSystem=2.16.840.1 .113883.3.989.2.1.1.19][1]/organizer/@classCode=CATEGORY][@moodCode=EVN]/component[@typeCode=COMP][substanceAdministration[1]/substanceAdministration[@classCode=SBADM][@moodCode=EVN]/outboundRelationship2[@typeCode=RSN][observation/code/@code=19][@ codeSystem=2.16.840.1.113883.3.989.2.1.1.19][1]/observation[@classCode=OBS][@moodCode =EVN]/value[@xsi:type=CE][@codeSystem=2.16.840.1.113883.6.163][1][1]/@code </pre> |
| e | D.8.r.7a | MedDRA パー ジョン | 4AN | Coded With Equivalents (CE) | <pre> /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049076UV/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/@code=2][@codeSystem=2.16.840.1 .113883.3.989.2.1.1.19][1]/organizer/@classCode=CATEGORY][@moodCode=EVN]/component[@typeCode=COMP][substanceAdministration[1]/substanceAdministration[@classCode=SBADM][@moodCode=EVN]/outboundRelationship2[@typeCode=CAUS][observation/code/@code=29][@ codeSystem=2.16.840.1.113883.3.989.2.1.1.19][1]/observation[@classCode=OBS][@moodCode =EVN]/value[@xsi:type=CE][@codeSystem=2.16.840.1.113883.6.163][1][1]/@codeSystemVersion </pre> |

(別添 3)

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|---|------------|---------------------------|-------|--------------------------------|---|---|---|
| e | D.9.2.r.2 | 報告された死因 (自由記載) | 250AN | Coded With Equivalents (CE) | originalText = Encapsulated Data (ED) | 値 | /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UV/r/controlActProcess[@classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUBJ][1]/investigationEvent[@classCode=INVTG][@moodCode=EVN]/component[@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment [@classCode=INVTG][@moodCode=EVN]/subject1[@typeCode=SBJ][1]/primaryRole[@classCode=INVSBJ]/subjectOf2[@typeCode=SBJ][observation/code[@code=5]][@codeSystem=2.16.84 0.1.113883.3.989.2.1.1.19][1]/observation[@classCode=OBS][@moodCode=EVN]/value[@xsi:type=CE][@codeSystem=2.16.840.1.113883.6.163][1]/originalText/text() |
| e | D.9.3 | 割検は実施されたか? | ブール型 | Boolean (BL) | 値 | /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UV/r/controlActProcess[@classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUBJ][1]/investigationEvent[@classCode=INVTG][@moodCode=EVN]/component[@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment [@classCode=INVTG][@moodCode=EVN]/subject1[@typeCode=SBJ][1]/primaryRole[@classCode=INVSBJ]/subjectOf2[@typeCode=SBJ][observation/code[@code=5]][@codeSystem=2.16.84 0.1.113883.3.989.2.1.1.19][1]/observation[@classCode=OBS][@moodCode=EVN]/value[@xsi:type=BL][1]/@value | |
| e | | | | | NullFlavor | /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UV/r/controlActProcess[@classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUBJ][1]/investigationEvent[@classCode=INVTG][@moodCode=EVN]/component[@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment [@classCode=INVTG][@moodCode=EVN]/subject1[@typeCode=SBJ][1]/primaryRole[@classCode=INVSBJ]/subjectOf2[@typeCode=SBJ][observation/code[@code=5]][@codeSystem=2.16.84 0.1.113883.3.989.2.1.1.19][1]/observation[@classCode=OBS][@moodCode=EVN]/value[@xsi:type=BL][1]/@nullFlavor | |
| h | D.9.4.r | 割検による死因 (必要に応じ 繰り返し返す) | | | 繰り返し返す ノード | /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UV/r/controlActProcess[@classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUBJ][1]/investigationEvent[@classCode=INVTG][@moodCode=EVN]/component[@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment [@classCode=INVTG][@moodCode=EVN]/subject1[@typeCode=SBJ][1]/primaryRole[@classCode=INVSBJ]/subjectOf2[@typeCode=SBJ][observation/code[@code=5]][@codeSystem=2.16.84 0.1.113883.3.989.2.1.1.19][1]/observation[@classCode=OBS][@moodCode=EVN]/outboundRelationship2[@typeCode=DRIV][observation/code[@code=8]][@codeSystem=2.16.840.1.113883.3.989.2.1.1.19] | |
| e | D.9.4.r.1a | 割検による死因の MedDRA バージョン | 4AN | Coded With Equivalents (CE) | codeSystemVersion= Character String (ST) | 値 | /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UV/r/controlActProcess[@classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUBJ][1]/investigationEvent[@classCode=INVTG][@moodCode=EVN]/component[@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment [@classCode=INVTG][@moodCode=EVN]/subject1[@typeCode=SBJ][1]/primaryRole[@classCode=INVSBJ]/subjectOf2[@typeCode=SBJ][observation/code[@code=5]][@codeSystem=2.16.84 0.1.113883.3.989.2.1.1.19][1]/observation[@classCode=OBS][@moodCode=EVN]/outboundRelationship2[@typeCode=DRIV][observation/code[@code=8]][@codeSystem=2.16.840.1.113883.3.989.2.1.1.19][1]/observation[@classCode=OBS][@moodCode=EVN]/value[@xsi:type=CE][@codeSystem=2.16.840.1.113883.6.163][1][1]/@codeSystemVersion |

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|---|------------|--------------------------|-------|--------------------------------|---|------------|--|
| e | D.9.4.r.1b | 剖検による死因 (MedDRA コード) | 8N | Coded With Equivalents (CE) | code=Character String (ST) | 値 | /MCCI_IN200100UV01[@ITSVersion='XML_1.0']/@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd'/PORR_IN049016UV/[/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']/subjectOr2[@typeCode='SBJ']/observation/code[@code=5]/@codesSystem='2.16.84.0.1.1.13883.3.989.2.1.1.19[/]/observation[@classCode='OBS']/@moodCode='EVN']/outcomeRelationship2[@typeCode='DRV']/observation/code/@code=8]/@codesSystem='2.16.84.0.1.1.13883.3.989.2.1.1.19[/]/observation[@classCode='OBS']/@moodCode='EVN']/value[@xs:type='CE']/@codeSystem='2.16.84.0.1.1.13883.6.163[/]/@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/[/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']/subjectOr2[@typeCode='SBJ']/observation/code[@code=5]/@codesSystem='2.16.84.0.1.1.13883.3.989.2.1.1.19[/]/observation[@classCode='OBS']/@moodCode='EVN']/outcomeRelationship2[@typeCode='DRV']/observation/code/@code=8]/@codesSystem='2.16.84.0.1.1.13883.3.989.2.1.1.19[/]/observation[@classCode='OBS']/@moodCode='EVN']/value[@xs:type='CE']/@codeSystem='2.16.84.0.1.1.13883.6.163[/]/@originalText(x) |
| h | D.10 | 親一子/胎児報告における、 親に関する情報 | | | | | |
| e | D.10.1 | 親の識別 | 60AN | Entity Name (EN) | name=Entity Name Part (ENXP) | 値 | /MCCI_IN200100UV01[@ITSVersion='XML_1.0']/@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd'/PORR_IN049016UV/[/controlActProcess[@classCode='CACT']/@moodCode=EVN]/subject[@typeCode='SUBJ']/investigationEvent[@classCode='INVESTG']/@moodCode=EVN]/component[@typeCode='COMP']/adverseEventAssessment[1]/adverseEventAssessment[@classCode='INVESTG']/@moodCode='EVN']/subject1[@typeCode='SBJ']/primaryRole[@classCode='INVSBJ']/player1[@classCode='PSN']/@determinerCode='INSTANCE']/role[@classCode='PR S']/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/[/controlActProcess[@classCode='CACT']/@moodCode=EVN]/subject[@typeCode='SUBJ']/investigationEvent[@classCode='INVESTG']/@moodCode=EVN]/component[@typeCode='COMP']/adverseEventAssessment[1]/adverseEventAssessment[@classCode='INVESTG']/@moodCode='EVN']/subject1[@typeCode='SBJ']/primaryRole[@classCode='INVSBJ']/player1[@classCode='PSN']/@determinerCode='INSTANCE']/role[@classCode='PR S']/associatedPerson[@classCode='PSN']/@determinerCode='INSTANCE']/name[1]/@nullFlavor |
| h | D.10.2 | 親の年齢情報 | | | | | |
| e | D.10.2.1 | 親の生年月日 | 日付/時間 | Point in Time (TS) | | 値 | /MCCI_IN200100UV01[@ITSVersion='XML_1.0']/@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd'/PORR_IN049016UV/[/controlActProcess[@classCode='CACT']/@moodCode=EVN]/subject[@typeCode='SUBJ']/investigationEvent[@classCode='INVESTG']/@moodCode=EVN]/component[@typeCode='COMP']/adverseEventAssessment[1]/adverseEventAssessment[@classCode='INVESTG']/@moodCode='EVN']/subject1[@typeCode='SBJ']/primaryRole[@classCode='INVSBJ']/player1[@classCode='PSN']/@determinerCode='INSTANCE']/role[@classCode='PR S']/associatedPerson[@classCode='PSN']/@determinerCode='INSTANCE']/birthTime/@value |

(別添 3)

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|---|-----------|-----------|-------|------------------------|------------|--|
| e | | | | | NullFlavor | <pre> /MCCI_IN200100UV01[@ITSVersion=XMML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PDRR_IN049016UV01/controlAct/process/@classCode=CACCT][@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) | 値 | <pre> /MCCI_IN200100UV01[@ITSVersion=XMML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PDRR_IN049016UV01/controlAct/process/@classCode=CACCT][@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]/subjectO2/@typeCode=SBJ[observation/code/@code=3][@codeSystem=2.16.840.1.11388 3.3.989.2.1.1.19][1]/observation/@classCode=OBS][@moodCode=EVN]/value/@xsi:type=PQ[1] /@value</pre> |
| e | D.10.2.2b | 親の年齢 (単位) | 50AN | Physical Quantity (PQ) | 値 | <pre> /MCCI_IN200100UV01[@ITSVersion=XMML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PDRR_IN049016UV01/controlAct/process/@classCode=CACCT][@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]/subjectO2/@typeCode=SBJ[observation/code/@code=3][@codeSystem=2.16.840.1.11388 3.3.989.2.1.1.19][1]/observation/@classCode=OBS][@moodCode=EVN]/value/@xsi:type=PQ[1] /@unit</pre> |
| e | D.10.3 | 親の最終月経日 | 日付/時間 | Point in Time (TS) | 値 | <pre> /MCCI_IN200100UV01[@ITSVersion=XMML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PDRR_IN049016UV01/controlAct/process/@classCode=CACCT][@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]/subjectO2/@typeCode=SBJ[observation/code/@code=22][@codeSystem=2.16.840.1.1138 8.3.989.2.1.1.19][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]/PDRR_IN049016UV01/controlAct/process/@classCode=CACCT][@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]/subjectO2/@typeCode=SBJ[observation/code/@code=22][@codeSystem=2.16.840.1.1138 8.3.989.2.1.1.19][1]/observation/@classCode=OBS][@moodCode=EVN]/value/@xsi:type=TS[1] /@nullFlavor</pre> |

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|---|------------|---------------------------|----|-----------------------------|----------------------------|-----------|--|
| e | D.10.4 | 親の体重 (kg) | 6N | Physical Quantity (PQ) | value=Real Number (REAL) | 値 | /MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PARR_IN049016UV1[controlActProcess/@classCode='CACT'][@moodCode='EVN']/subject/@typeCode='SUBJ'[/investigationEvent/@classCode='INVTG'][@moodCode='EVN']/component/@typeCode='COMP'[/adverseEventAssessment[1]/adverseEventAssessment/@classCode='INVTG'][@moodCode='EVN']/subject1/@typeCode='SBJ'[/primaryRole/@classCode='INVSBJ']/player1/@classCode='PSN'[/determinerCode='INSTANCE']/role/@classCode='PR S'[/subjectOr2/@typeCode='SBJ']/observation/code/@code='17'[@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']]/observation/@classCode='OBS'[@moodCode='EVN']/value[@xsi:type='PQ']/@unit='kg']/@value |
| e | D.10.5 | 親の身長 (cm) | 3N | Physical Quantity (PQ) | value=Real Number (REAL) | 値 | /MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PARR_IN049016UV1[controlActProcess/@classCode='CACT'][@moodCode='EVN']/subject/@typeCode='SUBJ'[/investigationEvent/@classCode='INVTG'][@moodCode='EVN']/component/@typeCode='COMP'[/adverseEventAssessment[1]/adverseEventAssessment/@classCode='INVTG'][@moodCode='EVN']/subject1/@typeCode='SBJ'[/primaryRole/@classCode='INVSBJ']/player1/@classCode='PSN'[/determinerCode='INSTANCE']/role/@classCode='PR S'[/subjectOr2/@typeCode='SBJ']/observation/code/@code='17'[@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']]/observation/@classCode='OBS'[@moodCode='EVN']/value[@xsi:type='PQ']/@unit='cm']/@value |
| e | D.10.6 | 親の性別 | 1N | Coded With Equivalents (CE) | code=Character String (ST) | 値 | /MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PARR_IN049016UV1[controlActProcess/@classCode='CACT'][@moodCode='EVN']/subject/@typeCode='SUBJ'[/investigationEvent/@classCode='INVTG'][@moodCode='EVN']/component/@typeCode='COMP'[/adverseEventAssessment[1]/adverseEventAssessment/@classCode='INVTG'][@moodCode='EVN']/subject1/@typeCode='SBJ'[/primaryRole/@classCode='INVSBJ']/player1/@classCode='PSN'[/determinerCode='INSTANCE']/role/@classCode='PR S'[/associatedPerson/@classCode='PSN'[@determinerCode='INSTANCE']/administrativeGenderCode/@codeSystem='1.0.5218']]/@code |
| e | | | | | NullFlavor | | /MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PARR_IN049016UV1[controlActProcess/@classCode='CACT'][@moodCode='EVN']/subject/@typeCode='SUBJ'[/investigationEvent/@classCode='INVTG'][@moodCode='EVN']/component/@typeCode='COMP'[/adverseEventAssessment[1]/adverseEventAssessment/@classCode='INVTG'][@moodCode='EVN']/subject1/@typeCode='SBJ'[/primaryRole/@classCode='INVSBJ']/player1/@classCode='PSN'[/determinerCode='INSTANCE']/role/@classCode='PR S'[/associatedPerson/@classCode='PSN'[@determinerCode='INSTANCE']/administrativeGenderCode/@codeSystem='1.0.5218']]/@nullFlavor |
| h | D.10.7 | 親の関連する治療歴及び随伴症状 | | | | | |
| h | D.10.7.1.r | 親の構造化された情報 (必要に応じて繰り返し返す) | | | | 繰り返し返すノード | /MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PARR_IN049016UV1[controlActProcess/@classCode='CACT'][@moodCode='EVN']/subject/@typeCode='SUBJ'[/investigationEvent/@classCode='INVTG'][@moodCode='EVN']/component/@typeCode='COMP'[/adverseEventAssessment[1]/adverseEventAssessment/@classCode='INVTG'][@moodCode='EVN']/subject1/@typeCode='SBJ'[/primaryRole/@classCode='INVSBJ']/player1/@classCode='PSN'[/determinerCode='INSTANCE']/role/@classCode='PR S'[/subjectOr2/@typeCode='SBJ']/organizer/code/@code='1'[@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']]/organizer/@classCode='CATEGORY'[@moodCode='EVN']/component/@typeCode='COMP'[/observation/code/@codeSystem='2.16.840.1.113883.6.163']] |

(別添3)

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|---|--------------|-----|--------|------------------------------------|-----------------------------------|--|
| e | D.10.7.1.r.3 | 継続 | ブール型 | Boolean (BL) | 値 | <pre> /MCCI_IN200100UV01[@ITSVersion='XML_1.0']/@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd;/PORR_IN049016UV/;/controlActProcess[@classCode='CACT']/@moo dCode='EVN']/subject/@typeCode='SUBJ'[/investigationEvent/@classCode='INVESTG']/@moodCo de='EVN']/component/@typeCode='COMP'[/adverseEventAssessment[1]/adverseEventAssessment [@classCode='INVESTG']/@moodCode='EVN']/subject1/@typeCode='SBJ'[/primaryRole/@classC ode='INVSBJ']/player1/@classCode='PSN'[/determinerCode='INSTANCE']/role/@classCode='PR S'[/subjectO2/@typeCode='SBJ']/organizer/code/@code='1'/@codeSystem='2.16.840.1.113883. 3.989.2.1.1.20'[/organizer/@classCode='CATEGORY']/@moodCode='EVN']/component/@typeC ode='COMP'[/observation/code/@codeSystem='2.16.840.1.113883.6.163'[/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'[/observation/@classCode='OBS']]/@mo odCode='EVN']/value[@xsi:type='BL']/@value </pre> |
| e | D.10.7.1.r.4 | 終了日 | 日付/時間 | Interval of Point in Time (VL<TS>) | 値 high=Interval Boundary (VXB) | <pre> /MCCI_IN200100UV01[@ITSVersion='XML_1.0']/@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd;/PORR_IN049016UV/;/controlActProcess[@classCode='CACT']/@moo dCode='EVN']/subject/@typeCode='SUBJ'[/investigationEvent/@classCode='INVESTG']/@moodCo de='EVN']/component/@typeCode='COMP'[/adverseEventAssessment[1]/adverseEventAssessment [@classCode='INVESTG']/@moodCode='EVN']/subject1/@typeCode='SBJ'[/primaryRole/@classC ode='INVSBJ']/player1/@classCode='PSN'[/determinerCode='INSTANCE']/role/@classCode='PR S'[/subjectO2/@typeCode='SBJ']/organizer/code/@code='1'/@codeSystem='2.16.840.1.113883. 3.989.2.1.1.20'[/organizer/@classCode='CATEGORY']/@moodCode='EVN']/component/@typeC ode='COMP'[/observation/code/@codeSystem='2.16.840.1.113883.6.163'[/observation/@classCo de='OBS']]/@moodCode='EVN']/effectiveTime/@xsi:type='IVL_TS'[/high/@value </pre> |
| e | | | | | NullFlavor | <pre> /MCCI_IN200100UV01[@ITSVersion='XML_1.0']/@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd;/PORR_IN049016UV/;/controlActProcess[@classCode='CACT']/@moo dCode='EVN']/subject/@typeCode='SUBJ'[/investigationEvent/@classCode='INVESTG']/@moodCo de='EVN']/component/@typeCode='COMP'[/adverseEventAssessment[1]/adverseEventAssessment [@classCode='INVESTG']/@moodCode='EVN']/subject1/@typeCode='SBJ'[/primaryRole/@classC ode='INVSBJ']/player1/@classCode='PSN'[/determinerCode='INSTANCE']/role/@classCode='PR S'[/subjectO2/@typeCode='SBJ']/organizer/code/@code='1'/@codeSystem='2.16.840.1.113883. 3.989.2.1.1.20'[/organizer/@classCode='CATEGORY']/@moodCode='EVN']/component/@typeC ode='COMP'[/observation/code/@codeSystem='2.16.840.1.113883.6.163'[/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> /MCCI_IN200100UV01[@ITSVersion='XML_1.0']/@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd;/PORR_IN049016UV/;/controlActProcess[@classCode='CACT']/@moo dCode='EVN']/subject/@typeCode='SUBJ'[/investigationEvent/@classCode='INVESTG']/@moodCo de='EVN']/component/@typeCode='COMP'[/adverseEventAssessment[1]/adverseEventAssessment [@classCode='INVESTG']/@moodCode='EVN']/subject1/@typeCode='SBJ'[/primaryRole/@classC ode='INVSBJ']/player1/@classCode='PSN'[/determinerCode='INSTANCE']/role/@classCode='PR S'[/subjectO2/@typeCode='SBJ']/organizer/code/@code='1'/@codeSystem='2.16.840.1.113883. 3.989.2.1.1.20'[/organizer/@classCode='CATEGORY']/@moodCode='EVN']/component/@typeC ode='COMP'[/observation/code/@codeSystem='2.16.840.1.113883.6.163'[/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'[/observation/@classCode='OBS']]@ moodCode='EVN']/value[@xsi:type='ED']/(text) </pre> |

(別添 3)

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|---|-------------|-----------------------------|----------------------|-----------------------------|--|--|
| e | D.10.7.2 | 親の関連する治療歴及び随伴症状の記述情報 | 10000AN | Encapsulated Data (ED) | 値 | <pre> /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UV01/controlAcProcess[@classCode=CACT][@moodCo 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]/subjectO2/@typeCode="SBJ"/organizer/code/@code="2"[@codeSystem="2.16.840.1.113883. 3.989.2.1.1.20][1]/organizer/@classCode="CATEGORY"[@moodCode="EVN"/component/@typeC ode="COMP"/observation/@code="18][@codeSystem="2.16.840.1.113883.3.989.2.1.1.19][1]/ observation/@classCode="OBS"[@moodCode="EVN"/value/@xsi:type="text"]/text() </pre> |
| h | D.10.8.r | 親の関連する過去の医薬品使用歴（必要に応じて繰り返す） | | | 繰り返し ノート | <pre> /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UV01/controlAcProcess[@classCode=CACT][@moodCo 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]/subjectO2/@typeCode="SBJ"/organizer/code/@code="2"[@codeSystem="2.16.840.1.113883. 3.989.2.1.1.20][1]/organizer/@classCode="CATEGORY"[@moodCode="EVN"/component/@typeC ode="COMP"/substanceAdministration] </pre> |
| 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) | <pre> /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UV01/controlAcProcess[@classCode=CACT][@moodCo 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]/subjectO2/@typeCode="SBJ"/organizer/code/@code="2"[@codeSystem="2.16.840.1.113883. 3.989.2.1.1.20][1]/organizer/@classCode="CATEGORY"[@moodCode="EVN"/component/@typeC ode="COMP"/substanceAdministration][@instanceOfKind="KIND"/name[1]/text() </pre> |
| 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) | <pre> /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UV01/controlAcProcess[@classCode=CACT][@moodCo 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]/subjectO2/@typeCode="SBJ"/organizer/code/@code="2"[@codeSystem="2.16.840.1.113883. 3.989.2.1.1.20][1]/organizer/@classCode="CATEGORY"[@moodCode="EVN"/component/@typeC ode="COMP"/substanceAdministration][@instanceOfKind="KIND"/name[1]/text() </pre> |

