

(別添3)



日米 EU 医薬品規制調和国際会議

ICH E2B 専門家作業部会

個別症例安全性報告 (ICSR) の電子的伝送に  
係る実装ガイド

付録 I (G)

技術的情報

バージョン 1.00 2012 年 11 月 14 日

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## I. 序

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

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

## II. 技術的情報

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

ICH 及び HL7 におけるデータ型を下表に示す。

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

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

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

| h:ヘッダ<br>e:エンティ<br>ティ | 項目番号    | 要素名  | ICH<br>データ型 | HL7データ型                         | HL7データ型<br>(下位構成要素)              | 分類          | Xpath   |
|-----------------------|---------|--|-------------|---------------------------------|----------------------------------|-------------|---|
| h                     | N.1     | ICH ICSR 伝送識別子 (バッチラッパー: BATCH WRAPPER)    |             |                                 |                                  |             |   |
| e                     | N.1.1   | バッチ内のメッセージの種類                              | 11A         | Character String with Code (SC) | code=Coded With Equivalents (CE) | 値           | /MCC_IN200100UV01[@ITSVersion=XML_1.0][@xmlns:schemaLocation=urn:hl7-org:v3 MCC_IN200100UV01.xsd]/name[@codeSystem=2.16.840.1.113883.3.989.2.1.1.1][@code   |
| e                     | N.1.2   | バッチ番号                                      | 100AN       | Instance Identifier (I)         | extension=Character String (ST)  | 値           | MCC_IN200100UV01[@ITSVersion=XML_1.0][@xmlns:schemaLocation=urn:hl7-org:v3 MCC_IN200100UV01.xsd]/id[@root=2.16.840.1.113883.3.989.2.1.3.22][@extension  |
| e                     | N.1.3   | バッチ送信者識別子                                  | 60AN        | Instance Identifier (I)         | extension=Character String (ST)  | 値           | /MCC_IN200100UV01[@ITSVersion=XML_1.0][@xmlns:schemaLocation=urn:hl7-org:v3 MCC_IN200100UV01.xsd]/sender[@typeCode=SEND][device[@classCode=DEVI][@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 (I)         | extension=Character String (ST)  | 値           | /MCC_IN200100UV01[@ITSVersion=XML_1.0][@xmlns:schemaLocation=urn:hl7-org:v3 MCC_IN200100UV01.xsd]/receiver[@typeCode=RCV][device[@classCode=DEVI][@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           | /MCC_IN200100UV01[@ITSVersion=XML_1.0][@xmlns:schemaLocation=urn:hl7-org:v3 MCC_IN200100UV01.xsd]/creationTime@value  |
| h                     | N.2.r   | ICH ICSR メッセージヘッダ (メッセージラッパー) (必要に応じて繰り返し) |             |                                 |                                  | 繰り返し<br>ノード | /MCC_IN200100UV01[@ITSVersion=XML_1.0][@xmlns:schemaLocation=urn:hl7-org:v3 MCC_IN200100UV01.xsd]/PORR_IN049016UV01   |
| e                     | N.2.r.1 | メッセージ識別子                                   | 100AN       | Instance Identifier (I)         | extension=Character String (ST)  | 値           | /MCC_IN200100UV01[@ITSVersion=XML_1.0][@xmlns:schemaLocation=urn:hl7-org:v3 MCC_IN200100UV01.xsd]/PORR_IN049016UV01[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 (I)         | extension=Character String (ST)  | 値           | /MCC_IN200100UV01[@ITSVersion=XML_1.0][@xmlns:schemaLocation=urn:hl7-org:v3 MCC_IN200100UV01.xsd]/PORR_IN049016UV01/sender[@typeCode=SEND][device[@classCode=DEVI][@determinerCode=INSTANCE][id[@root=2.16.840.1.113883.3.989.2.1.3.12][@extension  |
| e                     | N.2.r.3 | メッセージ受信者識別子                                | 60AN        | Instance Identifier (I)         | extension=Character String (ST)  | 値           | /MCC_IN200100UV01[@ITSVersion=XML_1.0][@xmlns:schemaLocation=urn:hl7-org:v3 MCC_IN200100UV01.xsd]/PORR_IN049016UV01/receiver[@typeCode=RCV][device[@classCode=DEVI][@determinerCode=INSTANCE][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           | /MCC_IN200100UV01[@ITSVersion=XML_1.0][@xmlns:schemaLocation=urn:hl7-org:v3 MCC_IN200100UV01.xsd]/PORR_IN049016UV01/creationTime@value  |
| h                     | C.1     | 症例安全性報告の識別                                 |             |                                 |                                  |             |   |
| e                     | C.1.1   | 送信者ごとに固有の (症例) 安全性報告識別子                    | 100AN       | Instance Identifier (I)         | extension=Character String (ST)  | 値           | /MCC_IN200100UV01[@ITSVersion=XML_1.0][@xmlns:schemaLocation=urn:hl7-org:v3 MCC_IN200100UV01.xsd]/PORR_IN049016UV01/controlActProcess[@classCode=CACT][@moodCode=EVN][subject[@typeCode=SUB][@investigationEventId[@classCode=INVESTIG][@moodCode=EVN][id[@root=2.16.840.1.113883.3.989.2.1.3.1][@extension |