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|---|-------------|------------------|----------------------|--|---|---|---|
| e | D.10.8.r.2b | 医薬品製品識別子 (MPID) | M5 ガイド ラインを参 照 | Coded With Equivalents (CE) | code=Character String (ST) | 値 | /MCCI_IN200100UV01[@ITSVersion='XML_1.0']/@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd/jPORR_IN049016UV/j/controlActProcess[@classCode='CACT']/@moodCode=EVN/jsubject/@typeCode='SUBJ'[/j/investigationEvent/@classCode='INVESTG']/@moodCode=EVN/jcomponent/@typeCode='COMP'[/j/adverseEventAssessment[1]/adverseEventAssessment/@classCode='INVESTG']/@moodCode=EVN/jsubject1/@typeCode='SB'[/j/primaryRole/@classCode='INVSBJ/player1/@classCode='PSN']/@determinerCode='INSTANCE'[/role/@classCode='PR-ST']/@subjectO12/@typeCode='SB'[/j/organizer/code/@code=2]/@codeSystem=2.16.840.1.113883.3.988.2.1.1.20[/j/organizer/@classCode='CATEGORY']/@moodCode=EVN/jcomponent/@typeCode=COMP[/j/substanceAdministration]/@substanceAdministration/@classCode='SBADM']/@moodCode=EVN/jconsumable/@typeCode='KIND'[/code/@codeSystem='TBD-MPID']/@code |
| e | D.10.8.r.3a | PhPID パージョン日付/番号 | M5 ガイド ラインを参 照 | Coded With Equivalents (CE) | codeSystemVersion=Character String (ST) | 値 | /MCCI_IN200100UV01[@ITSVersion='XML_1.0']/@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd/jPORR_IN049016UV/j/controlActProcess[@classCode='CACT']/@moodCode=EVN/jsubject/@typeCode='SUBJ'[/j/investigationEvent/@classCode='INVESTG']/@moodCode=EVN/jcomponent/@typeCode='COMP'[/j/adverseEventAssessment[1]/adverseEventAssessment/@classCode='INVESTG']/@moodCode=EVN/jsubject1/@typeCode='SB'[/j/primaryRole/@classCode='INVSBJ/player1/@classCode='PSN']/@determinerCode='INSTANCE'[/role/@classCode='PR-ST']/@subjectO12/@typeCode='SB'[/j/organizer/code/@code=2]/@codeSystem=2.16.840.1.113883.3.988.2.1.1.20[/j/organizer/@classCode='CATEGORY']/@moodCode=EVN/jcomponent/@typeCode=COMP[/j/substanceAdministration]/@substanceAdministration/@classCode='SBADM']/@moodCode=EVN/jconsumable/@typeCode='KIND'[/code/@codeSystem='TBD-PhPID']/@codeSystemVersion |
| e | D.10.8.r.3b | 製剤識別子 (PhPID) | M5 ガイド ラインを参 照 | Coded With Equivalents (CE) | code=Character String (ST) | 値 | /MCCI_IN200100UV01[@ITSVersion='XML_1.0']/@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd/jPORR_IN049016UV/j/controlActProcess[@classCode='CACT']/@moodCode=EVN/jsubject/@typeCode='SUBJ'[/j/investigationEvent/@classCode='INVESTG']/@moodCode=EVN/jcomponent/@typeCode='COMP'[/j/adverseEventAssessment[1]/adverseEventAssessment/@classCode='INVESTG']/@moodCode=EVN/jsubject1/@typeCode='SB'[/j/primaryRole/@classCode='INVSBJ/player1/@classCode='PSN']/@determinerCode='INSTANCE'[/role/@classCode='PR-ST']/@subjectO12/@typeCode='SB'[/j/organizer/code/@code=2]/@codeSystem=2.16.840.1.113883.3.988.2.1.1.20[/j/organizer/@classCode='CATEGORY']/@moodCode=EVN/jcomponent/@typeCode=COMP[/j/substanceAdministration]/@substanceAdministration/@classCode='SBADM']/@moodCode=EVN/jconsumable/@typeCode='KIND'[/j/instanceOfKind/@classCode='INST']/@kindOfProduct/@classCode='MMAT']/@determinerCode='KIND'[/code/@codeSystem='TBD-PhPID']/@code |
| e | D.10.8.r.4 | 開始日 | 日付/時間 | Interval of Point in Time (IVL<TS>) | low=Interval Boundary (IVXB) | 値 | /MCCI_IN200100UV01[@ITSVersion='XML_1.0']/@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd/jPORR_IN049016UV/j/controlActProcess[@classCode='CACT']/@moodCode=EVN/jsubject/@typeCode='SUBJ'[/j/investigationEvent/@classCode='INVESTG']/@moodCode=EVN/jcomponent/@typeCode='COMP'[/j/adverseEventAssessment[1]/adverseEventAssessment/@classCode='INVESTG']/@moodCode=EVN/jsubject1/@typeCode='SB'[/j/primaryRole/@classCode='INVSBJ/player1/@classCode='PSN']/@determinerCode='INSTANCE'[/role/@classCode='PR-ST']/@subjectO12/@typeCode='SB'[/j/organizer/code/@code=2]/@codeSystem=2.16.840.1.113883.3.988.2.1.1.20[/j/organizer/@classCode='CATEGORY']/@moodCode=EVN/jcomponent/@typeCode=COMP[/j/substanceAdministration]/@substanceAdministration/@classCode='SBADM']/@moodCode=EVN/jeffectiveTime/@xsi:type='IVL_TS'[/low/@value |

(別添 3)

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| e | | | | | NullFlavor | /MCCLI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCLI_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=PR S][1]/subjectOf2[@typeCode=SBJ][organizer/code/@code=2][@codeSystem=2.16.840.1.113883.3.989.2.1.1.20][1]/organizer[@classCode=CATEGORY][@moodCode=EVN]/component[@typeCode=COMP][substanceAdministration[r]/substanceAdministration[@classCode=SBADM][@moodCode=EVN]/effectiveTime[@xsi:type=IVL_TS]/low/@nullFlavor | |
| e | D.10.8.r.5 | 終了日 | 日付/時間 | Interval of Point in Time (IVL<TS>) | high=Interval Boundary (VXB) | 値 | /MCCLI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCLI_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=PR S][1]/subjectOf2[@typeCode=SBJ][organizer/code/@code=2][@codeSystem=2.16.840.1.113883.3.989.2.1.1.20][1]/organizer[@classCode=CATEGORY][@moodCode=EVN]/component[@typeCode=COMP][substanceAdministration[r]/substanceAdministration[@classCode=SBADM][@moodCode=EVN]/effectiveTime[@xsi:type=IVL_TS]/high/@value |
| e | | | | | NullFlavor | /MCCLI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCLI_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=PR S][1]/subjectOf2[@typeCode=SBJ][organizer/code/@code=2][@codeSystem=2.16.840.1.113883.3.989.2.1.1.20][1]/organizer[@classCode=CATEGORY][@moodCode=EVN]/component[@typeCode=COMP][substanceAdministration[r]/substanceAdministration[@classCode=SBADM][@moodCode=EVN]/effectiveTime[@xsi:type=IVL_TS]/high/@nullFlavor | |
| e | D.10.8.r.6a | 使用理由の メドRA パー ジョン | 4AN | Coded With Equivalents (CE) | codeSystemVersion=Character String (ST) | 値 | /MCCLI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCLI_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=PR S][1]/subjectOf2[@typeCode=SBJ][organizer/code/@code=2][@codeSystem=2.16.840.1.113883.3.989.2.1.1.20][1]/organizer[@classCode=CATEGORY][@moodCode=EVN]/component[@typeCode=COMP][substanceAdministration[r]/substanceAdministration[@classCode=SBADM][@moodCode=EVN]/outboundRelationship2[@typeCode=RSON][observation/code/@code=19][@codeSystem=2.16.840.1.113883.3.989.2.1.1.19][1]/observation[@classCode=OBS][@moodCode=EVN]/value[@xsi:type=CE][@codeSystem=2.16.840.1.113883.6.163][1][@codeSystemVersion |

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|---|-------------|------------------------|-----|-----------------------------|---|-------------------|--|
| e | D.10.8.r.6b | 使用理由 (MedDRA コード) | 8N | Coded With Equivalents (CE) | code=Character String (ST) | 値 | /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049076UV/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]/subject1[@typeCode=SB][1][primaryRole[@classCode=INVSBJ]/player1[@classCode=PSN][determinerCode=INSTANCE]/role[@classCode=PR S][1][subjectOf2[@typeCode=SB][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][@classCode=SBADM][@moodCode=EVN]/outboundRelationship2[@typeCode=RSN][observation/code=@code=19][@codeSystem=2.16.840.1.113883.3.989.2.1.1.19][1][observation/@classCode=OBS][@moodCode=EVN]/value[@xsi:type=CE][@codeSystem=2.16.840.1.113883.6.163][1][@code |
| e | D.10.8.r.7a | 副作用の MedDRA パージョ | 4AN | Coded With Equivalents (CE) | codeSystemVersion=Character String (ST) | 値 | /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049076UV/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]/subject1[@typeCode=SB][1][primaryRole[@classCode=INVSBJ]/player1[@classCode=PSN][determinerCode=INSTANCE]/role[@classCode=PR S][1][subjectOf2[@typeCode=SB][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][@classCode=SBADM][@moodCode=EVN]/outboundRelationship2[@typeCode=CAUS][observation/code=@code=29][@codeSystem=2.16.840.1.113883.3.989.2.1.1.19][1][observation/@classCode=OBS][@moodCode=EVN]/value[@xsi:type=CE][@codeSystem=2.16.840.1.113883.6.163][1][@codeSystemVersion |
| e | D.10.8.r.7b | 副作用 (MedDRA コード) | 8N | Coded With Equivalents (CE) | code=Character String (ST) | 値 | /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049076UV/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]/subject1[@typeCode=SB][1][primaryRole[@classCode=INVSBJ]/player1[@classCode=PSN][determinerCode=INSTANCE]/role[@classCode=PR S][1][subjectOf2[@typeCode=SB][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][@classCode=SBADM][@moodCode=EVN]/outboundRelationship2[@typeCode=CAUS][observation/code=@code=29][@codeSystem=2.16.840.1.113883.3.989.2.1.1.19][1][observation/@classCode=OBS][@moodCode=EVN]/value[@xsi:type=CE][@codeSystem=2.16.840.1.113883.6.163][1][@code |
| h | E.i | 副作用/有害事象 (必要に応じて繰り返す) | | | | 繰り返し 返す ノード | /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049076UV/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]/subject1[@typeCode=SB][1][primaryRole[@classCode=INVSBJ]/player1[@classCode=PSN][determinerCode=INSTANCE]/role[@classCode=PR S][1][subjectOf2[@typeCode=SB][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][@classCode=SBADM][@moodCode=EVN]/outboundRelationship2[@typeCode=CAUS][observation/code=@code=29][@codeSystem=2.16.840.1.113883.3.989.2.1.1.19][1][observation/@classCode=OBS][@moodCode=EVN]/value[@xsi:type=CE][@codeSystem=2.16.840.1.113883.6.163][1][@code |
| h | E.i.1 | 第一次情報源により報告された副作用/有害事象 | | | | | /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049076UV/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]/subject1[@typeCode=SB][1][primaryRole[@classCode=INVSBJ]/player1[@classCode=PSN][determinerCode=INSTANCE]/role[@classCode=PR S][1][subjectOf2[@typeCode=SB][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][@classCode=SBADM][@moodCode=EVN]/outboundRelationship2[@typeCode=CAUS][observation/code=@code=29][@codeSystem=2.16.840.1.113883.3.989.2.1.1.19][1][observation/@classCode=OBS][@moodCode=EVN]/value[@xsi:type=CE][@codeSystem=2.16.840.1.113883.6.163][1][@code |

| | | | | | | | |
|---|----------|----------------------------------|-------|-----------------------------|---|---|--|
| e | E.i.1.1a | 母国語で記載された、第一次情報源により報告された副作用/有害事象 | 250AN | Coded With Equivalents (CE) | originalText = Encapsulated Data (ED) | 値 | <pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:h7-org:v3 MCCL_IN200100UV01.xsd]/PORR_IN049016UV01/controlAcProcess[@classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUBJ][@investigationEvent[@classCode=INVSIG][@moodCode=EVN]/component[@typeCode=COMP][adverseEventAssessment[@adverseEventAssessment[@classCode=INVSIG][@moodCode=EVN]/subject1[@typeCode=SBJ][@primaryRole[@classCode=INVSBJ]/subjectO2[@typeCode=SBJ][@codeSystem=2.1.1.13883.3.989.2.1.1.19]]]]/observation[@classCode=OBS][@moodCode=EVN]/value[@xsi:type=CE][@codeSystem=2.16.840.1.113883.6.163][@originalText/text() </pre> |
| e | E.i.1.1b | 第一次情報源により報告された副作用/有害事象の言語 | 3A | Coded With Equivalents (CE) | originalText/language = Coded Simple Value (CS) | 値 | <pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:h7-org:v3 MCCL_IN200100UV01.xsd]/PORR_IN049016UV01/controlAcProcess[@classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUBJ][@investigationEvent[@classCode=INVSIG][@moodCode=EVN]/component[@typeCode=COMP][adverseEventAssessment[@adverseEventAssessment[@classCode=INVSIG][@moodCode=EVN]/subject1[@typeCode=SBJ][@primaryRole[@classCode=INVSBJ]/subjectO2[@typeCode=SBJ][@codeSystem=2.1.1.13883.3.989.2.1.1.19]]]]/observation[@classCode=OBS][@moodCode=EVN]/value[@xsi:type=CE][@codeSystem=2.16.840.1.113883.6.163][@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:h7-org:v3 MCCL_IN200100UV01.xsd]/PORR_IN049016UV01/controlAcProcess[@classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUBJ][@investigationEvent[@classCode=INVSIG][@moodCode=EVN]/component[@typeCode=COMP][adverseEventAssessment[@adverseEventAssessment[@classCode=INVSIG][@moodCode=EVN]/subject1[@typeCode=SBJ][@primaryRole[@classCode=INVSBJ]/subjectO2[@typeCode=SBJ][@codeSystem=2.1.1.13883.3.989.2.1.1.19]]]]/observation[@classCode=OBS][@moodCode=EVN]/value[@xsi:type=CE][@codeSystem=2.16.840.1.113883.6.163][@originalText/language </pre> |
| e | E.i.2.1a | 副作用 / 有害事象の MedDRA パージョン | 4AN | Coded With Equivalents (CE) | codeSystemVersion = Character String (ST) | 値 | <pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:h7-org:v3 MCCL_IN200100UV01.xsd]/PORR_IN049016UV01/controlAcProcess[@classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUBJ][@investigationEvent[@classCode=INVSIG][@moodCode=EVN]/component[@typeCode=COMP][adverseEventAssessment[@adverseEventAssessment[@classCode=INVSIG][@moodCode=EVN]/subject1[@typeCode=SBJ][@primaryRole[@classCode=INVSBJ]/subjectO2[@typeCode=SBJ][@codeSystem=2.1.1.13883.3.989.2.1.1.19]]]]/observation[@classCode=OBS][@moodCode=EVN]/value[@xsi:type=CE][@codeSystem=2.16.840.1.113883.6.163][@codeSystemVersion </pre> |
| e | E.i.2.1b | 副作用/有害事象 (MedDRA コード) | 8N | Coded With Equivalents (CE) | code = Character String (ST) | 値 | <pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:h7-org:v3 MCCL_IN200100UV01.xsd]/PORR_IN049016UV01/controlAcProcess[@classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUBJ][@investigationEvent[@classCode=INVSIG][@moodCode=EVN]/component[@typeCode=COMP][adverseEventAssessment[@adverseEventAssessment[@classCode=INVSIG][@moodCode=EVN]/subject1[@typeCode=SBJ][@primaryRole[@classCode=INVSBJ]/subjectO2[@typeCode=SBJ][@codeSystem=2.1.1.13883.3.989.2.1.1.19]]]]/observation[@classCode=OBS][@moodCode=EVN]/value[@xsi:type=CE][@codeSystem=2.16.840.1.113883.6.163][@code </pre> |

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|---|----------|--|------|-----------------------------|----------------------------|---|--|
| e | E.i.3.1 | 報告者によって重要とされた副作用/有害事象 | 1N | Coded With Equivalents (CE) | code=Character String (ST) | 値 | /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UV[1]/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[1][code=29][@codeSystem=2.16.840.1.113883.3.989.2.1.1.19][1]/observation[@classCode=OBS][@moodCode=EVN]/outboundRelationship2[@typeCode=PERT][observation[1][code=37][@codeSystem=2.16.840.1.113883.3.989.2.1.1.19][1]/observation[@classCode=OBS][@moodCode=EVN]/value[@xsi:type=CE][@codeSystem=2.16.840.1.113883.3.989.2.1.1.10][1][@code |
| h | E.i.3.2 | 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 コードリストのパージョン | | | | | /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=INVTG][@moodCode=EVN]/component[@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment[@classCode=INVTG][@moodCode=EVN]/subject1[@typeCode=SBJ][1]/primaryRole[classCode=INVSBJ]/subjectOf2[@typeCode=SBJ][observation[1][code=29][@codeSystem=2.16.840.1.113883.3.989.2.1.1.19][1]/observation[@classCode=OBS][@moodCode=EVN]/outboundRelationship2[@typeCode=PERT][observation[1][code=37][@codeSystem=2.16.840.1.113883.3.989.2.1.1.19][1]/observation[@classCode=OBS][@moodCode=EVN]/value[@xsi:type=CE][@codeSystem=2.16.840.1.113883.3.989.2.1.1.10][1][@codeSystemVersion |
| e | E.i.3.2a | 有害事象ごとの重要性の基盤 | ブール型 | Boolean (BL) | 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=INVTG][@moodCode=EVN]/component[@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment[@classCode=INVTG][@moodCode=EVN]/subject1[@typeCode=SBJ][1]/primaryRole[classCode=INVSBJ]/subjectOf2[@typeCode=SBJ][observation[1][code=29][@codeSystem=2.16.840.1.113883.3.989.2.1.1.19][1]/observation[@classCode=OBS][@moodCode=EVN]/outboundRelationship2[@typeCode=PERT][observation[1][code=34][@codeSystem=2.16.840.1.113883.3.989.2.1.1.19][1]/observation[@classCode=OBS][@moodCode=EVN]/value[@xsi:type=BL][1]/@value |
| e | | | | | NullFlavor | | /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UV[1]/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[1][code=29][@codeSystem=2.16.840.1.113883.3.989.2.1.1.19][1]/observation[@classCode=OBS][@moodCode=EVN]/outboundRelationship2[@typeCode=PERT][observation[1][code=34][@codeSystem=2.16.840.1.113883.3.989.2.1.1.19][1]/observation[@classCode=OBS][@moodCode=EVN]/value[@xsi:type=BL][1]/@nullFlavor |

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|---|----------|-----------------------------------|------|--------------|------------|--|
| e | E.i.3.2b | 生命を脅かすもの | ブール型 | Boolean (BL) | 値 | <pre> /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UV1/controlAcipProcess[@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]/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]/outbound Relationship2[@typeCode=PERT][observation/code[@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> /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UV1/controlAcipProcess[@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]/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]/outbound Relationship2[@typeCode=PERT][observation/code[@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> /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UV1/controlAcipProcess[@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]/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]/outbound Relationship2[@typeCode=PERT][observation/code[@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> /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UV1/controlAcipProcess[@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]/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]/outbound Relationship2[@typeCode=PERT][observation/code[@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> /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UV1/controlAcipProcess[@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]/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]/outbound Relationship2[@typeCode=PERT][observation/code[@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)

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| e | | | | NullFlavor | <pre> /MCCI_IN200100UV01[@ITSVersion='XML_1.0']/@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd'/PORR_IN049016UV/r/controlActProcess[@classCode='CACT']/@moodCode=EVN'/subject/@typeCode='SUBJ'[/investigationEvent/@classCode='INVTG']/@moodCode=EVN'/component/@typeCode='COMP'[/adverseEventAssessment[/adverseEventAssessment/@classCode='INVTG']]/@moodCode='EVN'/subject1/@typeCode='SBJ'[/primaryRole/@classCode='INVSBJ']/subjectOr2/@typeCode='SBJ'[/observation/@classCode='OBS']/@moodCode='EVN'[/outboundRelationship2/@typeCode='PERT']]/observation/@code='35'[/codesSystem='2.16.840.1.11388.3.3.989.2.1.1.19']]/observation/@classCode='OBS'[/@moodCode='EVN']/value[@xsi:type='BL']]/@value </pre> |
| e | E.i.3.2e | 先天異常を来すもの | ブール型 | Boolean (BL) | <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']/subjectOr2/@typeCode='SBJ'[/observation/@classCode='OBS']/@moodCode='EVN'[/outboundRelationship2/@typeCode='PERT']]/observation/@code='12'[/codesSystem='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 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']/subjectOr2/@typeCode='SBJ'[/observation/@classCode='OBS']/@moodCode='EVN'[/outboundRelationship2/@typeCode='PERT']]/observation/@code='12'[/codesSystem='2.16.840.1.11388.3.3.989.2.1.1.19']]/observation/@classCode='OBS'[/@moodCode='EVN']/value[@xsi:type='BL']]/@value </pre> |
| e | E.i.3.2f | その他の医学的に重要な状態 | ブール型 | Boolean (BL) | <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']/subjectOr2/@typeCode='SBJ'[/observation/@classCode='OBS']/@moodCode='EVN'[/outboundRelationship2/@typeCode='PERT']]/observation/@code='26'[/codesSystem='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 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']/subjectOr2/@typeCode='SBJ'[/observation/@classCode='OBS']/@moodCode='EVN'[/outboundRelationship2/@typeCode='PERT']]/observation/@code='26'[/codesSystem='2.16.840.1.11388.3.3.989.2.1.1.19']]/observation/@classCode='OBS'[/@moodCode='EVN']/value[@xsi:type='BL']]/@value </pre> |