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| e | C.1.2       | 作成の日付                     | 日付/時間  | Point in Time (TS)                 | 値           |
|---|-------------|---------------------------|--------|------------------------------------|-------------|
| e | C.1.3       | 報告の種類                     | 1N     | Coded With Equivalents (CE)        | 値           |
| e | C.1.4       | 情報源から最初に報告が入手された日         | 日付/時間  | Interval of Point in Time (VL<TS>) | 値           |
| e | C.1.5       | 本報告の最新情報入手日               | 日付/時間  | Point in Time (TS)                 | 値           |
| h | C.1.6       | 送信者が保有している利用可能な他の資料       |        |                                    |             |
| e | C.1.6.1     | 利用可能なその他の資料はあるか?          | ブール型   | Boolean (BL)                       | 値           |
| h | C.1.6.1.r   | 送信者が保有している資料(必要に応じ繰り返し返す) |        |                                    | 繰り返し<br>ノード |
| e | C.1.6.1.r.1 | 送信者が保有している資料              | 2000AN | Character String (ST)              | 値           |
| e | C.1.6.1.r.2 | 含まれる資料                    | N/A    | Encapsulated Data (ED)             | 値           |

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|   |             |                           |       |                             |             |   |
|---|-------------|---------------------------|-------|-----------------------------|-------------|---|
| 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           | /MCCLI_IN200100UV01@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3<br>MCCLI_IN200100UV01.xsd]PORR_IN049016UV01/controlActProcess[classCode=CACTI][@moodCode=EVN]/subject[typeCode=SUBJ][investigationEvent][@classCode=INVSIG][@moodCode=EVN]/component[typeCode=COMP][observationEvent][@code=23][@codeSystem=2.16.840.1.113883.3.989.2.1.1.19][observationEvent][@classCode=OBS][@moodCode=EVN]/value[@xsi:type=BL][value]  |
| e |             |                           |       |                             | NullFlavor  | /MCCLI_IN200100UV01@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3<br>MCCLI_IN200100UV01.xsd]PORR_IN049016UV01/controlActProcess[classCode=CACTI][@moodCode=EVN]/subject[typeCode=SUBJ][investigationEvent][@classCode=INVSIG][@moodCode=EVN]/component[typeCode=COMP][observationEvent][@code=23][@codeSystem=2.16.840.1.113883.3.989.2.1.1.19][observationEvent][@classCode=OBS][@moodCode=EVN]/value[@xsi:type=BL][@nullFlavor]  |
| h | C.1.8       | 世界的に固有の症例識別子              |       |                             |             |   |
| e | C.1.8.1     | 世界的に固有の症例識別子              | 100AN | Instance Identifier (I)     | 値           | /MCCLI_IN200100UV01@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3<br>MCCLI_IN200100UV01.xsd]PORR_IN049016UV01/controlActProcess[classCode=CACTI][@moodCode=EVN]/id[@root=2.16.840.1.113883.3.989.2.1.3.2][extension]   |