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| <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 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 low=Interval Boundary (IVXB)</p> | <p>値</p> | <p>/MCCLI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3/MCCLI_IN200100UV01.xsd']/PDRR_IN049016UVUJ/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']/observation[id]@code[@code='29'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']/observation[@classCode='OBS'][@moodCode='EVN']/effectiveTime[@xsi:type='IVL_TS']/low/@value</p> |
| <p>e</p> | | | | | <p>NullFlavor</p> | <p>NullFlavor</p> | <p>/MCCLI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3/MCCLI_IN200100UV01.xsd']/PDRR_IN049016UVUJ/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']/observation[id]@code[@code='29'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']/observation[@classCode='OBS'][@moodCode='EVN']/effectiveTime[@xsi:type='IVL_TS']/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ない場合 データ型 SXPRT を伴う最初の comp 項目 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ない場合 データ型 SXPRT を伴う最初の comp 項目 comp/low=Interval Boundary (IVXB)</p> | <p>値</p> | <p>/MCCLI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3/MCCLI_IN200100UV01.xsd']/PDRR_IN049016UVUJ/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']/observation[id]@code[@code='29'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']/observation[@classCode='OBS'][@moodCode='EVN']/effectiveTime[@xsi:type='SXPRT_TS']/comp/@xsi:type=IVL_TS/low/@value</p> |
| <p>e</p> | | | | | <p>NullFlavor</p> | <p>NullFlavor</p> | <p>/MCCLI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3/MCCLI_IN200100UV01.xsd']/PDRR_IN049016UVUJ/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']/observation[id]@code[@code='29'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']/observation[@classCode='OBS'][@moodCode='EVN']/effectiveTime[@xsi:type='SXPRT_TS']/comp/@nullFlavor</p> |

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| | | | <p>3.E.i.4、E.i.5 及び E.i.6 のすべての項目が表示される場合</p> <p>データ型 SXPB を伴う 2 番目の comp 項目</p> <p>HL7 データ型: Parenthetic Set Expression of Point in Time (SXPB<TS>)</p> | <p>3.E.i.4、E.i.5 及び E.i.6 のすべての項目が表示される場合</p> <p>データ型 SXPB を伴う 2 番目の comp 項目</p> <p>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_IN049016UV01/controlActProcess[@classCode=CACT][@mo dCode=EVN]/subject[@typeCode=SUBJ][@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[id][code=@code=29][@codeSystem=2.1 6.840.1.113883.3.989.2.1.1.19]]/observation[@classCode=OBS][@moodCode=EVN]/effectiveTi me[@xsi:type=SXPB_TS]/comp[@xsi:type=IVL_TS][@operator=A]/low/@value </pre> |
| | | | | <p>NullFlavor</p> | <pre> /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UV01/controlActProcess[@classCode=CACT][@mo dCode=EVN]/subject[@typeCode=SUBJ][@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[id][code=@code=29][@codeSystem=2.1 6.840.1.113883.3.989.2.1.1.19]]/observation[@classCode=OBS][@moodCode=EVN]/effectiveTi me[@xsi:type=SXPB_TS]/comp[@xsi:type=IVL_TS][@operator=A]/low/@nullFlavor </pre> |
| <p>e</p> | <p>E.i.5</p> <p>副作用/有害事象の終了日</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 (VL<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_IN049016UV01/controlActProcess[@classCode=CACT][@mo dCode=EVN]/subject[@typeCode=SUBJ][@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[id][code=@code=29][@codeSystem=2.1 6.840.1.113883.3.989.2.1.1.19]]/observation[@classCode=OBS][@moodCode=EVN]/effectiveTi me[@xsi:type=IVL_TS]/high/@value </pre> |
| <p>e</p> | | | | <p>NullFlavor</p> | <pre> /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UV01/controlActProcess[@classCode=CACT][@mo dCode=EVN]/subject[@typeCode=SUBJ][@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[id][code=@code=29][@codeSystem=2.1 6.840.1.113883.3.989.2.1.1.19]]/observation[@classCode=OBS][@moodCode=EVN]/effectiveTi me[@xsi:type=IVL_TS]/high/@nullFlavor </pre> |

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| | | | <p>2.E.i.4、E.i.5 及び E.i.6 のすべての項目が表示される場合</p> <p>データ型 SXPX を伴う最初の comp 項目</p> <p>HL7 データ型: Parenthetic Set Expression of Point in Time (SXPX<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 SXPX を伴う最初の comp 項目</p> <p>comp/high=Interval Boundary (IVXB)</p> | 値 | <pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/PERR_IN049016UVr/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][@typeCode=SBJ][1]/primaryRole[@classCode=INVSBJ]/subjectOf2[@typeCode=SBJ][observation[id]code=@code=29][@codeSystem=2.16.840.1.113883.3.989.2.1.1.19]]][observation[@classCode=OBS][@moodCode=EVN]/effectiveTime[@xsi:type=SXPX_TS]/comp[@xsi:type=IVL_TS]/high/@value </pre> |
| | | | <p>3.E.i.4、E.i.5 及び E.i.6 のすべての項目が表示される場合</p> <p>データ型 SXPX を伴う 2 番目の comp 項目</p> <p>HL7 データ型: Parenthetic Set Expression of Point in Time (SXPX<TS>)</p> | <p>NullFlavor</p> | 値 | <pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/PERR_IN049016UVr/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][@typeCode=SBJ][1]/primaryRole[@classCode=INVSBJ]/subjectOf2[@typeCode=SBJ][observation[id]code=@code=29][@codeSystem=2.16.840.1.113883.3.989.2.1.1.19]]][observation[@classCode=OBS][@moodCode=EVN]/effectiveTime[@xsi:type=SXPX_TS]/comp[@xsi:type=IVL_TS]/high/@value </pre> |
| | | | <p>3.E.i.4、E.i.5 及び E.i.6 のすべての項目が表示される場合</p> <p>データ型 SXPX を伴う 2 番目の comp 項目</p> <p>HL7 データ型: Parenthetic Set Expression of Point in Time (SXPX<TS>)</p> | <p>NullFlavor</p> | 値 | <pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/PERR_IN049016UVr/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][@typeCode=SBJ][1]/primaryRole[@classCode=INVSBJ]/subjectOf2[@typeCode=SBJ][observation[id]code=@code=29][@codeSystem=2.16.840.1.113883.3.989.2.1.1.19]]][observation[@classCode=OBS][@moodCode=EVN]/effectiveTime[@xsi:type=SXPX_TS]/comp[@xsi:type=IVL_TS][@operator=A]/high/@value </pre> |
| | | | <p>3.E.i.4、E.i.5 及び E.i.6 のすべての項目が表示される場合</p> <p>データ型 SXPX を伴う 2 番目の comp 項目</p> <p>HL7 データ型: Parenthetic Set Expression of Point in Time (SXPX<TS>)</p> | <p>NullFlavor</p> | 値 | <pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/PERR_IN049016UVr/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][@typeCode=SBJ][1]/primaryRole[@classCode=INVSBJ]/subjectOf2[@typeCode=SBJ][observation[id]code=@code=29][@codeSystem=2.16.840.1.113883.3.989.2.1.1.19]]][observation[@classCode=OBS][@moodCode=EVN]/effectiveTime[@xsi:type=SXPX_TS]/comp[@xsi:type=IVL_TS][@operator=A]/high/@value </pre> |

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| e | E.i.6a | 副作用/有害事象の持続期間 (数) | 5N | 1.E.i.4, E.i.5 及び E.i.6 のすべての項目が表示されない場合 HL7 データ型: Interval of Point in Time (IVL<TS>) | 1.E.i.4, E.i.5 及び E.i.6 のすべての項目が表示されない場合 width/value=Real Number (REAL) | 値 | /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PERR_IN049016UV[1]/controlActProcess[@classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUBJ][1]/investigationEvent[@classCode=INVSTG][@moodCode=EVN]/component[@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment[1]/classCode=INVSTG][@moodCode=EVN]/subject[1]/primaryRole/@classCode=INVSBJ][subjectOf2[@typeCode=SBJ][1]/primaryRole/@classCode=INVSBJ][subjectOf2[@typeCode=SBJ][observation[id][code][@code=29][@codeSystem=2.16.840.1.113883.3.989.2.1.1.19]]][observation[@classCode=OBS][@moodCode=EVN]/effectiveTime[@xsi:type=IVL_TS]/width/@value |
| e | E.i.6b | 副作用/有害事象の持続期間 (単位) | 50AN | 1.E.i.4, E.i.5 及び E.i.6 のすべての項目が表示されない場合 HL7 データ型: Parenthetic Set Expression of Point in Time (SXPRTS>) | 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 SXPRTS を伴う最初の comp 項目 HL7 データ型: Parenthetic Set Expression of Point in Time (SXPRTS>) | 値 | /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PERR_IN049016UV[1]/controlActProcess[@classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUBJ][1]/investigationEvent[@classCode=INVSTG][@moodCode=EVN]/component[@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment[1]/classCode=INVSTG][@moodCode=EVN]/subject[1]/primaryRole/@classCode=INVSBJ][subjectOf2[@typeCode=SBJ][1]/primaryRole/@classCode=INVSBJ][subjectOf2[@typeCode=SBJ][observation[id][code][@code=29][@codeSystem=2.16.840.1.113883.3.989.2.1.1.19]]][observation[@classCode=OBS][@moodCode=EVN]/effectiveTime[@xsi:type=SXPRTS]/comp[@xsi:type=IVL_TS][@operator=A]/width/@value |
| e | E.i.6b | 副作用/有害事象の持続期間 (単位) | 50AN | 1.E.i.4, E.i.5 及び E.i.6 のすべての項目が表示されない場合 HL7 データ型: Parenthetic Set Expression of Point in Time (SXPRTS>) | 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 SXPRTS を伴う 2 番目の comp 項目 HL7 データ型: Parenthetic Set Expression of Point in Time (SXPRTS>) | 値 | /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PERR_IN049016UV[1]/controlActProcess[@classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUBJ][1]/investigationEvent[@classCode=INVSTG][@moodCode=EVN]/component[@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment[1]/classCode=INVSTG][@moodCode=EVN]/subject[1]/primaryRole/@classCode=INVSBJ][subjectOf2[@typeCode=SBJ][1]/primaryRole/@classCode=INVSBJ][subjectOf2[@typeCode=SBJ][observation[id][code][@code=29][@codeSystem=2.16.840.1.113883.3.989.2.1.1.19]]][observation[@classCode=OBS][@moodCode=EVN]/effectiveTime[@xsi:type=SXPRTS]/comp[@xsi:type=IVL_TS][@operator=A]/width/@value |
| e | E.i.6b | 副作用/有害事象の持続期間 (単位) | 50AN | 1.E.i.4, E.i.5 及び E.i.6 のすべての項目が表示されない場合 HL7 データ型: Interval of Point in Time (IVL<TS>) | 1.E.i.4, E.i.5 及び E.i.6 のすべての項目が表示されない場合 width/unit=Coded Simple Value (CS) | 値 | /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PERR_IN049016UV[1]/controlActProcess[@classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUBJ][1]/investigationEvent[@classCode=INVSTG][@moodCode=EVN]/component[@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment[1]/classCode=INVSTG][@moodCode=EVN]/subject[1]/primaryRole/@classCode=INVSBJ][subjectOf2[@typeCode=SBJ][1]/primaryRole/@classCode=INVSBJ][subjectOf2[@typeCode=SBJ][observation[id][code][@code=29][@codeSystem=2.16.840.1.113883.3.989.2.1.1.19]]][observation[@classCode=OBS][@moodCode=EVN]/effectiveTime[@xsi:type=IVL_TS]/width/@unit |

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|---|-------|--------------------------------------|---|---|---|--|
| 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 SXPTR を伴う最初の comp 項目 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 のすべての項目が数値型 SXPTR を伴う最初の comp 項目の 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_IN049016UVJ/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ']/investigationEvent[@classCode='INVS']TG[@moodCode='EVN']/component[@typeCode='COMP']/adverseEventAssessment[1]/adverseEventAssessment[@classCode='INVS']TG[@moodCode='EVN']/subject1[@typeCode='SBJ']/primaryRole[classCode='INVSBJ']/subjectOf2[@typeCode='SBJ']/observation[id]@[code='29'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']/observation[@classCode='OBS'][@moodCode='EVN']/effectiveTime[@xsi:type='SXPTR_TS']/comp[@xsi:type='IVL_TS']/width/@unit</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 データ型 SXPTR を伴う 2 番目の comp 項目 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 のすべての項目が数値型 SXPTR を伴う 2 番目の comp 項目の 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_IN049016UVJ/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ']/investigationEvent[@classCode='INVS']TG[@moodCode='EVN']/component[@typeCode='COMP']/adverseEventAssessment[1]/adverseEventAssessment[@classCode='INVS']TG[@moodCode='EVN']/subject1[@typeCode='SBJ']/primaryRole[classCode='INVSBJ']/subjectOf2[@typeCode='SBJ']/observation[id]@[code='29'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']/observation[@classCode='OBS'][@moodCode='EVN']/effectiveTime[@xsi:type='SXPTR_TS']/comp[@xsi:type='IVL_TS']/operator='A']/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_IN049016UVJ/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ']/investigationEvent[@classCode='INVS']TG[@moodCode='EVN']/component[@typeCode='COMP']/adverseEventAssessment[1]/adverseEventAssessment[@classCode='INVS']TG[@moodCode='EVN']/subject1[@typeCode='SBJ']/primaryRole[classCode='INVSBJ']/subjectOf2[@typeCode='SBJ']/observation[id]@[code='29'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']/observation[@classCode='OBS'][@moodCode='EVN']/outboundRelationship2[@typeCode='PERT']/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='2.16.840.1.113883.3.989.2.1.1.11']/@code</pre> |
| | | 最終観察時の副作用/有害事象の転帰の ICH コードリストのパバージョン | | | | <pre>/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='INVS']TG[@moodCode='EVN']/component[@typeCode='COMP']/adverseEventAssessment[1]/adverseEventAssessment[@classCode='INVS']TG[@moodCode='EVN']/subject1[@typeCode='SBJ']/primaryRole[classCode='INVSBJ']/subjectOf2[@typeCode='SBJ']/observation[id]@[code='29'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']/observation[@classCode='OBS'][@moodCode='EVN']/outboundRelationship2[@typeCode='PERT']/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='2.16.840.1.113883.3.989.2.1.1.11']/@code</pre> |

(別添 3)

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|---|-------|--------------------------------|-------|-------------------------|----------------------------|---|
| e | E.i.8 | 医療専門家による医学的確認 | ブール型 | Boolean (BL) | 値 | <pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/PORR_IN049016UVUJ/controlActProcess[@classCode=CACT][@moo dCode=EVN]/subject[@typeCode=SUBJ][@investigationEvent[@classCode=INVESTG][@moodCo de=EVN]/component[@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment [@classCode=INVESTG][@moodCode=EVN]/subject[1]/primaryRole[@classC ode=INVSBJ]/subjectOf2[@typeCode=SBJ][@code=29][@codeSystem=2.1 6.840.1.113883.3.989.2.1.1.19][observation[@classCode=OBS][@moodCode=EVN]/bound Relationship2[@typeCode=PERT][observation[@code=24][@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 | E.i.9 | 副作用/有害事象が発現した国の識別 | 2A | Concept Descriptor (CD) | code=Character String (ST) | <pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/PORR_IN049016UVUJ/controlActProcess[@classCode=CACT][@moo dCode=EVN]/subject[@typeCode=SUBJ][@investigationEvent[@classCode=INVESTG][@moodCo de=EVN]/component[@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment [@classCode=INVESTG][@moodCode=EVN]/subject[1]/primaryRole[@classC ode=INVSBJ]/subjectOf2[@typeCode=SBJ][@code=29][@codeSystem=2.1 6.840.1.113883.3.989.2.1.1.19][observation[@classCode=OBS][@moodCode=EVN]/location[@typeCode=LOC][@locatedEntity[@classCode=LOCE]/locatedPlace[@classCode=COUNTRY][@determinerCode=INSTANCE][code[@codeSystem=1.0.3166.1.2.2]]@code </pre> |
| h | F.r | 患者の診断に関連する検査及び処置の結果(必要に応じ繰り返し) | | | 繰り返し ノード | <pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/PORR_IN049016UVUJ/controlActProcess[@classCode=CACT][@moo dCode=EVN]/subject[@typeCode=SUBJ][@investigationEvent[@classCode=INVESTG][@moodCo de=EVN]/component[@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment [@classCode=INVESTG][@moodCode=EVN]/subject[1]/primaryRole[@classC ode=INVSBJ]/subjectOf2[@typeCode=SBJ][@code=3][@codeSystem=2.16.840.1 113883.3.989.2.1.1.20][organizer[@classCode=CATEGORY][@moodCode=EVN]/component[@typeCode=COMP][observation[@code[@codeSystem=2.16.840.1.113883.6.163]] </pre> |
| e | F.r.1 | 日付(検査) | 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]/PORR_IN049016UVUJ/controlActProcess[@classCode=CACT][@moo dCode=EVN]/subject[@typeCode=SUBJ][@investigationEvent[@classCode=INVESTG][@moodCo de=EVN]/component[@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment [@classCode=INVESTG][@moodCode=EVN]/subject[1]/primaryRole[@classC ode=INVSBJ]/subjectOf2[@typeCode=SBJ][@code=3][@codeSystem=2.16.840.1 113883.3.989.2.1.1.20][organizer[@classCode=CATEGORY][@moodCode=EVN]/component[@typeCode=COMP][observation[@code[@codeSystem=2.16.840.1.113883.6.163]]r][observation[classCode=OBS][@moodCode=EVN]/effectiveTime[@value </pre> |
| e | | | | | NullFlavor | <pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/PORR_IN049016UVUJ/controlActProcess[@classCode=CACT][@moo dCode=EVN]/subject[@typeCode=SUBJ][@investigationEvent[@classCode=INVESTG][@moodCo de=EVN]/component[@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment [@classCode=INVESTG][@moodCode=EVN]/subject[1]/primaryRole[@classC ode=INVSBJ]/subjectOf2[@typeCode=SBJ][@code=3][@codeSystem=2.16.840.1 113883.3.989.2.1.1.20][organizer[@classCode=CATEGORY][@moodCode=EVN]/component[@typeCode=COMP][observation[@code[@codeSystem=2.16.840.1.113883.6.163]]r][observation[classCode=OBS][@moodCode=EVN]/effectiveTime[@nullFlavor </pre> |
| h | F.r.2 | 検査名 | | | | |

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|---|----------|---|-------|-----------------------------|-------------------------------------|---|---|
| e | F.r.2.1 | 検査名 (自由記載) | 250AN | Concept Descriptor (CD) | originalText=Encapsulated Data (ED) | 値 | <pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/PORR_IN049016UV/j/controlActProcess[@classCode=CACT][@moo dCode=EVN]/subject/@typeCode=SUBJ/j/investigationEvent[@classCode=INVTG][@moodCo de=EVN]/component/@typeCode=COMP/j/adverseEventAssessment[1]/adverseEventAssessment [@classCode=INVTG][@moodCode=EVN]/subject1/@typeCode=SBJ/j/primaryRole/@classCo de=INVSBJ/subjectOf2/@typeCode=SBJ/j/organizer/code/@code=3][@codeSystem=2.16.840.1 .113883.3.989.2.1.1.20][j/organizer/@classCode=CATEGORY][@moodCode=EVN]/component[@typeCode=COMP]/observation/code/@codeSystem=2.16.840.1.113883.6.163][j/observation/@ classCode=OBS][@moodCode=EVN]/code/originalText/text() </pre> |
| e | F.r.2.2a | 検査名の MedDRA パージョ ン | 4AN | 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/j/controlActProcess[@classCode=CACT][@moo dCode=EVN]/subject/@typeCode=SUBJ/j/investigationEvent[@classCode=INVTG][@moodCo de=EVN]/component/@typeCode=COMP/j/adverseEventAssessment[1]/adverseEventAssessment [@classCode=INVTG][@moodCode=EVN]/subject1/@typeCode=SBJ/j/primaryRole/@classCo de=INVSBJ/subjectOf2/@typeCode=SBJ/j/organizer/code/@code=3][@codeSystem=2.16.840.1 .113883.3.989.2.1.1.20][j/organizer/@classCode=CATEGORY][@moodCode=EVN]/component[@typeCode=COMP]/observation/code/@codeSystem=2.16.840.1.113883.6.163][j/observation/@ classCode=OBS][@moodCode=EVN]/code/@codeSystemVersion </pre> |
| e | F.r.2.2b | 検査名 (MedDRA コード) | 8N | 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/j/controlActProcess[@classCode=CACT][@moo dCode=EVN]/subject/@typeCode=SUBJ/j/investigationEvent[@classCode=INVTG][@moodCo de=EVN]/component/@typeCode=COMP/j/adverseEventAssessment[1]/adverseEventAssessment [@classCode=INVTG][@moodCode=EVN]/subject1/@typeCode=SBJ/j/primaryRole/@classCo de=INVSBJ/subjectOf2/@typeCode=SBJ/j/organizer/code/@code=3][@codeSystem=2.16.840.1 .113883.3.989.2.1.1.20][j/organizer/@classCode=CATEGORY][@moodCode=EVN]/component[@typeCode=COMP]/observation/code/@codeSystem=2.16.840.1.113883.6.163][j/observation/@ classCode=OBS][@moodCode=EVN]/code/@code </pre> |
| h | F.r.3 | 検査結果 | | | | | <pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/PORR_IN049016UV/j/controlActProcess[@classCode=CACT][@moo dCode=EVN]/subject/@typeCode=SUBJ/j/investigationEvent[@classCode=INVTG][@moodCo de=EVN]/component/@typeCode=COMP/j/adverseEventAssessment[1]/adverseEventAssessment [@classCode=INVTG][@moodCode=EVN]/subject1/@typeCode=SBJ/j/primaryRole/@classCo de=INVSBJ/subjectOf2/@typeCode=SBJ/j/organizer/code/@code=3][@codeSystem=2.16.840.1 .113883.3.989.2.1.1.20][j/organizer/@classCode=CATEGORY][@moodCode=EVN]/component[@typeCode=COMP]/observation/code/@codeSystem=2.16.840.1.113883.6.163][j/observation/@ classCode=OBS][@moodCode=EVN]/code/@code </pre> |
| e | F.r.3.1 | 検査結果 (コード) | 1N | 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/j/controlActProcess[@classCode=CACT][@moo dCode=EVN]/subject/@typeCode=SUBJ/j/investigationEvent[@classCode=INVTG][@moodCo de=EVN]/component/@typeCode=COMP/j/adverseEventAssessment[1]/adverseEventAssessment [@classCode=INVTG][@moodCode=EVN]/subject1/@typeCode=SBJ/j/primaryRole/@classCo de=INVSBJ/subjectOf2/@typeCode=SBJ/j/organizer/code/@code=3][@codeSystem=2.16.840.1 .113883.3.989.2.1.1.20][j/organizer/@classCode=CATEGORY][@moodCode=EVN]/component[@typeCode=COMP]/observation/code/@codeSystem=2.16.840.1.113883.6.163][j/observation/@ classCode=OBS][@moodCode=EVN]/interpretationCode/@codeSystem=2.16.840.1.113883.3.98 9.2.1.1.12][j/@code </pre> |
| | | 検査結果 (コード) に関する ICH コードリストのパー ジョン | | | | | <pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/PORR_IN049016UV/j/controlActProcess[@classCode=CACT][@moo dCode=EVN]/subject/@typeCode=SUBJ/j/investigationEvent[@classCode=INVTG][@moodCo de=EVN]/component/@typeCode=COMP/j/adverseEventAssessment[1]/adverseEventAssessment [@classCode=INVTG][@moodCode=EVN]/subject1/@typeCode=SBJ/j/primaryRole/@classCo de=INVSBJ/subjectOf2/@typeCode=SBJ/j/organizer/code/@code=3][@codeSystem=2.16.840.1 .113883.3.989.2.1.1.20][j/organizer/@classCode=CATEGORY][@moodCode=EVN]/component[@typeCode=COMP]/observation/code/@codeSystem=2.16.840.1.113883.6.163][j/observation/@ classCode=OBS][@moodCode=EVN]/interpretationCode/@codeSystem=2.16.840.1.113883.3.98 9.2.1.1.12][j/@codeSystemVersion </pre> |