| e | C.1.8.2     | 本症例の第一送信者                 | 1N    | Coded With Equivalents (CE) | 値           | /MCCLI_IN200100UV01@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3<br>MCCLI_IN200100UV01.xsd]PORR_IN049016UV01/controlActProcess[classCode=CACTI][@moodCode=EVN]/subject[typeCode=SUBJ][investigationEvent][@classCode=INVSIG][@moodCode=EVN]/outboundRelationship[typeCode=SPRT][relatedInvestigationCode=1][@codeSystem=2.16.840.1.113883.3.989.2.1.2.2][relatedInvestigation][@classCode=INVSIG][@moodCode=EVN]/subjectOr2[typeCode=SUBJ][controlActEvent][@classCode=CACTI][@moodCode=EVN]/author[typeCode=AUT][assignedEntity][@classCode=ASSIGNED][code][@codeSystem=2.16.840.1.113883.3.989.2.1.1.3][code] |
| h | C.1.9       | その他の症例識別子                 |       |                             |             |   |
| e | C.1.9.1     | 過去の伝送で記載されたその他の症例識別子はあるか? | ブール型  | Boolean (BL)                | 値           | /MCCLI_IN200100UV01@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3<br>MCCLI_IN200100UV01.xsd]PORR_IN049016UV01/controlActProcess[classCode=CACTI][@moodCode=EVN]/subjectOr2[typeCode=SUBJ][investigationEvent][@classCode=INVSIG][@moodCode=EVN]/subjectOr2[typeCode=SUBJ][investigationCharacteristic][@code=2][@codeSystem=2.16.840.1.113883.3.989.2.1.1.23][investigationCharacteristic][@classCode=OBS][@moodCode=EVN]/value[@xsi:type=BL][value]   |
| e |             |                           |       |                             | NullFlavor  | /MCCLI_IN200100UV01@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3<br>MCCLI_IN200100UV01.xsd]PORR_IN049016UV01/controlActProcess[classCode=CACTI][@moodCode=EVN]/subjectOr2[typeCode=SUBJ][investigationEvent][@classCode=INVSIG][@moodCode=EVN]/subjectOr2[typeCode=SUBJ][investigationCharacteristic][@code=2][@codeSystem=2.16.840.1.113883.3.989.2.1.1.23][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し)    |       |                             | 繰り返し<br>ノード | /MCCLI_IN200100UV01@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3<br>MCCLI_IN200100UV01.xsd]PORR_IN049016UV01/controlActProcess[classCode=CACTI][@moodCode=EVN]/subjectOr1[typeCode=SUBJ][investigationEvent][@classCode=INVSIG][@moodCode=EVN]/subjectOr1[typeCode=SUBJ][investigationEvent][@classCode=INVSIG][@moodCode=EVN]/value[@xsi:type=BL][@nullFlavor]   |
| e | C.1.9.1.r.1 | 症例識別子の情報源                 | 100AN | Instance Identifier (I)     | 値           | /MCCLI_IN200100UV01@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3<br>MCCLI_IN200100UV01.xsd]PORR_IN049016UV01/controlActProcess[classCode=CACTI][@moodCode=EVN]/subjectOr1[typeCode=SUBJ][investigationEvent][@classCode=INVSIG][@moodCode=EVN]/subjectOr1[typeCode=SUBJ][investigationEvent][@classCode=INVSIG][@moodCode=EVN]/value[@xsi:type=BL][@nullFlavor]   |

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|   |             |                               |        |                             |                                       |             |  |
|---|-------------|-------------------------------|--------|-----------------------------|---------------------------------------|-------------|--|
| e | C.1.9.1.r.2 | 症例識別子                         | 100AN  | Instance Identifier (I)     | extension=Character String (ST)       | 値           | /MCCI_IN200100UV01[@ITSVersion=XML_1.0T][@xsis:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PARR_IN049016UVJ/controlActProcess[@classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUBJT]/relatedInvestigationEvent[@classCode=INVESTG][@moodCode=EVN]/subjectOf2[@typeCode=SUBJT]/controlActEventOf2[@typeCode=SUBJT]/relatedInvestigationEventOf2[@typeCode=SUBJT] |
| 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し返す) | 100AN  | Instance Identifier (I)     | extension=Character String (ST)       | 値           | /MCCI_IN200100UV01[@ITSVersion=XML_1.0T][@xsis:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PARR_IN049016UVJ/controlActProcess[@classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUBJT]/relatedInvestigationEvent[@classCode=INVESTG][@moodCode=EVN]/subjectOf2[@typeCode=SUBJT]/relatedInvestigationEventOf2[@typeCode=SUBJT]                                     |
| h | C.1.11      | 報告破棄/修正                       |        |                             |                                       |             |  |
| e | C.1.11.1    | 報告破棄/修正                       | 1N     | Coded With Equivalents (CE) | code=Character String (ST)            | 値           | /MCCI_IN200100UV01[@ITSVersion=XML_1.0T][@xsis:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PARR_IN049016UVJ/controlActProcess[@classCode=CACT][@moodCode=EVN]/subjectOf2[@typeCode=SUBJT]/relatedInvestigationEvent[@classCode=INVESTG][@moodCode=EVN]/subjectOf2[@typeCode=SUBJT]/relatedInvestigationEventOf2[@typeCode=SUBJT]                                  |
| e | C.1.11.2    | 報告破棄/修正理由                     | 2000AN | Coded With Equivalents (CE) | originalText = Encapsulated Data (ED) | 値           | /MCCI_IN200100UV01[@ITSVersion=XML_1.0T][@xsis:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PARR_IN049016UVJ/controlActProcess[@classCode=CACT][@moodCode=EVN]/subjectOf2[@typeCode=SUBJT]/relatedInvestigationEvent[@classCode=INVESTG][@moodCode=EVN]/subjectOf2[@typeCode=SUBJT]  |
| h | C.2.r       | 第一次情報源 (必要に応じて繰り返し返す)         |        |                             |                                       | 繰り返し<br>ノード | /MCCI_IN200100UV01[@ITSVersion=XML_1.0T][@xsis:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PARR_IN049016UVJ/controlActProcess[@classCode=CACT][@moodCode=EVN]/subjectOf2[@typeCode=SUBJT]   |
| h | C.2.r.1     | 報告者の氏名                        |        |                             |                                       |             | /MCCI_IN200100UV01[@ITSVersion=XML_1.0T][@xsis:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PARR_IN049016UVJ/controlActProcess[@classCode=CACT][@moodCode=EVN]/subjectOf2[@typeCode=SUBJT]   |
| e | C.2.r.1.1   | 報告者の職名                        | 50AN   | Person Name (PN)            | prefix=Entity Name Part (ENXP)        | 値           | /MCCI_IN200100UV01[@ITSVersion=XML_1.0T][@xsis:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PARR_IN049016UVJ/controlActProcess[@classCode=CACT][@moodCode=EVN]/subjectOf2[@typeCode=SUBJT]   |
| e |             |                               |        |                             |                                       | NullFlavor  | /MCCI_IN200100UV01[@ITSVersion=XML_1.0T][@xsis:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PARR_IN049016UVJ/controlActProcess[@classCode=CACT][@moodCode=EVN]/subjectOf2[@typeCode=SUBJT]   |



(別添 3)