(別添3)

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|---|---------|--------------|-----|---|--|---|--|
| e | F.1.3.2 | 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[1]/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=CATEGORY][@moodCode=EVN]/component[1.13883.3.989.2.1.1.20][1]/organizer[@classCode=CATEGORY][@moodCode=EVN]/component[@typeCode=COMP][observation/code/@codesSystem=2.16.840.1.113883.6.163][1]/observation[@classCode=OBS][@moodCode=EVN]/value[@xsi:type=IVL_PQ][1]/center/@value |
| e | | | | | 2.GT low=Interval Boundary (IVXB) | 値 | /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UV[1]/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=CATEGORY][@moodCode=EVN]/component[1.13883.3.989.2.1.1.20][1]/organizer[@classCode=CATEGORY][@moodCode=EVN]/component[@typeCode=COMP][observation/code/@codesSystem=2.16.840.1.113883.6.163][1]/observation[@classCode=OBS][@moodCode=EVN]/value[@xsi:type=IVL_PQ][1]/high/@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[1]/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=CATEGORY][@moodCode=EVN]/component[1.13883.3.989.2.1.1.20][1]/organizer[@classCode=CATEGORY][@moodCode=EVN]/component[@typeCode=COMP][observation/code/@codesSystem=2.16.840.1.113883.6.163][1]/observation[@classCode=OBS][@moodCode=EVN]/value[@xsi:type=IVL_PQ][1]/high/@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[1]/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=CATEGORY][@moodCode=EVN]/component[1.13883.3.989.2.1.1.20][1]/organizer[@classCode=CATEGORY][@moodCode=EVN]/component[@typeCode=COMP][observation/code/@codesSystem=2.16.840.1.113883.6.163][1]/observation[@classCode=OBS][@moodCode=EVN]/value[@xsi:type=IVL_PQ][1]/low/@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[1]/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=CATEGORY][@moodCode=EVN]/component[1.13883.3.989.2.1.1.20][1]/organizer[@classCode=CATEGORY][@moodCode=EVN]/component[@typeCode=COMP][observation/code/@codesSystem=2.16.840.1.113883.6.163][1]/observation[@classCode=OBS][@moodCode=EVN]/value[@xsi:type=IVL_PQ][1]/low/@value |

(別添 3)

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|---|---------|-----------|------|---|--|--|
| e | F.r.3.3 | 検査結果 (単位) | 50AN | Interval of Physical Quantity (IVL<PQ>) | 1.EQ center/value/unit=Physical Quantity (PQ) | <pre> /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 /MCCI_IN200100UV01.xsd]/PQRR_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]/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=OBS][@moodCode=EVN]/value[IVL_PQ][1]/center/@unit </pre> |
| e | | | | | 2.GT low/value/unit=Coded Simple Value (CS) | <pre> /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 /MCCI_IN200100UV01.xsd]/PQRR_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]/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=OBS][@moodCode=EVN]/value[IVL_PQ][high/@nullFlavor=PINF][1]/low/@inclusive=false/@unit </pre> |
| e | | | | | 3.GE low/value/unit=Coded Simple Value (CS) | <pre> /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 /MCCI_IN200100UV01.xsd]/PQRR_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]/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=OBS][@moodCode=EVN]/value[IVL_PQ][high/@nullFlavor=PINF][1]/low/@inclusive=true/@unit </pre> |
| e | | | | | 4.LT high/value/unit=Coded Simple Value (CS) | <pre> /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 /MCCI_IN200100UV01.xsd]/PQRR_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]/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=OBS][@moodCode=EVN]/value[IVL_PQ][low/@nullFlavor=NINF][1]/high/@inclusive=false/@unit </pre> |

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|---|---------------------------------------|--------|---------------------------|---|---|--|
| e | | | | 5.LE high/Value/unit=Code d Simple Value (CS) | 値 | /MCCI_IN200100UV01[ITSVersion=XML_1.0][xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UV[controlActProcess/@classCode=CACT][@moodCo dCode=EVN]/subject/@typeCode=SUBJ[1]/investigationEvent[1]adverseEventAssessment de=EVN]/component/@typeCode=COMP[1]adverseEventAssessment[1]adverseEventAssessment [1]adverseEventAssessment[1]adverseEventAssessment[1]adverseEventAssessment [1]adverseEventAssessment[1]adverseEventAssessment[1]adverseEventAssessment[1] @classCode=INVSUBJ/@moodCode=EVN]/subject[1]/primaryRole/@class Code=EVN]/subjectOf2/@typeCode=SBJ[1]/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=2.16.840.1.113883.6.163][r/observation/@ classCode=OBS][@moodCode=EVN]/value/@xsi:type=IVL_PQ][low/@nullFlavor=NINF][r/high /@inclusive=true]/@unit |
| e | F.r.3.4 検査結果に関する非構造化 字一タ (自由記載) | 2000AN | Encapsulated Data (ED) | | 値 | /MCCI_IN200100UV01[ITSVersion=XML_1.0][xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UV[controlActProcess/@classCode=CACT][@moodCo dCode=EVN]/subject/@typeCode=SUBJ[1]/investigationEvent[1]adverseEventAssessment de=EVN]/component/@typeCode=COMP[1]adverseEventAssessment[1]adverseEventAssessment [1]adverseEventAssessment[1]adverseEventAssessment[1]adverseEventAssessment[1] @classCode=INVSUBJ/@moodCode=EVN]/subject[1]/primaryRole/@class Code=EVN]/subjectOf2/@typeCode=SBJ[1]/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=2.16.840.1.113883.6.163][r/observation/@ classCode=OBS][@moodCode=EVN]/value/@xsi:type=ED][1]/text() |
| e | F.r.4 正常範囲 低値 | 50AN | Physical Quantity (PQ) | value=Real Number (REAL) | 値 | /MCCI_IN200100UV01[ITSVersion=XML_1.0][xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UV[controlActProcess/@classCode=CACT][@moodCo dCode=EVN]/subject/@typeCode=SUBJ[1]/investigationEvent[1]adverseEventAssessment de=EVN]/component/@typeCode=COMP[1]adverseEventAssessment[1]adverseEventAssessment [1]adverseEventAssessment[1]adverseEventAssessment[1]adverseEventAssessment[1] @classCode=INVSUBJ/@moodCode=EVN]/subject[1]/primaryRole/@class Code=EVN]/subjectOf2/@typeCode=SBJ[1]/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=2.16.840.1.113883.6.163][r/observation/@ classCode=OBS][@moodCode=EVN]/referenceRange/@typeCode=REFV][observationRange/int erpretationCode/@code=L][@codeSystem=2.16.840.1.113883.5.83][1]/observationRange/@class Code=OBS][@moodCode=EVN.CRT]/value/@xsi:type=PQ][@value |
| e | F.r.5 正常範囲 高値 | 50AN | Physical Quantity (PQ) | value=Real Number (REAL) | 値 | /MCCI_IN200100UV01[ITSVersion=XML_1.0][xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UV[controlActProcess/@classCode=CACT][@moodCo dCode=EVN]/subject/@typeCode=SUBJ[1]/investigationEvent[1]adverseEventAssessment de=EVN]/component/@typeCode=COMP[1]adverseEventAssessment[1]adverseEventAssessment [1]adverseEventAssessment[1]adverseEventAssessment[1]adverseEventAssessment[1] @classCode=INVSUBJ/@moodCode=EVN]/subject[1]/primaryRole/@class Code=EVN]/subjectOf2/@typeCode=SBJ[1]/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=2.16.840.1.113883.6.163][r/observation/@ classCode=OBS][@moodCode=EVN]/referenceRange/@typeCode=REFV][observationRange/int erpretationCode/@code=H][@codeSystem=2.16.840.1.113883.5.83][1]/observationRange/@class Code=OBS][@moodCode=EVN.CRT]/value/@xsi:type=PQ][@value |

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|---|-------|-------------------|--------|-----------------------------|-------------|--|
| e | F.r.6 | 備考 | 2000AN | Encapsulated Data (ED) | 値 | <pre> /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PDRR_IN049016UV/j/controlActProcess[@classCode=CACT][@moodCo dCode=EVN]/subject[@typeCode=SUBJ][j]/investigationEvent[@classCode=INVTG][@moodCo de=EVN]/component[@typeCode=COMP][j]adverseEventAssessment[1]j/adverseEventAssessment [@classCode=INVTG][@moodCode=EVN]/subject[1]@typeCode=SBJ][1]primaryRole[@classC ode=INVSBJ]/subjectOf2[@typeCode=EVN]/organizer[@code=3][@moodCode=EVN]/component[.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][j]/observation/co de[@code=10][@codeSystem=2.16.840.1.113883.3.989.2.1.1.19][observation/@classCode=OBS][@moodCode=EVN]/value[@xsi:type=ED][j]/text() </pre> |
| e | F.r.7 | その他の情報 | ブール型 | Boolean (BL) | 値 | <pre> /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PDRR_IN049016UV/j/controlActProcess[@classCode=CACT][@moodCo dCode=EVN]/subject[@typeCode=SUBJ][j]/investigationEvent[@classCode=INVTG][@moodCo de=EVN]/component[@typeCode=COMP][j]adverseEventAssessment[1]j/adverseEventAssessment [@classCode=INVTG][@moodCode=EVN]/subject[1]@typeCode=SBJ][1]primaryRole[@classC ode=INVSBJ]/subjectOf2[@typeCode=EVN]/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=2.16.840.1.113883.6.163][j]/observation/co classCode=OBS][@moodCode=EVN]/outboundRelationship2[@typeCode=REFR][j]observation/co de[@code=25][@codeSystem=2.16.840.1.113883.3.989.2.1.1.19][observation/@classCode=OBS][@moodCode=EVN]/value[@xsi:type=BL][j]/@value </pre> |
| h | G.k | 医薬品情報 (必要に応じ繰り返し) | | | 繰り返し ノード | <pre> /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PDRR_IN049016UV/j/controlActProcess[@classCode=CACT][@moodCo dCode=EVN]/subject[@typeCode=SUBJ][j]/investigationEvent[@classCode=INVTG][@moodCo de=EVN]/component[@typeCode=COMP][j]adverseEventAssessment[1]j/adverseEventAssessment [@classCode=INVTG][@moodCode=EVN]/subject[1]@typeCode=SBJ][1]primaryRole[@classC ode=INVSBJ]/subjectOf2[@typeCode=EVN]/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]f() </pre> |
| e | G.k.1 | 医薬品関与の位置付け | 1N | Coded With Equivalents (CE) | 値 | <pre> /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PDRR_IN049016UV/j/controlActProcess[@classCode=CACT][@moodCo dCode=EVN]/subject[@typeCode=SUBJ][j]/investigationEvent[@classCode=INVTG][@moodCo de=EVN]/component[@typeCode=COMP][j]adverseEventAssessment[1]j/adverseEventAssessment [@classCode=INVTG][@moodCode=EVN]/subject[1]@typeCode=COMP][causalityAssessme nt/code[@code=20][@codeSystem=2.16.840.1.113883.3.989.2.1.1.19][causalityAssessme nt/code=OBS][@moodCode=EVN]/subject2[@typeCode=SUBJ]/productUseReference[@classCo de=SBADM][@moodCode=EVN]/id[@root=UUJID of drug][value[@xsi:type=CE][@codeSystem=2.16.840.1.113883.3.989.2.1.1.13][j]/@code k-th </pre> |

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| h | G.k.2 | 医薬品関与の位置付けに関するICHコードリストのバージョン | | | /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UV[controlActProcess/@classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUBJ][investigationEvent/@classCode=INVTG][@moodCode=EVN]/component[@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment/@classCode=INVTG][@moodCode=EVN]/component[@typeCode=COMP][causalityAssessment/@classCode=OBS][@moodCode=EVN][subject2/@typeCode=SUBJ]/productUseReference/@classCode=SBADM][@moodCode=EVN][id/@root=UIID of drug][value[@xsi:type=CE]][@codeSystem=2.16.840.1.113883.3.989.2.1.1.13][@codeSystemVersion] |
| h | G.k.2.1 | 医薬品の識別 医薬品の固有識別子/製剤の固有識別子 | | | /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UV[controlActProcess/@classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUBJ][investigationEvent/@classCode=INVTG][@moodCode=EVN]/component[@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment/@classCode=INVTG][@moodCode=EVN]/subject[1]/primaryRole/@classCode=INVSBJ[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]/@typeCode=COMP[substanceAdministration/@k/substanceAdministration/@classCode=SBADM][@moodCode=EVN]/consumable/@typeCode=CSM[1]/instanceOfKind/@classCode=INSTJ[kindOfProduct/@classCode=MMAT][@determinerCode=KIND][@codeSystem=TBD-MPID][@codeSystemVersion] |
| e | G.k.2.1.1a | M5 ガイド ラインを参照 | Coded With Equivalents (CE) | codeSystemVersion= Character String (ST) | 値 |
| e | G.k.2.1.1b | M5 ガイド ラインを参照 | Coded With Equivalents (CE) | code=Character String (ST) | 値 |
| e | G.k.2.1.2a | PhPID バージョン日付/番号 | Coded With Equivalents (CE) | codeSystemVersion= Character String (ST) | 値 |

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| e | G.k.2.3.r.2a | 成分/特定成分の ID パー ジョン日付/番号 | M5 ガイド ラインを参 照 | Coded With Equivalents (CE) | code=SystemVersion= Character String (ST) | 値 | /MCCI_IN200100UV01@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UV/r/controlActProcess/@classCode=CACT][@moo dCode=EVN]/subject/@typeCode=SUBJ][1]/investigationEvent/@classCode=INVESTG][@moodCo de=EVN]/component/@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment /@classCode=INVESTG][@moodCode=EVN]/subject[1]/@typeCode=SBJ][1]/primaryRole/@classC ode=INVSBJ]/subjectOf2/@typeCode=SBJ][organizer/code/@code=4][@codeSystem=2.16.840.1 113883.3.989.2.1.1.20][1]/organizer/@classCode=CATEGORY][@moodCode=EVN]/component[@typeCode=COMP][substanceAdministration/forK/substanceAdministration/@classCode=SBADM][@moodCode=EVN]/consumable/@typeCode=CSM][1]/instanceOfKind/@classCode=INST]/kind OfProduct/@classCode=MMA][1]/determinerCode=KIND]/ingredient/@classCode=ACTI][r/ingre dientSubstance/@classCode=MMA][1]/determinerCode=KIND]/code/@codeSystem=TBD-Substa nce]/@codeSystemVersion |
| e | G.k.2.3.r.2b | 成分/特定成分の ID | M5 ガイド ラインを参 照 | Coded With Equivalents (CE) | code=Character String (ST) | 値 | /MCCI_IN200100UV01@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UV/r/controlActProcess/@classCode=CACT][@moo dCode=EVN]/subject/@typeCode=SUBJ][1]/investigationEvent/@classCode=INVESTG][@moodCo de=EVN]/component/@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment /@classCode=INVESTG][@moodCode=EVN]/subject[1]/@typeCode=SBJ][1]/primaryRole/@classC ode=INVSBJ]/subjectOf2/@typeCode=SBJ][organizer/code/@code=4][@codeSystem=2.16.840.1 113883.3.989.2.1.1.20][1]/organizer/@classCode=CATEGORY][@moodCode=EVN]/component[@typeCode=COMP][substanceAdministration/forK/substanceAdministration/@classCode=SBADM][@moodCode=EVN]/consumable/@typeCode=CSM][1]/instanceOfKind/@classCode=INST]/kind OfProduct/@classCode=MMA][1]/determinerCode=KIND]/ingredient/@classCode=ACTI][r/ingre dientSubstance/@classCode=MMA][1]/determinerCode=KIND]/code/@codeSystem=TBD-Substa nce]/@code |
| e | G.k.2.3.r.3a | 含量 (数) | 10N | Physical Quantity (PQ) | value=Real Number (REAL) | 値 | /MCCI_IN200100UV01@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UV/r/controlActProcess/@classCode=CACT][@moo dCode=EVN]/subject/@typeCode=SUBJ][1]/investigationEvent/@classCode=INVESTG][@moodCo de=EVN]/component/@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment /@classCode=INVESTG][@moodCode=EVN]/subject[1]/@typeCode=SBJ][1]/primaryRole/@classC ode=INVSBJ]/subjectOf2/@typeCode=SBJ][organizer/code/@code=4][@codeSystem=2.16.840.1 113883.3.989.2.1.1.20][1]/organizer/@classCode=CATEGORY][@moodCode=EVN]/component[@typeCode=COMP][substanceAdministration/forK/substanceAdministration/@classCode=SBADM][@moodCode=EVN]/consumable/@typeCode=CSM][1]/instanceOfKind/@classCode=INST]/kind OfProduct/@classCode=MMA][1]/determinerCode=KIND]/ingredient/@classCode=ACTI][r/quant ity/denominator/@value=1]/numerator/@value |
| e | G.k.2.3.r.3b | 含量 (単位) | 50AN | Physical Quantity (PQ) | unit=Coded Simple Value (CS) | 値 | /MCCI_IN200100UV01@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UV/r/controlActProcess/@classCode=CACT][@moo dCode=EVN]/subject/@typeCode=SUBJ][1]/investigationEvent/@classCode=INVESTG][@moodCo de=EVN]/component/@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment /@classCode=INVESTG][@moodCode=EVN]/subject[1]/@typeCode=SBJ][1]/primaryRole/@classC ode=INVSBJ]/subjectOf2/@typeCode=SBJ][organizer/code/@code=4][@codeSystem=2.16.840.1 113883.3.989.2.1.1.20][1]/organizer/@classCode=CATEGORY][@moodCode=EVN]/component[@typeCode=COMP][substanceAdministration/forK/substanceAdministration/@classCode=SBADM][@moodCode=EVN]/consumable/@typeCode=CSM][1]/instanceOfKind/@classCode=INST]/kind OfProduct/@classCode=MMA][1]/determinerCode=KIND]/ingredient/@classCode=ACTI][r/quant ity/denominator/@value=1]/numerator/@value |

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|---|---------|---------------------|------|--------------------------|---------------------------------|---|---|
| e | G.k.2.4 | 医薬品を入手した国の識別 | 2A | Postal Address (AD) | country=Address Part (ADXP) | 値 | /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049076UV/j/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[@typeCode=COMP][substanceAdministration[k]/substanceAdministration[@classCode=SBADM][@moodCode=EVN]/consumable[@typeCode=ACT][1]/instanceOfKind[@classCode=INST]/subjectOf[@typeCode=SBJ][1]/productEvent[@classCode=ACT][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) | | 値 | /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049076UV/j/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[@typeCode=COMP][substanceAdministration[k]/substanceAdministration[@classCode=SBADM][@moodCode=EVN]/outboundRelationship[2][@typeCode=PERT][observation/code/@code=6][@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 |
| h | G.k.3 | 医薬品の承認の取得者及び承認/申請番号 | | | | | |
| e | G.k.3.1 | 承認/申請番号 | 35AN | Instance Identifier (II) | extension=Character String (ST) | 値 | /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049076UV/j/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[@typeCode=COMP][substanceAdministration[k]/substanceAdministration[@classCode=SBADM][@moodCode=EVN]/consumable[@typeCode=ACT][1]/instanceOfKind[@classCode=INST]/kindOfProduct[@classCode=MMA][@determinerCode=KIND]/asManufacturedProduct[@classCode=MANU]/subjectOf[@typeCode=SBJ][1]/approval[@classCode=CNTRCT][@moodCode=EVN]/id[@root=2,16,840.1,113883.3,989.2.1.3,4][@extension |

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| e | G.k.3.2 | 承認/申請国 | 2A | Coded With Equivalents (OE) | code=Character String (ST) | 値 | /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UV/j/controlActProcess[@classCode=CACT][@moodCode=EVS]/subject/@typeCode=SUBJ][j/investigationEvent[(@classCode=INVSIG][@moodCode=EVS]/component[(@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment[(@classCode=INVSIG][@moodCode=EVS]/subject[1/@typeCode=SB,][j/primaryRole[(@classCode=INVSBJ]/subjectOf2[(@typeCode=EVN][organizer/@code=4][@codeSystem=2.16.840.1.113883.3.989.2.1.1.20][j/organizer[(@typeCode=CATGORY][@moodCode=EVS]/component[1/@typeCode=COMP][substanceAdministration/fd][k/substanceAdministration[(@classCode=SBADM][@moodCode=EVS]/consumable[(@typeCode=CSM][j/instanceOfKind[(@classCode=INST][j/kindOfProduct[(@classCode=MMAAT][@terminerCode=KIND][asManufacturedProduct[(@classCode=MANU]/subjectOf[(@typeCode=SB,][j/approval[(@classCode=CNTRCT][@moodCode=EVS]/author[(@typeCode=AUT][territorialAuthority[(@classCode=TERR][territory[(@classCode=NAT][@territorialCode=INSTAN][@codeSystem=1.0.3166.1.2.2][/@code] |
| e | G.k.3.3 | 承認の取得者/申請者の名称 | 60AN | Organization Name (ON) | name=Entity Name Part (ENXP) | 値 | /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UV/j/controlActProcess[@classCode=CACT][@moodCode=EVS]/subject/@typeCode=SUBJ][j/investigationEvent[(@classCode=INVSIG][@moodCode=EVS]/component[(@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment[(@classCode=INVSIG][@moodCode=EVS]/subject[1/@typeCode=SB,][j/primaryRole[(@classCode=INVSBJ]/subjectOf2[(@typeCode=EVN][organizer/@code=4][@codeSystem=2.16.840.1.113883.3.989.2.1.1.20][j/organizer[(@typeCode=CATGORY][@moodCode=EVS]/component[1/@typeCode=COMP][substanceAdministration/fd][k/substanceAdministration[(@classCode=SBADM][@moodCode=EVS]/consumable[(@typeCode=CSM][j/instanceOfKind[(@classCode=INST][j/kindOfProduct[(@classCode=MMAAT][@terminerCode=KIND][asManufacturedProduct[(@classCode=MANU]/subjectOf[(@typeCode=SB,][j/approval[(@classCode=CNTRCT][@moodCode=EVS]/author[(@typeCode=HLD][j/role[(@classCode=HLDD][playingOrganization[(@classCode=ORG][@territorialCode=INSTAN][@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) | | | | 繰り返し返すノード | /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UV/j/controlActProcess[@classCode=CACT][@moodCode=EVS]/subject/@typeCode=SUBJ][j/investigationEvent[(@classCode=INVSIG][@moodCode=EVS]/component[(@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment[(@classCode=INVSIG][@moodCode=EVS]/subject[1/@typeCode=SB,][j/primaryRole[(@classCode=INVSBJ]/subjectOf2[(@typeCode=EVN][organizer/@code=4][@codeSystem=2.16.840.1.113883.3.989.2.1.1.20][j/organizer[(@typeCode=CATGORY][@moodCode=EVS]/component[1/@typeCode=COMP][substanceAdministration/fd][k/substanceAdministration[(@classCode=SBADM][@moodCode=EVS]/youtboundRelationship2[(@typeCode=COMP][substanceAdministration] |
| e | G.k.4.r.1a | 投与量(数) | 8N | Physical Quantity (PQ) | value=Real Number (REAL) | 値 | /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UV/j/controlActProcess[@classCode=CACT][@moodCode=EVS]/subject/@typeCode=SUBJ][j/investigationEvent[(@classCode=INVSIG][@moodCode=EVS]/component[(@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment[(@classCode=INVSIG][@moodCode=EVS]/subject[1/@typeCode=SB,][j/primaryRole[(@classCode=INVSBJ]/subjectOf2[(@typeCode=EVN][organizer/@code=4][@codeSystem=2.16.840.1.113883.3.989.2.1.1.20][j/organizer[(@typeCode=CATGORY][@moodCode=EVS]/component[1/@typeCode=COMP][substanceAdministration/fd][k/substanceAdministration[(@classCode=SBADM][@moodCode=EVS]/youtboundRelationship2[(@typeCode=COMP][substanceAdministration][j/substanceAdministration[(@classCode=SBADM][@moodCode=EVS]/doseQuantity/@value] |

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| e | | | | G.k.4.r.3 の単位が合 計の場合： Physical Quantity (PQ) | value=Real Number (REAL) | 値 | /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049076UV[1]/controlActProcess[@classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUBJ][1]/investigationEvent[@classCode=INVSTG][@moodCode=EVN]/component[@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment[@classCode=INVSTG][@typeCode=EVN]/subject1[@typeCode=SBJ][1]/primaryRole[@classCode=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[113883.3.989.2.1.1.20][1]/organizer/@classCode=CATEGORY][@moodCode=EVN]/component[1][@moodCode=EVN]/outboundRelationship2[@typeCode=COMP][substanceAdministration][@classCode=SBADM][@xsi:type=PQ][@nullFlavor=UNK][numerator/@xsi:type=PQ][@value |
| e | G.k.4.r.1b | 投与量 (単位) | 50AN | Physical Quantity (PQ) | unit=Coded Simple Value (CS) | 値 | /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049076UV[1]/controlActProcess[@classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUBJ][1]/investigationEvent[@classCode=INVSTG][@moodCode=EVN]/component[@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment[@classCode=INVSTG][@typeCode=EVN]/subject1[@typeCode=SBJ][1]/primaryRole[@classCode=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][@moodCode=EVN]/outboundRelationship2[@typeCode=COMP][substanceAdministration][@classCode=SBADM][@xsi:type=PQ][@nullFlavor=UNK][numerator/@xsi:type=PQ][@value |
| e | | | | G.k.4.r.3 の単位が合 計の場合： Physical Quantity (PQ) | unit=Coded Simple Value (CS) | 値 | /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049076UV[1]/controlActProcess[@classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUBJ][1]/investigationEvent[@classCode=INVSTG][@moodCode=EVN]/component[@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment[@classCode=INVSTG][@typeCode=EVN]/subject1[@typeCode=SBJ][1]/primaryRole[@classCode=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[113883.3.989.2.1.1.20][1]/organizer/@classCode=CATEGORY][@moodCode=EVN]/component[1][@moodCode=EVN]/outboundRelationship2[@typeCode=COMP][substanceAdministration][@classCode=SBADM][@xsi:type=PQ][@nullFlavor=UNK][numerator/@xsi:type=PQ][@unit |

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| <p>e</p> | <p>G.k.4.r.2</p> | <p>投与間隔の単位数</p> <p>4N</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 SXPX を伴う最初の comp 項目 Parenthetic Set Expression of Time (SXPX_TS) [Periodic Interval of Time (PVL_TS)]</p> | <p>値</p> <p>period/Value=Real Number (REAL)</p> | <pre> /MCCL_IN200100UV01[ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/PORR_IN049016UV[controlActProcess/@classCode=CACT][@moodCode=EVN]/subject/@typeCode=SUBJ[adverseEventAssessment/@classCode=INVESTG][@moodCode=EVN]/component/@typeCode=COMP[adverseEventAssessment[1]/adverseEventAssessment/@classCode=INVESTG][@moodCode=EVN]/subject1[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/fd][substanceAdministration/@classCode=SBADM][@moodCode=EVN]/outboundRelationship2[@typeCode=COMP][substanceAdministration/@classCode=SBADM][@moodCode=EVN]/effectiveTime[@xsi:type=SXPX_TS]/comp[@xsi:type=PVL_TS]/period/@value </pre> |
| | | | <p>2.以下のデータ項目の2つを超える値が表示される場合: 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 SXPX を伴う 2 番目の comp 項目 Parenthetic Set Expression of Time (SXPX_TS) [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[controlActProcess/@classCode=CACT][@moodCode=EVN]/subject/@typeCode=SUBJ[adverseEventAssessment/@classCode=INVESTG][@moodCode=EVN]/component/@typeCode=COMP[adverseEventAssessment[1]/adverseEventAssessment/@classCode=INVESTG][@moodCode=EVN]/subject1[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/fd][substanceAdministration/@classCode=SBADM][@moodCode=EVN]/effectiveTime[@xsi:type=SXPX_TS]/comp[@xsi:type=PVL_TS]/operator[A]/period/@value </pre> |

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| <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>period/value=Real Number (REAL)</p> | <p>値</p> | <pre>/MCCI_IN200100UV01[@ITSVersion="XML_1.0"]/@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd"/> <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"/> <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[1]/ <substanceAdministration/@classCode="SBADM"/> <@moodCode="EVN"/> <outboundRelationship2/@typeCode="COMP"/> <substanceAdministration/@classCode="SBADM"/> <@moodCode="EVN"/> <effectiveTime/@xsi:type="PVL_TS"/> </value></pre> |
| <p>e</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>Parentetic Set Expression of Time (SXPTR_TS) [Periodic Interval of Time (PVL_TS)]</p> | <p>period/unit=Coded Simple Value (CS)</p> | <p>値</p> | <pre>/MCCI_IN200100UV01[@ITSVersion="XML_1.0"]/@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd"/> <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"/> <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[1]/ <substanceAdministration/@classCode="SBADM"/> <@moodCode="EVN"/> <outboundRelationship2/@typeCode="COMP"/> <substanceAdministration/@classCode="SBADM"/> <@moodCode="EVN"/> <effectiveTime/@xsi:type="SXPTR_TS"/> </comp/@unit></pre> |

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| | <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 SXPTR を伴う 2 番目の comp 項目</p> <p>Parenthetic Set Expression of Time (SXPTR_TS) [Periodic Interval of Time (PIVL_TS)]</p> | <p>値</p> <pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/PORR_IN049076UV/r/controlActProcess[@classCode=CACT][@moodCode=EVN]/subject/@typeCode=SUBJ/1/investigationEvent[@classCode=INVTG][@moodCode=EVN]/component/@typeCode=COMP/1/adverseEventAssessment[1]/adverseEventAssessment[@classCode=INVTG][@moodCode=EVN]/subject1/@typeCode=SBJ/1/primaryRole/@classCode=INVSBJ/subjectOf2/@typeCode=SBJ/organizer/code/@code=4][@codeSystem=2.16.840.1.113883.3.989.2.1.1.20][1]/organizer/@classCode=CATEGORY/1/@moodCode=EVN/component/@typeCode=EVN/outboundRelationship2/@typeCode=COMP/1/substanceAdministration[r]/substanceAdministration/@classCode=SBADM/1/@moodCode=EVN/period/@unit TS]/comp[@xsi:type=PVL_TS][@operator=A]/period/@unit </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>Periodic Interval of Time (PIVL_TS)</p> | <p>値</p> <pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/PORR_IN049076UV/r/controlActProcess[@classCode=CACT][@moodCode=EVN]/subject/@typeCode=SUBJ/1/investigationEvent[@classCode=INVTG][@moodCode=EVN]/component/@typeCode=COMP/1/adverseEventAssessment[1]/adverseEventAssessment[@classCode=INVTG][@moodCode=EVN]/subject1/@typeCode=SBJ/1/primaryRole/@classCode=INVSBJ/subjectOf2/@typeCode=SBJ/organizer/code/@code=4][@codeSystem=2.16.840.1.113883.3.989.2.1.1.20][1]/organizer/@classCode=CATEGORY/1/@moodCode=EVN/component/@typeCode=COMP/1/substanceAdministration[r]/substanceAdministration/@classCode=SBADM/1/@moodCode=EVN/period/@unit S']/period/@unit </pre> <p>period/unit=Coded Simple Value (CS)</p> |

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| <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:</p> <p>1) G.k.4.r.2, G.k.4.r.3 2) G.k.4.r.4 3) G.k.4.r.5 4) G.k.4.r.6a, G.k.4.r.6b</p> <p>データ型 SXPB を併用最初の comp 項目</p> <p>Parenthetic Set Expression of Time (SXPB_TS) [Interval of Point in Time (IVL_TS)]</p> | <p>low=Interval Boundary (IVXB)</p> <p>値</p> | <pre> /MCC1_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCC1_IN200100UV01.xsd]/PORR_IN049016UV/rj/controlActProcess[@classCode=CACT][@moo dCode=EVN]/subject/@typeCode=SUBJ/rj/investigationEvent[@classCode=INVTG][@moodCo de=EVN]/component/@typeCode=COMP/rj/adverseEventAssessment[1]/adverseEventAssessment [@classCode=INVTG][@moodCode=EVN]/subject1/@typeCode=SBJ/rj/primaryRole/@classC ode=INVSBJ/subjectOf2/@typeCode=SBJ/rj/organizer/code/@code=4][@codeSystem=2.16.840.1 .119883.3.989.2.1.1.20][1]/jorganizer/@classCode=CATEGORY][@moodCode=EVN]/component /@typeCode=COMP/jsubstanceAdministration/d[K]/substanceAdministration[@classCode=SBADM][@moodCode=EVN]/outboundRelationship2/@typeCode=COMP/jsubstanceAdministration[r]/sub stanceAdministration[@classCode=SBADM][@moodCode=EVN]/effectiveTime/@xsi:type=SXPB_ TS]/comp/@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/rj/controlActProcess[@classCode=CACT][@moo dCode=EVN]/subject/@typeCode=SUBJ/rj/investigationEvent[@classCode=INVTG][@moodCo de=EVN]/component/@typeCode=COMP/rj/adverseEventAssessment[1]/adverseEventAssessment [@classCode=INVTG][@moodCode=EVN]/subject1/@typeCode=SBJ/rj/primaryRole/@classC ode=INVSBJ/subjectOf2/@typeCode=SBJ/rj/organizer/code/@code=4][@codeSystem=2.16.840.1 .119883.3.989.2.1.1.20][1]/jorganizer/@classCode=CATEGORY][@moodCode=EVN]/component /@typeCode=COMP/jsubstanceAdministration/d[K]/substanceAdministration[@classCode=SBADM][@moodCode=EVN]/outboundRelationship2/@typeCode=COMP/jsubstanceAdministration[r]/sub stanceAdministration[@classCode=SBADM][@moodCode=EVN]/effectiveTime/@xsi:type=SXPB_ TS]/comp/@xsi:type=IVL_TS/low/@nullFlavor </pre> |

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| <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 SXPB を伴う 2 番目の comp 項目</p> <p>Parenthetic Set Expression of Time (SXPB_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/f/controlActProcess[@classCode="CACT"]/@moodCode="EVN"/subject/@typeCode="SUBJ"/investigationEvent[@classCode="INVTG"]/@moodCode="EVN"/component/@typeCode="COMP"/adverseEventAssessment[1]/adverseEventAssessment[@classCode="INVTG"]/@moodCode="EVN"/subject1/@typeCode="SBJ"/primaryRole/@classCode="INVSBJ"/subjectOf2/@typeCode="SBJ"/organizer/code/@code="4"]/@codeSystem="2.16.840.1.113883.3.989.2.1.1.20"]/organizer/@classCode="CATEGORY"/@moodCode="EVN"/component/@typeCode="COMP"/substanceAdministration/f/K/substanceAdministration/@classCode="SBADM"]/@moodCode="EVN"/outboundRelationship2/@typeCode="COMP"/substanceAdministration/@classCode="SBADM"]/@moodCode="EVN"/effectiveTime/@xsi:type="SXPB_TS"/comp/@xsi:type="IVL_TS"]/@operator="A"/row/@value </pre> | <p>NullFlavor</p> <pre> /MCCI_IN200100UV01[@ITSVersion="XML_1.0"]/@xsi:schemaLocation="urn:hl7-org:v3 MCCI_IN200100UV01.xsd"/PORR_IN049016UV/f/controlActProcess[@classCode="CACT"]/@moodCode="EVN"/subject/@typeCode="SUBJ"/investigationEvent[@classCode="INVTG"]/@moodCode="EVN"/component/@typeCode="COMP"/adverseEventAssessment[1]/adverseEventAssessment[@classCode="INVTG"]/@moodCode="EVN"/subject1/@typeCode="SBJ"/primaryRole/@classCode="INVSBJ"/subjectOf2/@typeCode="SBJ"/organizer/code/@code="4"]/@codeSystem="2.16.840.1.113883.3.989.2.1.1.20"]/organizer/@classCode="CATEGORY"/@moodCode="EVN"/component/@typeCode="COMP"/substanceAdministration/f/K/substanceAdministration/@classCode="SBADM"]/@moodCode="EVN"/outboundRelationship2/@typeCode="COMP"/substanceAdministration/@classCode="SBADM"]/@moodCode="EVN"/effectiveTime/@xsi:type="SXPB_TS"/comp/@xsi:type="IVL_TS"]/@operator="A"/row/@nullFlavor </pre> |
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|---|--------------------------------|--------------|--|---|----------|--|
| e | | | <p>3.以下のデータ項目の1つの値のみが表 示される場合</p> <ol style="list-style-type: none"> 1) G.k.4.r.2、 G.k.4.r.3 2) G.k.4.r.4 3) G.k.4.r.5 4) G.k.4.r.6a、 G.k.4.r.6b <p>Interval of Point in Time (IVL_TS)</p> | <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]/PORR_IN049016UV01/controlAct/process/@classCode=CACT][@moo dCode=EVN]/subject/@typeCode=SUBJ[1]/investigationEvent/@classCode=INVTG][@moodCo de=EVN]/component/@typeCode=COMP[adverseEventAssessment[1]/adverseEventAssessment [1]/classCode=INVTG][@moodCode=EVN]/subject[1]/typeCode=SBJ[1]/primaryRole/@classC ode=INVSBJ[1]/subjectO2/@typeCode=SBJ[1]/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[1]/substanceAdministration[id][K]/substanceAdministration/@classCode=SBADM][@moodCode=EVN]/outboundRelationship[2]/typeCode=COMP[1]/substanceAdministration[id]/sub stanceAdministration/@classCode=SBADM][@moodCode=EVN]/effectiveTime/@xsi:type=IVL_TS]/low/@value</pre> |
| e | | | | <p>NullFlavor</p> | <p>値</p> | <pre>/MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UV01/controlAct/process/@classCode=CACT][@moo dCode=EVN]/subject/@typeCode=SUBJ[1]/investigationEvent/@classCode=INVTG][@moodCo de=EVN]/component/@typeCode=COMP[adverseEventAssessment[1]/adverseEventAssessment [1]/classCode=INVTG][@moodCode=EVN]/subject[1]/typeCode=SBJ[1]/primaryRole/@classC ode=INVSBJ[1]/subjectO2/@typeCode=SBJ[1]/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[1]/substanceAdministration[id][K]/substanceAdministration/@classCode=SBADM][@moodCode=EVN]/outboundRelationship[2]/typeCode=COMP[1]/substanceAdministration[id]/sub stanceAdministration/@classCode=SBADM][@moodCode=EVN]/effectiveTime/@xsi:type=IVL_TS]/low/@value</pre> |
| e | <p>G.k.4.r.5 医薬品の投与終了日</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:</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 SXPRT を併 用最初の comp 項目</p> <p>Parentthetic Set Expression of Time (SXPRT_TS) [Interval of Point in Time (IVL_TS)]</p> | <p>high=Interval Boundary (VXB)</p> | <p>値</p> | <pre>/MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UV01/controlAct/process/@classCode=CACT][@moo dCode=EVN]/subject/@typeCode=SUBJ[1]/investigationEvent/@classCode=INVTG][@moodCo de=EVN]/component/@typeCode=COMP[adverseEventAssessment[1]/adverseEventAssessment [1]/classCode=INVTG][@moodCode=EVN]/subject[1]/typeCode=SBJ[1]/primaryRole/@classC ode=INVSBJ[1]/subjectO2/@typeCode=SBJ[1]/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[1]/substanceAdministration[id][K]/substanceAdministration/@classCode=SBADM][@moodCode=EVN]/outboundRelationship[2]/typeCode=COMP[1]/substanceAdministration[id]/sub stanceAdministration/@classCode=SBADM][@moodCode=EVN]/effectiveTime/@xsi:type=SXPRT_ TS]/comp/@xsi:type=IVL_TS]/high/@value</pre> |

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| <p>/MCC1_IN200100UV01[@ITSVersion='XML_1.0']/@xsi:schemaLocation=urn:hl7-org:v3 MCC1_IN200100UV01.xsd/PORR_IN049016UVI/ControlActProcess[@classCode='CACT']/@moodCode=EVN/subject/@typeCode='SUBJ'[/investigationEvent/@classCode='INVESTG']/@moodCode=EVN/comp/@typeCode='COMP'[/adverseEventAssessment/1]/adverseEventAssessment[@classCode='INVESTG']/@moodCode='EVN'[/subject/1]/primaryRole/@classCode='INVSBJ'[/subject/2]/typeCode='SBJ'[/organizer/code=4]/@codeSystem='2.16.840.1.113883.3.989.2.1.1.20'[/organizer/@classCode='CATEGORY']/@moodCode='EVN'[/component/1]/@typeCode='COMP'[/substanceAdministration/d]/substanceAdministration[@classCode='SBADM']/@moodCode='EVN'[/outboundRelationship/2]/@typeCode='SBADM']/@moodCode='EVN'[/effectiveTime/@xsi:type='SXPR_TS']/comp/@xsi:type='IVL_TS'[/high/@nullFlavor</p> | <p>/MCC1_IN200100UV01[@ITSVersion='XML_1.0']/@xsi:schemaLocation=urn:hl7-org:v3 MCC1_IN200100UV01.xsd/PORR_IN049016UVI/ControlActProcess[@classCode='CACT']/@moodCode=EVN/subject/@typeCode='SUBJ'[/investigationEvent/@classCode='INVESTG']/@moodCode=EVN/comp/@typeCode='COMP'[/adverseEventAssessment/1]/adverseEventAssessment[@classCode='INVESTG']/@moodCode='EVN'[/subject/1]/primaryRole/@classCode='INVSBJ'[/subject/2]/typeCode='SBJ'[/organizer/code=4]/@codeSystem='2.16.840.1.113883.3.989.2.1.1.20'[/organizer/@classCode='CATEGORY']/@moodCode='EVN'[/component/1]/@typeCode='COMP'[/substanceAdministration/d]/substanceAdministration[@classCode='SBADM']/@moodCode='EVN'[/outboundRelationship/2]/@typeCode='SBADM']/@moodCode='EVN'[/effectiveTime/@xsi:type='SXPR_TS']/comp/@xsi:type='IVL_TS'[/operator='A']/high/@value</p> | <p>/MCC1_IN200100UV01[@ITSVersion='XML_1.0']/@xsi:schemaLocation=urn:hl7-org:v3 MCC1_IN200100UV01.xsd/PORR_IN049016UVI/ControlActProcess[@classCode='CACT']/@moodCode=EVN/subject/@typeCode='SUBJ'[/investigationEvent/@classCode='INVESTG']/@moodCode=EVN/comp/@typeCode='COMP'[/adverseEventAssessment/1]/adverseEventAssessment[@classCode='INVESTG']/@moodCode='EVN'[/subject/1]/primaryRole/@classCode='INVSBJ'[/subject/2]/typeCode='SBJ'[/organizer/code=4]/@codeSystem='2.16.840.1.113883.3.989.2.1.1.20'[/organizer/@classCode='CATEGORY']/@moodCode='EVN'[/component/1]/@typeCode='COMP'[/substanceAdministration/d]/substanceAdministration[@classCode='SBADM']/@moodCode='EVN'[/outboundRelationship/2]/@typeCode='COMP'[/substanceAdministration/1]/substanceAdministration[@classCode='SBADM']/@moodCode='EVN'[/effectiveTime/@xsi:type='SXPR_TS']/comp/@xsi:type='IVL_TS'[/operator='A']/high/@nullFlavor</p> | <p>NullFlavor</p> | <p>値</p> | <p>NullFlavor</p> |
| <p>2.以下の子データ項目の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>データ型 SXPR を伴う 2 番目の comp 項目</p> <p>Parenthetic Set Expression of Time (SXPR_TS) [Intervale of Point in Time (IVL_TS)]</p> | | | | | |

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| e | | <p>3.以下のデータ項目の1つの値のみが表示される場合</p> <ol style="list-style-type: none"> 1) G.k.4.r.2、 G.k.4.r.3 2) G.k.4.r.4 3) G.k.4.r.5 4) G.k.4.r.6a、 G.k.4.r.6b <p>Interval of Point in Time (IVL_TS)</p> | <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[1]/controlActProcess[@classCode="CACT"]/@moo dCode=EVN]/subject[@typeCode="SUBJ"]/investigationEvent[@classCode="INVTG"]/@moodCo de=EVN]/component[@typeCode="COMP"]/adverseEventAssessment[1]/adverseEventAssessment [@classCode="INVTG"]/@moodCode=EVN]/subject1[@typeCode="SBJ"]/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 /@typeCode="COMP"/substanceAdministration[1]/substanceAdministration[@classCode="SBADM "]/@moodCode=EVN]/outboundRelationship2[@typeCode="COMP"/substanceAdministration]/r/sub stanceAdministration[@classCode="SBADM"]/@moodCode=EVN]/effectiveTime/@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> <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 SXPX を伴う最初の comp 項目</p> <p>Parenthetic Set Expression of Time (SXPX_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"/]PORR_IN049016UV[1]/controlActProcess[@classCode="CACT"]/@moo dCode=EVN]/subject[@typeCode="SUBJ"]/investigationEvent[@classCode="INVTG"]/@moodCo de=EVN]/component[@typeCode="COMP"]/adverseEventAssessment[1]/adverseEventAssessment [@classCode="INVTG"]/@moodCode=EVN]/subject1[@typeCode="SBJ"]/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 /@typeCode="COMP"/substanceAdministration[1]/substanceAdministration[@classCode="SBADM "]/@moodCode=EVN]/outboundRelationship2[@typeCode="COMP"/substanceAdministration]/r/sub stanceAdministration[@classCode="SBADM"]/@moodCode=EVN]/effectiveTime/@xsi:type="IVL_TS "/high/@nullFlavor </pre> |
| e | G.k.4.r.6a 医薬品投与期間 (数) | 5N | width=value=Real Number (REAL) | <pre> /MCCI_IN200100UV01[@ITSVersion="XML_1.0"][@xsi:schemaLocation="urn:hl7-org:v3 MCCI_IN200100UV01.xsd"/]PORR_IN049016UV[1]/controlActProcess[@classCode="CACT"]/@moo dCode=EVN]/subject[@typeCode="SUBJ"]/investigationEvent[@classCode="INVTG"]/@moodCo de=EVN]/component[@typeCode="COMP"]/adverseEventAssessment[1]/adverseEventAssessment [@classCode="INVTG"]/@moodCode=EVN]/subject1[@typeCode="SBJ"]/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 /@typeCode="COMP"/substanceAdministration[1]/substanceAdministration[@classCode="SBADM "]/@moodCode=EVN]/outboundRelationship2[@typeCode="COMP"/substanceAdministration]/r/sub stanceAdministration[@classCode="SBADM"]/@moodCode=EVN]/effectiveTime/@xsi:type="SXPX_ TS"/comp[@xsi:type="IVL_TS"/width/@value </pre> |

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| | | <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> /MCCL_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCL_IN200100UV01.xsd']/PORR_IN049016UV01/controlActProcess[@classCode='CACT']/@moodCode='EVN']/subject[@typeCode='SUBJ']/investigationEvent[@classCode='INVESTG']/@moodCode='EVN']/component[@typeCode='COMP']/adverseEventAssessment[1]/adverseEventAssessment[@classCode='INVSTG']/@moodCode='EVN']/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/fk/substanceAdministration/@classCode='SBADM']/@moodCode='EVN']/outboundRelationship2/@typeCode='COMP']/substanceAdministration/@classCode='SBADM']/@moodCode='EVN']/effectiveTime/@xsi:type='SXPР_TS']/comp[@xsi:type='IVL_TS']/@operator='A']/width/@value </pre> |
| | <p>width/Value=Real Number (REAL)</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>Interval of Point in Time (IVL_TS)</p> | <p>値</p> <pre> /MCCL_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCL_IN200100UV01.xsd']/PORR_IN049016UV01/controlActProcess[@classCode='CACT']/@moodCode='EVN']/subject[@typeCode='SUBJ']/investigationEvent[@classCode='INVESTG']/@moodCode='EVN']/component[@typeCode='COMP']/adverseEventAssessment[1]/adverseEventAssessment[@classCode='INVSTG']/@moodCode='EVN']/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/fk/substanceAdministration/@classCode='SBADM']/@moodCode='EVN']/outboundRelationship2/@typeCode='COMP']/substanceAdministration/@classCode='SBADM']/@moodCode='EVN']/effectiveTime/@xsi:type='IVL_TS']/width/@value </pre> |

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| <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: 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) [Interval of Point in Time (IVL_TS)]</p> | <p>width/unit=Coded Simple Value (CS)</p> | <p>値</p> | <pre> /MCCL_IN200100UV01[@ITSVersion='XML_1.0']/@xsi:schemaLocation='urn:hl7-org:v3 MCCL_IN200100UV01.xsd'/PORR_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[/@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[/@classCode='SBADM']/@moodCode='EVN']/outboundRelationship2[/@typeCode='COMP']/substanceAdministration[/@classCode='SBADM']/@moodCode='EVN']/effectiveTime[/@xsi:type='SXPР_TS']/comp[/@xsi:type='IVL_TS']/width/@unit </pre> |
| | | | | <p>2.以下のデータ項目の2つを超える値が表示される場合: 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2番目の comp 項目 Parenthetic Set Expression of Time (SXPР_TS)[Interval of Point in Time (IVL_TS)]</p> | <p>値</p> | <pre> /MCCL_IN200100UV01[@ITSVersion='XML_1.0']/@xsi:schemaLocation='urn:hl7-org:v3 MCCL_IN200100UV01.xsd'/PORR_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[/@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[/@classCode='SBADM']/@moodCode='EVN']/outboundRelationship2[/@typeCode='COMP']/substanceAdministration[/@classCode='SBADM']/@moodCode='EVN']/effectiveTime[/@xsi:type='SXPР_TS']/comp[/@xsi:type='IVL_TS']/operator='A'/width/@unit </pre> | |

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| <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"> G.k.4.r.2, G.k.4.r.3 G.k.4.r.4 G.k.4.r.5 G.k.4.r.6a, G.k.4.r.6b | <p>width/unit=Coded Simple Value (CS)</p> | <p>値</p> | <pre>/MCC1_IN200100UV01/@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCC1_IN200100UV01.xsd]/PDRR_IN049016UV[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[@typeCode=COMP][substanceAdministration[id][k]/substanceAdministration[@classCode=SBADM][@moodCode=EVN]/outboundRelationship2[@typeCode=COMP][substanceAdministration][r]/sub stanceAdministration[@classCode=SBADM][@moodCode=EVN]/effectiveTime[IVL_TS]/width/@unit</pre> |
| <p>e</p> | <p>G.k.4.r.7</p> | <p>パッチ/ロット番号</p> | <p>35AN</p> | <p>Character String (ST)</p> | <p>値</p> |
| <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>Encapsulated Data (ED)</p> | <p>値</p> |
| <p>h</p> | <p>G.k.4.r.9</p> | <p>医薬品剤形</p> | | | <p>値</p> |
| <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>Coded With Equivalents (CE)</p> | <p>値</p> |

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| e | | | NullFlavor | | <pre> MCC1_IN200100UV01@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCC1_IN200100UV01.xsd]/PQR_IN049016UV[controlActProcess/@classCode=CACT][@moo dCode=EVN]/subject/@typeCode=SUB,J[1]/investigationEvent/@classCode=INVTG][@moodCo de=EVN]/component/@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment /@classCode=INVTG][@moodCode=EVN]/subject1/@typeCode=SB,J[1]/primaryRole/@classC ode=INVSBJ]/subjectOf2/@typeCode=SB,J][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[1]/substanceAdministration/@classCode=SBADM][@moodCode=EVN]/outboundRelationship2/@typeCode=COMP][substanceAdministration]/r/sub stanceAdministration/@classCode=SBADM][@moodCode=EVN]/consumable/@typeCode=C5M][1/instanceOfKind/@classCode=INST]/kindOfProduct/@classCode=MMAT][@determinerCode=KI ND]/formCode/@codeSystem=TBDD-DoseForm]/originalText/@nullFlavor </pre> |
| e | G.k.4.r.9.2a | 医薬品剤形の ID バージョン 日付/番号 | M5 ガイド ラインを参 照 | Coded With Equivalents (CE) | <pre> MCC1_IN200100UV01@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCC1_IN200100UV01.xsd]/PQR_IN049016UV[controlActProcess/@classCode=CACT][@moo dCode=EVN]/subject/@typeCode=SUB,J[1]/investigationEvent/@classCode=INVTG][@moodCo de=EVN]/component/@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment /@classCode=INVTG][@moodCode=EVN]/subject1/@typeCode=SB,J[1]/primaryRole/@classC ode=INVSBJ]/subjectOf2/@typeCode=SB,J][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[1]/substanceAdministration/@classCode=SBADM][@moodCode=EVN]/outboundRelationship2/@typeCode=COMP][substanceAdministration]/r/sub stanceAdministration/@classCode=SBADM][@moodCode=EVN]/consumable/@typeCode=C5M][1/instanceOfKind/@classCode=INST]/kindOfProduct/@classCode=MMAT][@determinerCode=KI ND]/formCode/@codeSystem=TBDD-DoseForm]/@codeSystemVersion </pre> |
| 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) | <pre> MCC1_IN200100UV01@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCC1_IN200100UV01.xsd]/PQR_IN049016UV[controlActProcess/@classCode=CACT][@moo dCode=EVN]/subject/@typeCode=SUB,J[1]/investigationEvent/@classCode=INVTG][@moodCo de=EVN]/component/@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment /@classCode=INVTG][@moodCode=EVN]/subject1/@typeCode=SB,J[1]/primaryRole/@classC ode=INVSBJ]/subjectOf2/@typeCode=SB,J][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[1]/substanceAdministration/@classCode=SBADM][@moodCode=EVN]/outboundRelationship2/@typeCode=COMP][substanceAdministration]/r/sub stanceAdministration/@classCode=SBADM][@moodCode=EVN]/consumable/@typeCode=C5M][1/instanceOfKind/@classCode=INST]/kindOfProduct/@classCode=MMAT][@determinerCode=KI ND]/formCode/@codeSystem=TBDD-DoseForm]/@code </pre> |
| h | G.k.4.r.10 | 投与経路 | | | <pre> MCC1_IN200100UV01@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCC1_IN200100UV01.xsd]/PQR_IN049016UV[controlActProcess/@classCode=CACT][@moo dCode=EVN]/subject/@typeCode=SUB,J[1]/investigationEvent/@classCode=INVTG][@moodCo de=EVN]/component/@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment /@classCode=INVTG][@moodCode=EVN]/subject1/@typeCode=SB,J[1]/primaryRole/@classC ode=INVSBJ]/subjectOf2/@typeCode=SB,J][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[1]/substanceAdministration/@classCode=SBADM][@moodCode=EVN]/outboundRelationship2/@typeCode=COMP][substanceAdministration]/r/sub stanceAdministration/@classCode=SBADM][@moodCode=EVN]/consumable/@typeCode=C5M][1/instanceOfKind/@classCode=INST]/kindOfProduct/@classCode=MMAT][@determinerCode=KI ND]/formCode/@codeSystem=TBDD-DoseForm]/@code </pre> |
| e | G.k.4.r.10.1 | 投与経路 (自由記載) | 60AN | Coded With Equivalents (CE) | <pre> MCC1_IN200100UV01@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCC1_IN200100UV01.xsd]/PQR_IN049016UV[controlActProcess/@classCode=CACT][@moo dCode=EVN]/subject/@typeCode=SUB,J[1]/investigationEvent/@classCode=INVTG][@moodCo de=EVN]/component/@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment /@classCode=INVTG][@moodCode=EVN]/subject1/@typeCode=SB,J[1]/primaryRole/@classC ode=INVSBJ]/subjectOf2/@typeCode=SB,J][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[1]/substanceAdministration/@classCode=SBADM][@moodCode=EVN]/outboundRelationship2/@typeCode=COMP][substanceAdministration]/r/sub stanceAdministration/@classCode=SBADM][@moodCode=EVN]/consumable/@typeCode=C5M][1/instanceOfKind/@classCode=INST]/kindOfProduct/@classCode=MMAT][@determinerCode=KI ND]/formCode/@codeSystem=TBDD-DoseForm]/@code </pre> |

(別添 3)

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| 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) | codeSystemVersion= Character String (ST) | Null Flavor | /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/PDRR_IN049016UVUJ/controlActProcess[@classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUBJ][@investigationEvent[@classCode=INVESTG][@moodCode=EVN]/component[@typeCode=COMP][@adverseEventAssessment[1][adverseEventAssessment de=EVN]/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[113883.3.989.2.1.1.20][1]organizer[@classCode=CATEGORY][@moodCode=EVN]/component[@typeCode=COMP][substanceAdministration/fk][substanceAdministration/@classCode=SBADM][@moodCode=EVN]/outboundRelationship2[@typeCode=COMP][substanceAdministration]/r/sub stanceAdministration/@classCode=SBADM][@moodCode=EVN]/routeCode[@codeSystem=2.16. 840.1.113883.3.989.2.1.1.14]/originalText/@nullFlavor |
| e | G.k.4.r.10.2b | 投与経路の ID | M5 ガイド ラインを参 (3N)を参 照 | Coded With Equivalents (CE) | code=Character String (ST) | 値 | /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/PDRR_IN049016UVUJ/controlActProcess[@classCode=CACT][@moo dCode=EVN]/subject[@typeCode=SUBJ][1]/investigationEvent[@classCode=INVESTG][@moodCo de=EVN]/component[@typeCode=COMP][@adverseEventAssessment[1][adverseEventAssessment de=EVN]/classCode=INVESTG][@moodCode=EVN]/subject1[@typeCode=SBJ][1]primaryRole[@classC ode=INVSBJ]/subjectOf2[@typeCode=SBJ][organizer/code/@code=4][@codeSystem=2.16.840.1 113883.3.989.2.1.1.20][1]organizer[@classCode=CATEGORY][@moodCode=EVN]/component[113883.3.989.2.1.1.20][1]organizer[@classCode=CATEGORY][@moodCode=EVN]/component[@typeCode=COMP][substanceAdministration/fk][substanceAdministration/@classCode=SBADM][@moodCode=EVN]/outboundRelationship2[@typeCode=COMP][substanceAdministration]/r/sub stanceAdministration/@classCode=SBADM][@moodCode=EVN]/routeCode[@codeSystem=2.16. 840.1.113883.3.989.2.1.1.14]/@codeSystemVersion |
| h | G.k.4.r.11 | 親への投与経路 (親子ノ胎 児報告の場合) | | | | 値 | /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/PDRR_IN049016UVUJ/controlActProcess[@classCode=CACT][@moo dCode=EVN]/subject[@typeCode=SUBJ][1]/investigationEvent[@classCode=INVESTG][@moodCo de=EVN]/component[@typeCode=COMP][@adverseEventAssessment[1][adverseEventAssessment de=EVN]/classCode=INVESTG][@moodCode=EVN]/subject1[@typeCode=SBJ][1]primaryRole[@classC ode=INVSBJ]/subjectOf2[@typeCode=SBJ][organizer/code/@code=4][@codeSystem=2.16.840.1 113883.3.989.2.1.1.20][1]organizer[@classCode=CATEGORY][@moodCode=EVN]/component[113883.3.989.2.1.1.20][1]organizer[@classCode=CATEGORY][@moodCode=EVN]/component[@typeCode=COMP][substanceAdministration/fk][substanceAdministration/@classCode=SBADM][@moodCode=EVN]/outboundRelationship2[@typeCode=COMP][substanceAdministration]/r/sub stanceAdministration/@classCode=SBADM][@moodCode=EVN]/routeCode[@codeSystem=2.16. 840.1.113883.3.989.2.1.1.14]/@code |
| e | G.k.4.r.11.1 | 親への投与経路 (自由記載) | 60AN | Coded With Equivalents (CE) | originalText=Encapsu lated Data (ED) | 値 | /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/PDRR_IN049016UVUJ/controlActProcess[@classCode=CACT][@moo dCode=EVN]/subject[@typeCode=SUBJ][1]/investigationEvent[@classCode=INVESTG][@moodCo de=EVN]/component[@typeCode=COMP][@adverseEventAssessment[1][adverseEventAssessment de=EVN]/classCode=INVESTG][@moodCode=EVN]/subject1[@typeCode=SBJ][1]primaryRole[@classC ode=INVSBJ]/subjectOf2[@typeCode=SBJ][organizer/code/@code=4][@codeSystem=2.16.840.1 113883.3.989.2.1.1.20][1]organizer[@classCode=CATEGORY][@moodCode=EVN]/component[113883.3.989.2.1.1.20][1]organizer[@classCode=CATEGORY][@moodCode=EVN]/component[@typeCode=COMP][substanceAdministration/fk][substanceAdministration/@classCode=SBADM][@moodCode=EVN]/outboundRelationship2[@typeCode=COMP][substanceAdministration]/r/sub stanceAdministration/@classCode=SBADM][@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]/@originalText/text() |

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|---|---|---------------------------------|--------------------------------|--|--|
| e | | | NullFlavor | | <pre> /MCCI_IN200100UV01[@ITSVersion=XMML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UV[controlActProcess[@classCode=CACT]][@moodCo dCode=EVN]/subject/@typeCode=SUBJ[1]/investigationEvent[1][@classCode=INVESTG][@moodCo de=EVN]/component/@typeCode=COMP[1][adverseEventAssessment[1][adverseEventAssessment][@classCode=INVESTG][@moodCode=EVN]/subject1[1][typeCode=SB.J][1]/primaryRole[1][@classC ode=INVSBJ]/subjectO2[1][typeCode=SB.J][organizer/@code=4][@codeSystem=2.16.840.1 13883.3.989.2.1.1.20][1]/organizer/@classCode=CATEGORY[1][@moodCode=EVN]/component [1][@typeCode=EVN]/outboundRelationship2[1][typeCode=COMP][substanceAdministration][r]/sub stanceAdministration[1][@classCode=SBADM][@moodCode=EVN]/inboundRelationship[1][typeCode =REFR][observation/code/@code=28][@codeSystem=2.16.840.1.13883.3.989.2.1.1.19][1]/obse rvation[1][classCode=OBS][1][originalText/@nullFlavor </pre> |
| 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) | 値 codeSystemVersion= Character String (ST) | <pre> /MCCI_IN200100UV01[@ITSVersion=XMML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UV[controlActProcess[@classCode=CACT]][@moodCo dCode=EVN]/subject/@typeCode=SUBJ[1]/investigationEvent[1][adverseEventAssessment][@classCode=INVESTG][@moodCode=EVN]/subject1[1][typeCode=SB.J][1]/primaryRole[1][@classC ode=INVSBJ]/subjectO2[1][typeCode=SB.J][organizer/@code=4][@codeSystem=2.16.840.1 13883.3.989.2.1.1.20][1]/organizer/@classCode=CATEGORY[1][@moodCode=EVN]/component [1][@typeCode=EVN]/outboundRelationship2[1][typeCode=COMP][substanceAdministration][r]/sub stanceAdministration[1][@classCode=SBADM][@moodCode=EVN]/inboundRelationship[1][typeCode =REFR][observation/code/@code=28][@codeSystem=2.16.840.1.13883.3.989.2.1.1.19][1]/obse rvation[1][classCode=OBS][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 (3N) を参 照 | Coded With Equivalents (CE) | 値 code=Character String (ST) | <pre> /MCCI_IN200100UV01[@ITSVersion=XMML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UV[controlActProcess[@classCode=CACT]][@moodCo dCode=EVN]/subject/@typeCode=SUBJ[1]/investigationEvent[1][adverseEventAssessment][@classCode=INVESTG][@moodCode=EVN]/subject1[1][typeCode=SB.J][1]/primaryRole[1][@classC ode=INVSBJ]/subjectO2[1][typeCode=SB.J][organizer/@code=4][@codeSystem=2.16.840.1 13883.3.989.2.1.1.20][1]/organizer/@classCode=CATEGORY[1][@moodCode=EVN]/component [1][@typeCode=EVN]/outboundRelationship2[1][typeCode=COMP][substanceAdministration][r]/sub stanceAdministration[1][@classCode=SBADM][@moodCode=EVN]/inboundRelationship[1][typeCode =REFR][observation/code/@code=28][@codeSystem=2.16.840.1.13883.3.989.2.1.1.19][1]/obse rvation[1][classCode=OBS][1][value/@xsi:type=CE][@codeSystem=2.16.840.1 13883.3.989.2.1.1.14][1]/@code </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) | 値 value=Real Number (REAL) | <pre> /MCCI_IN200100UV01[@ITSVersion=XMML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UV[controlActProcess[@classCode=CACT]][@moodCo dCode=EVN]/subject/@typeCode=SUBJ[1]/investigationEvent[1][adverseEventAssessment][@classCode=INVESTG][@moodCode=EVN]/component/@typeCode=COMP[1][adverseEventAssessment][@classCode=INVESTG][@moodCode=EVN]/subject1[1][typeCode=SB.J][1]/primaryRole[1][@classC ode=INVSBJ]/subjectO2[1][typeCode=SB.J][organizer/@code=4][@codeSystem=2.16.840.1 13883.3.989.2.1.1.20][1]/organizer/@classCode=CATEGORY[1][@moodCode=EVN]/component[1][@typeCode=EVN]/outboundRelationship2[1][typeCode=COMP][substanceAdministration][r]/sub stanceAdministration[1][@classCode=SBADM][@moodCode=EVN]/inboundRelationship[1][typeCode =REFR][observation/code/@code=28][@codeSystem=2.16.840.1.13883.3.989.2.1.1.19][1]/obse rvation[1][classCode=OBS][1][value/@xsi:type=CE][@codeSystem=2.16.840.1 13883.3.989.2.1.1.14][1]/@code </pre> |

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|---|---------|-------------------------|------|------------------------|------------------------------|--|
| e | G.k.5b | 副作用／有害事象発現までの累積総投与量（単位） | 50AN | Physical Quantity (PQ) | unit=Coded Simple Value (CS) | 値 /MCC1_IN200100UV01[@ITSVersion="XML_1.0"]/@xsi:schemaLocation="urn:hl7-org:v3 MCC1_IN200100UV01.xsd"/PORR_IN049016UV/[]/controlActProcess[@classCode="CACT"]/@moodCode="EVN"/subject[@typeCode="SUBJ"]/[]/investigationEvent1[@classCode="INVESTG"]/@moodCode="EVN"/component[@typeCode="COMP"]/[]/adverseEventAssessment1[1]/adverseEventAssessment[@classCode="INVESTG"]/@moodCode="EVN"/subject1[@typeCode="SB"]/[]/primaryRole/@classCode="INVSBJ"/subjectOf2[@typeCode="SB"]/organizer/@code="4"/[]/@codeSystem="2.16.840.1.113883.3.989.2.1.1.20"/[]/organizer/@classCode="CATEGORY"/[]/@moodCode="EVN"/component1/@typeCode="COMP"/[]/substanceAdministration1/@classCode="SBADM"/[]/@moodCode="EVN"/outboundRelationship2/@typeCode="SUMM"/[]/observation/@code="14"/[]/@codeSystem="2.16.840.1.113883.3.989.2.1.1.19"/[]/observation/@classCode="OBS"/[]/@moodCode="EVN"/value/@xsi:type="PQ"/[]/@unit |
| 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_IN049016UV/[]/controlActProcess[@classCode="CACT"]/@moodCode="EVN"/subject[@typeCode="SUBJ"]/[]/investigationEvent1[@classCode="INVESTG"]/@moodCode="EVN"/component[@typeCode="COMP"]/[]/adverseEventAssessment1[1]/adverseEventAssessment[@classCode="INVESTG"]/@moodCode="EVN"/subject1[@typeCode="SB"]/[]/primaryRole/@classCode="INVSBJ"/subjectOf2[@typeCode="SB"]/organizer/@code="4"/[]/@codeSystem="2.16.840.1.113883.3.989.2.1.1.20"/[]/organizer/@classCode="CATEGORY"/[]/@moodCode="EVN"/component1/@typeCode="COMP"/[]/substanceAdministration1/@classCode="SBADM"/[]/@moodCode="EVN"/outboundRelationship2/@typeCode="PERT"/[]/observation/@code="16"/[]/@codeSystem="2.16.840.1.113883.3.989.2.1.1.19"/[]/observation/@classCode="OBS"/[]/@moodCode="EVN"/value/@xsi:type="PQ"/[]/@unit |
| 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_IN049016UV/[]/controlActProcess[@classCode="CACT"]/@moodCode="EVN"/subject[@typeCode="SUBJ"]/[]/investigationEvent1[@classCode="INVESTG"]/@moodCode="EVN"/component[@typeCode="COMP"]/[]/adverseEventAssessment1[1]/adverseEventAssessment[@classCode="INVESTG"]/@moodCode="EVN"/subject1[@typeCode="SB"]/[]/primaryRole/@classCode="INVSBJ"/subjectOf2[@typeCode="SB"]/organizer/@code="4"/[]/@codeSystem="2.16.840.1.113883.3.989.2.1.1.20"/[]/organizer/@classCode="CATEGORY"/[]/@moodCode="EVN"/component1/@typeCode="COMP"/[]/substanceAdministration1/@classCode="SBADM"/[]/@moodCode="EVN"/outboundRelationship2/@typeCode="PERT"/[]/observation/@code="16"/[]/@codeSystem="2.16.840.1.113883.3.989.2.1.1.19"/[]/observation/@classCode="OBS"/[]/@moodCode="EVN"/value/@xsi:type="PQ"/[]/@unit |
| 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_IN049016UV/[]/controlActProcess[@classCode="CACT"]/@moodCode="EVN"/subject[@typeCode="SUBJ"]/[]/investigationEvent1[@classCode="INVESTG"]/@moodCode="EVN"/component[@typeCode="COMP"]/[]/adverseEventAssessment1[1]/adverseEventAssessment[@classCode="INVESTG"]/@moodCode="EVN"/subject1[@typeCode="SB"]/[]/primaryRole/@classCode="INVSBJ"/subjectOf2[@typeCode="SB"]/organizer/@code="4"/[]/@codeSystem="2.16.840.1.113883.3.989.2.1.1.20"/[]/organizer/@classCode="CATEGORY"/[]/@moodCode="EVN"/component1/@typeCode="COMP"/[]/substanceAdministration1/@classCode="SBADM"/[]/@moodCode="EVN"/inboundRelationship1/@typeCode="RSON"/[]/observation/@code="19"/[]/@codeSystem="2.16.840.1.113883.3.989.2.1.1.19"/[] |

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|--|-------------------|------------------------------------|---|--|
| <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> <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=INVTG][@moodCode=EVN]/component[@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment[@classCode=INVSBJ][@moodCode=EVN]/subject[1]/typeCode=SBJ][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]/moodCode=COMP][substanceAdministration/dj[k]/substanceAdministration[@classCode=SBADM][@typeCode=EVN]/inboundRelationship[@typeCode=RSON][observation/@code=19][@codeSystem=2.16.840.1.113883.3.989.2.1.1.19][1]/observation/@classCode=OBS][@moodCode=EVN][performer[@typeCode=PRF]/assignedEntity[@classCode=ASSIGNED][code=3][@codeSystem=2.16.840.1.113883.3.989.2.1.1.21][1]/value[@xsi:type=CE][@codeSystem=2.16.840.1.113883.6.163][1]/originalText/text()</p> |
| <p>e</p> | <p>NullFlavor</p> | <p>NullFlavor</p> | <p>NullFlavor</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=INVTG][@moodCode=EVN]/component[@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment[@classCode=INVSBJ][@moodCode=EVN]/subject[1]/typeCode=SBJ][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]/moodCode=COMP][substanceAdministration/dj[k]/substanceAdministration[@classCode=SBADM][@typeCode=EVN]/inboundRelationship[@typeCode=RSON][observation/@code=19][@codeSystem=2.16.840.1.113883.3.989.2.1.1.19][1]/observation/@classCode=OBS][@moodCode=EVN][performer[@typeCode=PRF]/assignedEntity[@classCode=ASSIGNED][code=3][@codeSystem=2.16.840.1.113883.3.989.2.1.1.21][1]/value[@xsi:type=CE][@codeSystem=2.16.840.1.113883.6.163][1]/originalText/@nullFlavor</p> |
| <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> <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=INVTG][@moodCode=EVN]/component[@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment[@classCode=INVSBJ][@moodCode=EVN]/subject[1]/typeCode=SBJ][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]/moodCode=COMP][substanceAdministration/dj[k]/substanceAdministration[@classCode=SBADM][@typeCode=EVN]/inboundRelationship[@typeCode=RSON][observation/@code=19][@codeSystem=2.16.840.1.113883.3.989.2.1.1.19][1]/observation/@classCode=OBS][@moodCode=EVN][performer[@typeCode=PRF]/assignedEntity[@classCode=ASSIGNED][code=3][@codeSystem=2.16.840.1.113883.3.989.2.1.1.21][1]/value[@xsi:type=CE][@codeSystem=2.16.840.1.113883.6.163][1]/originalText/@nullFlavor</p> |

(別添 3)

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|---|-------------|--|-----|-----------------------------|----------------------------|---|--|
| e | G.k.7.r.2b | 使用理由 (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]/PDRR_IN049016UVJ/controlActProcess[@classCode=CACT][@moo dCode=EVN]/subject[@typeCode=SUBJ][@investigationEvent][@classCode=INVTG][@moodCo de=EVN]/component[@typeCode=COMP][@adverseEventAssessment][@adverseEventAssessment [@classCode=INVTG][@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][@substanceAdministration/@classCode=SBADM][@moodCode=EVN]/inboundRelationship[@typeCode=RSO][@observation/@code=19][@c odeSystem=2.16.840.1.13883.3.989.2.1.1.19][@observation/@classCode=OBS][@moodCode= EVN]/performer[@typeCode=PRF][assignedEntity/@classCode=ASSIGNED][code/@code=3][@c odeSystem=2.16.840.1.13883.3.989.2.1.1.21][1][value/@xsi:type=CE][@codeSystem=2.16.840. 1.13883.3.989.2.1.1.15][1][code /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/PDRR_IN049016UVJ/controlActProcess[@classCode=CACT][@moo dCode=EVN]/subject[@typeCode=SUBJ][@investigationEvent][@classCode=INVTG][@moodCo de=EVN]/component[@typeCode=COMP][@adverseEventAssessment][@adverseEventAssessment [@classCode=INVTG][@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][@substanceAdministration/@classCode=SBADM][@moodCode=EVN]/inboundRelationship[@typeCode=CAUS][@act/code[@codeSystem=2.16.840 1.13883.3.989.2.1.1.15][1][act/@classCode=ACT][@moodCode=EVN]/code/@codeSystem=2. 16.840.1.13883.3.989.2.1.1.15][1][code /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/PDRR_IN049016UVJ/controlActProcess[@classCode=CACT][@moo dCode=EVN]/subject[@typeCode=SUBJ][@investigationEvent][@classCode=INVTG][@moodCo de=EVN]/component[@typeCode=COMP][@adverseEventAssessment][@adverseEventAssessment [@classCode=INVTG][@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][@substanceAdministration/@classCode=SBADM][@moodCode=EVN]/inboundRelationship[@typeCode=ACT][@moodCode=EVN]/code/@codeSystem=2. 16.840.1.13883.3.989.2.1.1.15][1][code /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/PDRR_IN049016UVJ/controlActProcess[@classCode=CACT][@moo dCode=EVN]/subject[@typeCode=SUBJ][@investigationEvent][@classCode=INVTG][@moodCo de=EVN]/component[@typeCode=COMP][@adverseEventAssessment][@adverseEventAssessment [@classCode=INVTG][@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][@substanceAdministration/@classCode=SBADM][@moodCode=EVN]/inboundRelationship[@typeCode=CAUS][@act/code/@codeSystem=2.16.840 1.13883.3.989.2.1.1.15][1][act/@classCode=ACT][@moodCode=EVN]/code/@codeSystem=2. 16.840.1.13883.3.989.2.1.1.15][1][code </pre> |
| e | G.k.8 | 医薬品に対して取られた処 置 | 1N | Concept Descriptor (CD) | code=Character String (ST) | 値 | |
| h | G.k.9.i | 医薬品に対して取られた処 置に関する ICH コードリス トのバージョン | | | | | |
| e | G.k.9.i.1 | 医薬品と副作用／有害事象 のマトリックス (必要に応じ 繰り返し返す) | N/A | | | 値 | <pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/PDRR_IN049016UVJ/controlActProcess[@classCode=CACT][@moo dCode=EVN]/subject[@typeCode=SUBJ][@investigationEvent][@classCode=INVTG][@moodCo de=EVN]/component[@typeCode=COMP][@adverseEventAssessment][@adverseEventAssessment [@classCode=INVTG][@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][@substanceAdministration/@classCode=SBADM][@moodCode=EVN]/inboundRelationship[@typeCode=ACT][@moodCode=EVN]/code/@codeSystem=2. 16.840.1.13883.3.989.2.1.1.15][1][code </pre> |
| h | G.k.9.i.2.r | 医薬品と副作用／有害事象 の因果関係 (必要に応じ繰り 返し返す) | | | | 値 | <pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/PDRR_IN049016UVJ/controlActProcess[@classCode=CACT][@moo dCode=EVN]/subject[@typeCode=SUBJ][@investigationEvent][@classCode=INVTG][@moodCo de=EVN]/component[@typeCode=COMP][@adverseEventAssessment][@adverseEventAssessment [@classCode=INVTG][@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][@substanceAdministration/@classCode=SBADM][@moodCode=EVN]/inboundRelationship[@typeCode=OBS][@moodCode=EVN]/code/@codeSystem=2. 16.840.1.13883.3.989.2.1.1.15][1][act/@classCode=ACT][@moodCode=EVN]/code/@codeSystem=2. 16.840.1.13883.3.989.2.1.1.15][1][code </pre> |

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|----------|----------------------|--|-------------|------------------------------------|--|----------|--|
| <p>e</p> | <p>G.k.9.i.2.r.1</p> | <p>評価の情報源</p> | <p>60AN</p> | <p>Coded With Equivalents (CE)</p> | <p>originalText=Encapsulated Data (ED)</p> | <p>値</p> | <pre> /MCCI_IN200100UV01[@ITSVersion=XMML_1.0' MCCI_IN200100UV01.xsd/PORR_IN049076UV/r/controlAcProcess[@classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUBJ][1]/investigationEvent[@classCode=INVTG][@moodCode=EVN]/component[@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessmentn/code[@code=39][@codeSystem=2.16.840.1.113883.3.989.2.1.1.19][r/causalityAssessment/@classCode=OBS][@moodCode=EVN][subject1[@typeCode=SUBJ]/adverseEffectReference[@classCode=OBS][@moodCode=EVN]/rd[@root=UJID of i-th reaction][subject2[@typeCode=SUBJ]/productUseReference[@classCode=SBADM][@moodCode=EVN]/rd[@root=UJID of k-th drug]/author[@typeCode=AUT][1]/assignedEntity[@classCode=ASSIGNED]/code/originalText/text() </pre> |
| <p>e</p> | <p>G.k.9.i.2.r.2</p> | <p>評価方法</p> | <p>60AN</p> | <p>Coded With Equivalents (CE)</p> | <p>originalText=Encapsulated Data (ED)</p> | <p>値</p> | <pre> /MCCI_IN200100UV01[@ITSVersion=XMML_1.0' MCCI_IN200100UV01.xsd/PORR_IN049076UV/r/controlAcProcess[@classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUBJ][1]/investigationEvent[@classCode=INVTG][@moodCode=EVN]/component[@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessmentn/code[@code=39][@codeSystem=2.16.840.1.113883.3.989.2.1.1.19][r/causalityAssessment/@classCode=OBS][@moodCode=EVN][subject1[@typeCode=SUBJ]/adverseEffectReference[@classCode=OBS][@moodCode=EVN]/rd[@root=UJID of i-th reaction][subject2[@typeCode=SUBJ]/productUseReference[@classCode=SBADM][@moodCode=EVN]/rd[@root=UJID of k-th drug]/methodCode[1]/originalText/text() </pre> |
| <p>e</p> | <p>G.k.9.i.2.r.3</p> | <p>評価結果</p> | <p>60AN</p> | <p>Character String (ST)</p> | <p>value=Real Number (REAL)</p> | <p>値</p> | <pre> /MCCI_IN200100UV01[@ITSVersion=XMML_1.0' MCCI_IN200100UV01.xsd/PORR_IN049076UV/r/controlAcProcess[@classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUBJ][1]/investigationEvent[@classCode=INVTG][@moodCode=EVN]/component[@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessmentn/code[@code=39][@codeSystem=2.16.840.1.113883.3.989.2.1.1.19][r/causalityAssessment/@classCode=OBS][@moodCode=EVN][subject1[@typeCode=SUBJ]/adverseEffectReference[@classCode=OBS][@moodCode=EVN]/rd[@root=UJID of i-th reaction][subject2[@typeCode=SUBJ]/productUseReference[@classCode=SBADM][@moodCode=EVN]/rd[@root=UJID of k-th drug]/value[@xsi:type=ST]/text() </pre> |
| <p>e</p> | <p>G.k.9.i.3.1a</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 (数)</p> | <p>5N</p> | <p>Physical Quantity (PQ)</p> | <p>value=Real Number (REAL)</p> | <p>値</p> | <pre> /MCCI_IN200100UV01[@ITSVersion=XMML_1.0' MCCI_IN200100UV01.xsd/PORR_IN049076UV/r/controlAcProcess[@classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUBJ][1]/investigationEvent[@classCode=INVTG][@moodCode=EVN]/component[@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessmentn/code[@code=4][@codeSystem=2.16.840.1.113883.3.989.2.1.1.20][r/component/@typeCode=INVSBJ]/subjectOr2[@typeCode=SBJ]/organizer[@classCode=CATEGORY][@moodCode=EVN][code[@code=4][@codeSystem=2.16.840.1.113883.3.989.2.1.1.20][r/component/@typeCode=COMP][substanceAdministration[k]/substanceAdministration[@classCode=SBADM][@moodCode=EVN]/outboundRelationship[1[@typeCode=SA][actReference[@classCode=OBS][@moodCode=EVN]/rd[@root=UJID of i-th reaction]]/pauseQuantity/@value </pre> |

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|---|--------------|---------------------------------|------|-----------------------------|------------------------------|---|
| e | G.k.9.i.3.1b | 医薬品の投与開始から副作用/有害事象発現までの時間間隔(単位) | 50AN | Physical Quantity (PQ) | unit=Coded Simple Value (CS) | <pre> /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UV1/controlActProcess[@classCode=CACT][@moo dCode=EVN]/subject/@typeCode=SUBJ[1]/investigationEvent[@classCode=INVTG][@moodCo de=EVN]/component/@typeCode=COMP[1]/adverseEventAssessment[1]/adverseEventAssessme nt[@classCode=INVTG][@moodCode=EVN]/subject1/@typeCode=SBJ[1]/primaryRole/@classC ode=INVSBJ[1]/subjectOf2/@typeCode=SBJ[1]/organizer/@classCode=CATEGORY[1]/moodCode= EVN][code=4][@codeSystem=2.16.840.1.113883.3.989.2.1.1.20][1]/component/@typeCo de=COMP[1]/substanceAdministration/dj[k]/substanceAdministration[@classCode=SBADM][@moo dCode=EVN]/outboundRelationship1/@typeCode=SAE[1]/actReference[@classCode=OBS][@moo dCode=EVN]/id[@root=UUIID of i-th reaction]/pauseQuantity/@unit </pre> |
| e | G.k.9.i.3.2a | 医薬品の最終投与から副作用/有害事象発現までの時間間隔(数) | 5N | Physical Quantity (PQ) | value=Real Number (REAL) | <pre> /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UV1/controlActProcess[@classCode=CACT][@moo dCode=EVN]/subject/@typeCode=SUBJ[1]/investigationEvent[@classCode=INVTG][@moodCo de=EVN]/component/@typeCode=COMP[1]/adverseEventAssessment[1]/adverseEventAssessme nt[@classCode=INVTG][@moodCode=EVN]/subject1/@typeCode=SBJ[1]/primaryRole/@classC ode=INVSBJ[1]/subjectOf2/@typeCode=SBJ[1]/organizer/@classCode=CATEGORY[1]/moodCode= EVN][code=4][@codeSystem=2.16.840.1.113883.3.989.2.1.1.20][1]/component/@typeCo de=COMP[1]/substanceAdministration/dj[k]/substanceAdministration[@classCode=SBADM][@moo dCode=EVN]/outboundRelationship1/@typeCode=SAE[1]/actReference[@classCode=OBS][@moo dCode=EVN]/id[@root=UUIID of i-th reaction]/pauseQuantity/@value </pre> |
| e | G.k.9.i.3.2b | 医薬品の最終投与から副作用/有害事象発現までの時間間隔(単位) | 50AN | Physical Quantity (PQ) | unit=Coded Simple Value (CS) | <pre> /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UV1/controlActProcess[@classCode=CACT][@moo dCode=EVN]/subject/@typeCode=SUBJ[1]/investigationEvent[@classCode=INVTG][@moodCo de=EVN]/component/@typeCode=COMP[1]/adverseEventAssessment[1]/adverseEventAssessme nt[@classCode=INVTG][@moodCode=EVN]/subject1/@typeCode=SBJ[1]/primaryRole/@classC ode=INVSBJ[1]/subjectOf2/@typeCode=SBJ[1]/organizer/@classCode=CATEGORY[1]/moodCode= EVN][code=4][@codeSystem=2.16.840.1.113883.3.989.2.1.1.20][1]/component/@typeCo de=COMP[1]/substanceAdministration/dj[k]/substanceAdministration[@classCode=SBADM][@moo dCode=EVN]/outboundRelationship1/@typeCode=SAE[1]/actReference[@classCode=OBS][@moo dCode=EVN]/id[@root=UUIID of i-th reaction]/pauseQuantity/@unit </pre> |
| e | G.k.9.i.4 | 再投与で副作用は再発したか? | 1N | Coded With Equivalents (CE) | code=Character String (ST) | <pre> /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UV1/controlActProcess[@classCode=CACT][@moo dCode=EVN]/subject/@typeCode=SUBJ[1]/investigationEvent[@classCode=INVTG][@moodCo de=EVN]/component/@typeCode=COMP[1]/adverseEventAssessment[1]/adverseEventAssessme nt[@classCode=INVTG][@moodCode=EVN]/subject1/@typeCode=SBJ[1]/primaryRole/@classC ode=INVSBJ[1]/subjectOf2/@typeCode=SBJ[1]/organizer/@classCode=CATEGORY[1]/moodCode= EVN][code=4][@codeSystem=2.16.840.1.113883.3.989.2.1.1.20][1]/component/@typeCo de=COMP[1]/substanceAdministration/dj[k]/substanceAdministration[@classCode=SBADM][@moo dCode=EVN]/outboundRelationship2/@typeCode=PERT[1]/observation/code[@code=3][1]/codeSy stem=2.16.840.1.113883.3.989.2.1.1.19][1]/observation[@classCode=OBS][@moodCode=EVN]/id boundRelationship1/@typeCode=REFR[1]/actReference[@classCode=OBS][@moodCode=EVN]/id of i-th reaction][value[@xsi:type=CE][@codeSystem=2.16.840.1.113883.3.989.2.1.1.16][1][@code </pre> |

(別添3)

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|--|--|--|-----------------------------------|----------|---|------------------------------------|----|-----------------------------|----------------------------|---|---|
| | | | 再投与で副作用は再発したか？に関するICHコードリストのバージョン | G.k.10.r | e | 医薬品に関するその他の情報 (コード化) (必要に応じ繰り返し返す) | 2N | Coded With Equivalents (CE) | code=Character String (ST) | 値 | <pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 dCode=EVN]/subject[@typeCode=SUBJ][!investigationEvent/@classCode=INVTG][!moodCo de=EVN]/component[@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment [@classCode=INVTG][!moodCode=EVN]/subject[@typeCode=SBJ][!primaryRole/@classCo de=INVTG][!subjectOf2/@typeCode=SBJ][organizer/@classCode=CATEGORY][!moodCode= EVN][code/@code=4][!@codeSystem=2,16,840,1,113883,3,989,2,1,1,20][!component/@typeCo de=COMP][substanceAdministration[id][k]/substanceAdministration/@classCode=SBADM][!moo dCode=EVN]/outboundRelationship2[@typeCode=PERT][observation/@code=@code=3][!@codeSy stem=2,16,840,1,113883,3,989,2,1,1,19][observation/@classCode=OBS][!@moodCode=EVN][ou tboundRelationship[1/@typeCode=REFR][actReference/@classCode=OBS][!@moodCode=EVN][i d/@root=UUID of reaction]]/value[!@xsi:type=CE][!@codeSystem=2,16,840,1,113883,3,989,2,1,1,16][!@codeSystem nVersion /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 dCode=EVN]/subject[@typeCode=SUBJ][!investigationEvent/@classCode=INVTG][!moodCo de=EVN]/component[@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment [@classCode=INVTG][!moodCode=EVN]/subject[@typeCode=SBJ][!primaryRole/@classCo de=INVTG][!subjectOf2/@typeCode=SBJ][organizer/@classCode=CATEGORY][!moodCode= EVN][code/@code=4][!@codeSystem=2,16,840,1,113883,3,989,2,1,1,20][!component/@typeCo de=COMP][substanceAdministration[id][k]/substanceAdministration/@classCode=SBADM][!@moodCode=EVN]/outboundRelationship2[@typeCode=REFR][observation/@code=@code=9][!@ codeSystem=2,16,840,1,113883,3,989,2,1,1,19][!@codeSystem=2,16,840,1,113883,3,989,2,1,1,17][!@code EVN]/value[!@xsi:type=CE][!@codeSystem=2,16,840,1,113883,3,989,2,1,1,17][!@code /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 dCode=EVN]/subject[@typeCode=SUBJ][!investigationEvent/@classCode=INVTG][!moodCo de=EVN]/component[@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment [@classCode=INVTG][!moodCode=EVN]/subject[@typeCode=SBJ][!primaryRole/@classCo de=INVTG][!subjectOf2/@typeCode=SBJ][organizer/@classCode=CATEGORY][!moodCode= EVN][code/@code=4][!@codeSystem=2,16,840,1,113883,3,989,2,1,1,20][!component/@typeCo de=COMP][substanceAdministration[id][k]/substanceAdministration/@classCode=SBADM][!@moodCode=EVN]/outboundRelationship2[@typeCode=REFR][observation/@code=@code=9][!@ codeSystem=2,16,840,1,113883,3,989,2,1,1,19][!@codeSystem=2,16,840,1,113883,3,989,2,1,1,17][!@code EVN]/value[!@xsi:type=CE][!@codeSystem=2,16,840,1,113883,3,989,2,1,1,17][!@code /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 dCode=EVN]/subject[@typeCode=SUBJ][!investigationEvent/@classCode=INVTG][!moodCo de=EVN]/component[@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment [@classCode=INVTG][!moodCode=EVN]/subject[@typeCode=SBJ][!primaryRole/@classCo de=INVTG][!subjectOf2/@typeCode=SBJ][organizer/@classCode=CATEGORY][!moodCode= EVN][code/@code=4][!@codeSystem=2,16,840,1,113883,3,989,2,1,1,20][!component/@typeCo de=COMP][substanceAdministration[id][k]/substanceAdministration/@classCode=SBADM][!@moodCode=EVN]/outboundRelationship2[@typeCode=REFR][observation/@code=@code=9][!@ codeSystem=2,16,840,1,113883,3,989,2,1,1,19][!@codeSystem=2,16,840,1,113883,3,989,2,1,1,17][!@code EVN]/value[!@xsi:type=CE][!@codeSystem=2,16,840,1,113883,3,989,2,1,1,17][!@code </pre> |
| | | | 再投与で副作用は再発したか？に関するICHコードリストのバージョン | G.k.10.r | e | 医薬品に関するその他の情報 (コード化) (必要に応じ繰り返し返す) | 2N | Coded With Equivalents (CE) | code=Character String (ST) | 値 | <pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 dCode=EVN]/subject[@typeCode=SUBJ][!investigationEvent/@classCode=INVTG][!moodCo de=EVN]/component[@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment [@classCode=INVTG][!moodCode=EVN]/subject[@typeCode=SBJ][!primaryRole/@classCo de=INVTG][!subjectOf2/@typeCode=SBJ][organizer/@classCode=CATEGORY][!moodCode= EVN][code/@code=4][!@codeSystem=2,16,840,1,113883,3,989,2,1,1,20][!component/@typeCo de=COMP][substanceAdministration[id][k]/substanceAdministration/@classCode=SBADM][!@moodCode=EVN]/outboundRelationship2[@typeCode=REFR][observation/@code=@code=9][!@ codeSystem=2,16,840,1,113883,3,989,2,1,1,19][!@codeSystem=2,16,840,1,113883,3,989,2,1,1,17][!@code EVN]/value[!@xsi:type=CE][!@codeSystem=2,16,840,1,113883,3,989,2,1,1,17][!@code /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 dCode=EVN]/subject[@typeCode=SUBJ][!investigationEvent/@classCode=INVTG][!moodCo de=EVN]/component[@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment [@classCode=INVTG][!moodCode=EVN]/subject[@typeCode=SBJ][!primaryRole/@classCo de=INVTG][!subjectOf2/@typeCode=SBJ][organizer/@classCode=CATEGORY][!moodCode= EVN][code/@code=4][!@codeSystem=2,16,840,1,113883,3,989,2,1,1,20][!component/@typeCo de=COMP][substanceAdministration[id][k]/substanceAdministration/@classCode=SBADM][!@moodCode=EVN]/outboundRelationship2[@typeCode=REFR][observation/@code=@code=9][!@ codeSystem=2,16,840,1,113883,3,989,2,1,1,19][!@codeSystem=2,16,840,1,113883,3,989,2,1,1,17][!@code EVN]/value[!@xsi:type=CE][!@codeSystem=2,16,840,1,113883,3,989,2,1,1,17][!@code /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 dCode=EVN]/subject[@typeCode=SUBJ][!investigationEvent/@classCode=INVTG][!moodCo de=EVN]/component[@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment [@classCode=INVTG][!moodCode=EVN]/subject[@typeCode=SBJ][!primaryRole/@classCo de=INVTG][!subjectOf2/@typeCode=SBJ][organizer/@classCode=CATEGORY][!moodCode= EVN][code/@code=4][!@codeSystem=2,16,840,1,113883,3,989,2,1,1,20][!component/@typeCo de=COMP][substanceAdministration[id][k]/substanceAdministration/@classCode=SBADM][!@moodCode=EVN]/outboundRelationship2[@typeCode=REFR][observation/@code=@code=9][!@ codeSystem=2,16,840,1,113883,3,989,2,1,1,19][!@codeSystem=2,16,840,1,113883,3,989,2,1,1,17][!@code EVN]/value[!@xsi:type=CE][!@codeSystem=2,16,840,1,113883,3,989,2,1,1,17][!@code </pre> |
| | | | 再投与で副作用は再発したか？に関するICHコードリストのバージョン | G.k.10.r | e | 医薬品に関するその他の情報 (コード化) (必要に応じ繰り返し返す) | 2N | Coded With Equivalents (CE) | code=Character String (ST) | 値 | <pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 dCode=EVN]/subject[@typeCode=SUBJ][!investigationEvent/@classCode=INVTG][!moodCo de=EVN]/component[@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment [@classCode=INVTG][!moodCode=EVN]/subject[@typeCode=SBJ][!primaryRole/@classCo de=INVTG][!subjectOf2/@typeCode=SBJ][organizer/@classCode=CATEGORY][!moodCode= EVN][code/@code=4][!@codeSystem=2,16,840,1,113883,3,989,2,1,1,20][!component/@typeCo de=COMP][substanceAdministration[id][k]/substanceAdministration/@classCode=SBADM][!@moodCode=EVN]/outboundRelationship2[@typeCode=REFR][observation/@code=@code=9][!@ codeSystem=2,16,840,1,113883,3,989,2,1,1,19][!@codeSystem=2,16,840,1,113883,3,989,2,1,1,17][!@code EVN]/value[!@xsi:type=CE][!@codeSystem=2,16,840,1,113883,3,989,2,1,1,17][!@code /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 dCode=EVN]/subject[@typeCode=SUBJ][!investigationEvent/@classCode=INVTG][!moodCo de=EVN]/component[@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment [@classCode=INVTG][!moodCode=EVN]/subject[@typeCode=SBJ][!primaryRole/@classCo de=INVTG][!subjectOf2/@typeCode=SBJ][organizer/@classCode=CATEGORY][!moodCode= EVN][code/@code=4][!@codeSystem=2,16,840,1,113883,3,989,2,1,1,20][!component/@typeCo de=COMP][substanceAdministration[id][k]/substanceAdministration/@classCode=SBADM][!@moodCode=EVN]/outboundRelationship2[@typeCode=REFR][observation/@code=@code=9][!@ codeSystem=2,16,840,1,113883,3,989,2,1,1,19][!@codeSystem=2,16,840,1,113883,3,989,2,1,1,17][!@code EVN]/value[!@xsi:type=CE][!@codeSystem=2,16,840,1,113883,3,989,2,1,1,17][!@code </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 | <pre> /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UV[controlActProcess/@classCode=CACT][@moo dCode=EVN]/subject/@typeCode=SUBJ[adverseEventAssessment[1]/adverseEventAssessment de=EVN]/component/@typeCode=COMP[adverseEventAssessment[1]/adverseEventAssessment [@classCode=INVTG][@moodCode=EVN]/subject/@typeCode=SBJ[primaryRole/@classC ode=INVSBJ/subjectOf/@typeCode=SBJ][organizer/@code=4][@codeSystem=2.16.840.1 113883.3.989.2.1.1.19][1][organizer/@classCode=CATEGORY][@moodCode=EVN]/component[@typeCode=COMP][substanceAdministration[k]/substanceAdministration/@classCode=SBADM][@moodCode=EVN]/outboundRelationship2/@typeCode=REFR[observation/@code=2][@ codeSystem=2.16.840.1.113883.3.989.2.1.1.19][1][observation/@classCode=OBS][@moodCode =EVN]/value[@xsi:type=ST][1]/text() </pre> |
| h | H | 症例概要及びその他の情報の記述 | | | | |
| e | H.1 | 臨床経過、治療処置、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 | <pre> /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UV[controlActProcess/@classCode=CACT][@moo dCode=EVN]/subject/@typeCode=SUBJ[1]/investigationEvent/@classCode=CACT][@moodCo de=EVN]/text() </pre> |
| e | H.2 | 報告者の意見 | 20000AN | Encapsulated Data (ED) | 値 | <pre> /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UV[controlActProcess/@classCode=CACT][@moo dCode=EVN]/component/@typeCode=COMP[adverseEventAssessment[1]/adverseEventAssessment [@classCode=INVTG][@moodCode=EVN]/component1/@typeCode=COMP[observationEvent[code/@code=10][@codeSystem=2.16.840.1.113883.3.989.2.1.1.19][author/@typeCode=AUT][as signedEntity/@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 () </pre> |
| 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 | <pre> /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UV[controlActProcess/@classCode=CACT][@moo dCode=EVN]/component/@typeCode=COMP[adverseEventAssessment[1]/adverseEventAssessment [@classCode=INVTG][@moodCode=EVN]/component1/@typeCode=COMP[observationEvent[code/@code=15][@codeSystem=2.16.840.1.113883.3.989.2.1.1.19][author/@typeCode=AUT][as signedEntity/@classCode=ASSIGNED]/code/@code=1][@codeSystem=2.16.840.1.113883.3.989. 2.1.1.21][1] </pre> |
| e | H.3.r.1a | 送信者による診断名 / 症候群及び / 又は副作用 / 有害事象の再分類の MedDRAバージョン | 4AN | Coded With Equivalents (CE) | 値 | <pre> /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PORR_IN049016UV[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]/component1/@typeCode=COMP[observationEvent[code/@code=15][@codeSystem=2.16.840.1.113883.3.989.2.1.1.19][author/@typeCode=AUT][as signedEntity/@classCode=ASSIGNED]/code/@code=1][@codeSystem=2.16.840.1.113883.3.989. 2.1.1.21][1][observationEvent/@classCode=OBS][@moodCode=EVN]/value[@xsi:type=CE][@c odeSystem=2.16.840.1.113883.6.163][codeSystemVersion </pre> |

| | | | | | | | |
|---|----------|--|----------|--------------------------------|-------------------------------------|-------------|---|
| e | H.3.r.1b | 送信者による診断名/症状 群及び/又は副作用/有害 事象の再分類(MedDRA コー ド) | 8N | Coded With Equivalents (CE) | code=Character String (ST) | 値 | /MCCI_IN200100UV01[(@ITSVersion=XMML_1.0)]/@xsi:schemaLocation=urn:h17-org:v3 MCCI_IN200100UV01.xsd/PORR_IN049016UV[/(controlActProcess/@classCode=CACT)]/@moodCo de=EVN[/subject/@typeCode=SUBJ]]/investigationEvent[(@classCode=INVTG)]/@moodCo de=EVN[/component/@typeCode=COMP]/adverseEventAssessment[1]/adverseEventAssessment [1]/classCode=INVTG[@typeCode=EVN]/component1[1]/typeCode=COMP]/observationEvent[code/@code=15]]/@codeSystem=2.16.840.1.113883.3.989.2.1.1.19]]/author[(@typeCode=AUT)]/as signedEntity[(@classCode=ASSIGNED)]/@code/@code=1]]/@codeSystem=2.16.840.1.113883.3.989. 2.1.1.21]]]]/observationEvent[(@classCode=OBS)]/@moodCode=EVN]/value[(@xsi:type=CE)]/@c odeSystem=2.16.840.1.113883.3.989.2.1.1.19]]/code |
| e | H.4 | 送信者の意見 | 20000AN | Encapsulated Data (ED) | | 値 | /MCCI_IN200100UV01[(@ITSVersion=XMML_1.0)]/@xsi:schemaLocation=urn:h17-org:v3 MCCI_IN200100UV01.xsd/PORR_IN049016UV[/(controlActProcess/@classCode=CACT)]/@moodCo de=EVN[/subject/@typeCode=SUBJ]]/investigationEvent[(@classCode=INVTG)]/@moodCo de=EVN[/component/@typeCode=COMP]/adverseEventAssessment[1]/adverseEventAssessment [1]/classCode=INVTG[@typeCode=EVN]/component1[1]/typeCode=COMP]/observationEvent[code/@code=10]]/@codeSystem=2.16.840.1.113883.3.989.2.1.1.19]]/author[(@typeCode=AUT)]/as signedEntity[(@classCode=ASSIGNED)]/@code/@code=1]]/@codeSystem=2.16.840.1.113883.3.989. 2.1.1.21]]]]/observationEvent[(@classCode=OBS)]/@moodCode=EVN]/value[(@xsi:type=ED)]/text 0 |
| h | H.5.r | 母国語で記載された症例概 要及び報告者の意見 (必要に 応じ繰り返す) | | | | 繰り返す コード | /MCCI_IN200100UV01[(@ITSVersion=XMML_1.0)]/@xsi:schemaLocation=urn:h17-org:v3 MCCI_IN200100UV01.xsd/PORR_IN049016UV[/(controlActProcess/@classCode=CACT)]/@moodCo de=EVN[/subject/@typeCode=SUBJ]]/investigationEvent[(@classCode=INVTG)]/@moodCo de=EVN[/component/@typeCode=COMP]/observationEvent[(@code=@code=36)]/@codeSystem=2. 16.840.1.113883.3.989.2.1.1.19]]/author[(@typeCode=AUT)]/assignedEntity[(@classCode=ASSIGN ED)]/@code/@code=2]]/@codeSystem=2.16.840.1.113883.3.989.2.1.1.21]]]] |
| e | H.5.r.1a | 症例概要及び報告者の意見 に関する記述情報 | 100000AN | Encapsulated Data (ED) | | 値 | /MCCI_IN200100UV01[(@ITSVersion=XMML_1.0)]/@xsi:schemaLocation=urn:h17-org:v3 MCCI_IN200100UV01.xsd/PORR_IN049016UV[/(controlActProcess/@classCode=CACT)]/@moodCo de=EVN[/subject/@typeCode=SUBJ]]/investigationEvent[(@classCode=INVTG)]/@moodCo de=EVN[/component/@typeCode=COMP]/observationEvent[(@code=@code=36)]/@codeSystem=2. 16.840.1.113883.3.989.2.1.1.19]]/author[(@typeCode=AUT)]/assignedEntity[(@classCode=ASSIGN ED)]/@code/@code=2]]/@codeSystem=2.16.840.1.113883.3.989.2.1.1.21]]]]/observationEvent[(@cl assCode=OBS)]/@moodCode=EVN]/value[(@xsi:type=ED)]/text0 |
| e | H.5.r.1b | 症例概要及び報告者の意見 の記載言語 | 3A | Encapsulated Data (ED) | language=Coded Simple Value (CS) | 値 | /MCCI_IN200100UV01[(@ITSVersion=XMML_1.0)]/@xsi:schemaLocation=urn:h17-org:v3 MCCI_IN200100UV01.xsd/PORR_IN049016UV[/(controlActProcess/@classCode=CACT)]/@moodCo de=EVN[/subject/@typeCode=SUBJ]]/investigationEvent[(@classCode=INVTG)]/@moodCo de=EVN[/component/@typeCode=COMP]/observationEvent[(@code=@code=36)]/@codeSystem=2. 16.840.1.113883.3.989.2.1.1.19]]/author[(@typeCode=AUT)]/assignedEntity[(@classCode=ASSIGN ED)]/@code/@code=2]]/@codeSystem=2.16.840.1.113883.3.989.2.1.1.21]]]]/observationEvent[(@cl assCode=OBS)]/@moodCode=EVN]/value[(@xsi:type=ED)]/@language |

| ヘッダ e:エン タイプ | フィールド 番号 | フィールド 番号 | フィールド名 | ICSRメッ セージにおけ るフィールド 番号 | ICHデー タ型 | HL7デー タ型 | HL7デー タ型 (下位構成要素) | 分類 | Xpath |
|--------------------|-------------|-------------|----------------------|----------------------------------|-------------|-----------------------------|------------------------------------|----|--|
| h | ACK.M/A | | ICH ICSR バッチ確認 応答 | | | | | | |
| e | ACK.M.1 | | 確認応答バッチ番号 | | 100AN | Instance Identifier (II) | extension=Character String (ST) | 値 | /MCCI_IN200101UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200101UV01.xsd]/id[@root=2.16.840.1.113883.3.989.2.1.3.20]/@extension |
| e | ACK.M.2 | N.1.4 | 確認応答バッチ送信 者識別子 | | 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 | N.1.3 | 確認応答バッチ受信 者識別子 | | 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 | N.1.2 | ICSR 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]/acknowledgement[@typeCode=targetBatchId][@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]/attentionLineKeywordText[@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 | N.1.5 | ICSR バッチ伝送日 | | 日付/時 間 | Point in Time (TS) | | 値 | /MCCI_IN200101UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200101UV01.xsd]/attentionLineKeywordText[@code=3][@codeSystem=2.16.840.1.11 3883.3.989.2.1.1.24][@value[@xsi:type=TS]/@value |

(別添 3)

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|---|-----------|--------------------|-------|--------------------------|---------|--|
| e | ACK.A.4 | 伝送確認応答コード | 2A | Coded Value (CS) | 値 | /MCCI_IN200101UV01[@ITSVersion=XML_1.0][@xmlns:schemaLocation=urn:hl7-org:v3 MCCI_IN200101UV01.xsd]/acknowledgement/@typeCode |
| e | ACK.A.5 | パッチバリデーションエラー | 250AN | Encapsulated Data (ED) | 値 | /MCCI_IN200101UV01[@ITSVersion=XML_1.0][@xmlns:schemaLocation=urn:hl7-org:v3 MCCI_IN200101UV01.xsd]/acknowledgement/@typeCode/acknowledgementDetail[1]/text/text0 |
| h | ACK.B.r | ICH ICSR メッセージ確認応答 | | | 繰り返しノード | /MCCI_IN200101UV01[@ITSVersion=XML_1.0][@xmlns:schemaLocation=urn:hl7-org:v3 MCCI_IN200101UV01.xsd]/MCCI_IN000002UV01 |
| e | ACK.B.r.1 | ICSR メッセージ番号 | 100AN | Instance Identifier (II) | 値 | /MCCI_IN200101UV01[@ITSVersion=XML_1.0][@xmlns:schemaLocation=urn:hl7-org:v3 MCCI_IN200101UV01.xsd]/MCCI_IN000002UV01[r]/acknowledgement[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=XML_1.0][@xmlns: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送信者 | 60AN | Instance Identifier (II) | 値 | /MCCI_IN200101UV01[@ITSVersion=XML_1.0][@xmlns: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 | 60AN | Instance Identifier (II) | 値 | /MCCI_IN200101UV01[@ITSVersion=XML_1.0][@xmlns: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 メッセージ作成日 | 日付/時間 | Point in Time (TS) | 値 | /MCCI_IN200101UV01[@ITSVersion=XML_1.0][@xmlns: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]]/value[@xmlns: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=XML_1.0][@xmlns: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=XMML_1.0][@xsi:schemaLocation=urn:hl7-org:v3:MCCI_IN200101UV01.xsd]/MCCI_IN000002UV01[r]/acknowledgement[@typeCode=1]/acknowledgementDetail[1]/text/text() |
|---|-----------|-----------------|-------|------------------------|---|---|

2. 複数の XML 表現に関する XML 断片

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

2.1 開始日、終了日及び持続期間

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

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

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

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

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

```

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

```

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

```

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

```



```

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

```

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

```

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

```

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

```

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

```

```

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

```

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

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

IVL_TSの例：

```

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

```

PIVL_TSのもう1つの例：

```

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

```

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

```

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

```

```

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

```

2.2. F 検査結果

2.2.1. F.r.3.2 値及び限定子

2.2.1.1. 値 (例: "10 mg/dL")

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

```

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

```

2.2.1.2. 値より大きい (例: "> 10 mg/dL")

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

```

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

```

2.2.1.3. 値より小さい (例: "< 10 mg/dL")

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

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

2.2.1.4. 値以上 (例: ">= 10 mg/dL")

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

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

2.2.1.5. 値以下 (例: "<= 10 mg/dL")

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

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

2.2.2 F.r.3.2 及び F.r.3.3

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

```

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

```

2.2.3. F.r.3.1

```

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

```

2.2.4. F.r.3.4

```

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

```

2.3. G.k.4 投与量の例

2.3.1. 1日当たり1/回

```

<outboundRelationship2 typeCode="COMP">
  <substanceAdministration classCode="SBADM" moodCode="EVN">
    <text>1 per day</text>
    <effectiveTime xsi:type="SXPRTS">
      <comp xsi:type="PIVLTST">
        <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="TVL_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ゼー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ーベーションコードと値の組合せを用いて表す。

例:

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

IV. 参考

ICSR メッセージにおける E2B (R3) データ項目構造

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