|   |           |              |      |                  |                                |            |  |
|---|-----------|--------------|------|------------------|--------------------------------|------------|--|
| e | C.2.r.1.2 | 報告者の名前       | 60AN | Person Name (PN) | given=Entity Name Part (ENXP)  | 値          | <pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation='urn:hl7-org:v3 MCCL_IN200100UV01.xsd']/P_ORR_IN049016UV1/controlActProcess[@classCode=CACT][@mo dCode=EVN]/subject[@typeCode=SUBJT1]/relatedInvestigation[@code=2][@code de=EVN]/outboundRelationship[@typeCode=SPRT1]/relatedInvestigation[@code=2][@code System=2.16.840.1.113883.3.989.2.1.1.22][r/relatedInvestigation[@classCode=INVTG][@mo dCode=EVN]/subjectOf2[@typeCode=SUBJ]/controlActEvent[@classCode=CACT][@mo dCode=EVN]/author[@typeCode=AUT]/assignedEntity[@classCode=ASSIGNED]/assignedPerson[ sCode=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']/P_ORR_IN049016UV1/controlActProcess[@classCode=CACT][@mo dCode=EVN]/subject[@typeCode=SUBJT1]/relatedInvestigation[@code=2][@code de=EVN]/outboundRelationship[@typeCode=SPRT1]/relatedInvestigation[@code=2][@code System=2.16.840.1.113883.3.989.2.1.1.22][r/relatedInvestigation[@classCode=INVTG][@mo dCode=EVN]/subjectOf2[@typeCode=SUBJ]/controlActEvent[@classCode=CACT][@mo dCode=EVN]/author[@typeCode=AUT]/assignedEntity[@classCode=ASSIGNED]/assignedPerson[ sCode=PSN][@determinerCode=INSTANCE]/name/given[2]/text() </pre> |
| e | C.2.r.1.4 | 報告者の姓        | 60AN | Person Name (PN) | family=Entity Name Part (ENXP) | 値          | <pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation='urn:hl7-org:v3 MCCL_IN200100UV01.xsd']/P_ORR_IN049016UV1/controlActProcess[@classCode=CACT][@mo dCode=EVN]/subject[@typeCode=SUBJT1]/relatedInvestigation[@code=2][@code System=2.16.840.1.113883.3.989.2.1.1.22][r/relatedInvestigation[@classCode=INVTG][@mo dCode=EVN]/subjectOf2[@typeCode=SUBJ]/controlActEvent[@classCode=CACT][@mo dCode=EVN]/author[@typeCode=AUT]/assignedEntity[@classCode=ASSIGNED]/assignedPerson[ sCode=PSN][@determinerCode=INSTANCE]/name/given[2]/text() </pre>   |
| h | C.2.r.2   | 報告者の住所及び電話番号 |      |                  |                                | NullFlavor | <pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation='urn:hl7-org:v3 MCCL_IN200100UV01.xsd']/P_ORR_IN049016UV1/controlActProcess[@classCode=CACT][@mo dCode=EVN]/subject[@typeCode=SUBJT1]/relatedInvestigation[@code=2][@code System=2.16.840.1.113883.3.989.2.1.1.22][r/relatedInvestigation[@classCode=INVTG][@mo dCode=EVN]/subjectOf2[@typeCode=SUBJ]/controlActEvent[@classCode=CACT][@mo dCode=EVN]/author[@typeCode=AUT]/assignedEntity[@classCode=ASSIGNED]/assignedPerson[ sCode=PSN][@determinerCode=INSTANCE]/name/family[1]/text() </pre>  |

(別添3)

|   |           |             |       |                           |  |            |  |
|---|-----------|-------------|-------|---------------------------|--|------------|--|
| e | C.2.r.2.1 | 報告者の組織      | 60AN  | Organization Name<br>(ON) | name=Entity Name<br>Part (ENXP)            | 値          | <pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0T]@xsi:schemaLocation='urn:h7-org:v3 MCCL_IN200100UV01.xsd'j/PORR_IN049016UVj/controlActProcess[ @classCode=CACTI]@moo dCode=EVN/j/subject/@typeCode=SUBJ/j/investigationEvent[ @classCode=INVSTGT]@moodCo de=EVN/j/outboundRelationship[ @typeCode=SPRT/j/relatedInvestigation/code[ @code=2I]@code System=2,16.840.1.113883.3.989.2.1.1.22]j/relatedInvestigation[ @classCode=INVSTGT]@mood Code=EVN/j/subjectOr2[ @typeCode=SUBJ/j/controlActEvent[ @classCode=ASSIGNED/j/representedOrganizatio n[ @classCode=AUT] /assignedEntity[ @classCode=ASSIGNED/j/representedOrganizatio n[ @classCode=ORGE] /determinerCode=INSTANCE] /assignedEntity[ @classCode=ASSIGNED] /r epresentedOrganization[ @classCode=ORGE] /determinerCode=INSTANCE] /name/text() </pre> |
| e |           |             |       |                           |  | NullFlavor | <pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0T]@xsi:schemaLocation='urn:h7-org:v3 MCCL_IN200100UV01.xsd'j/PORR_IN049016UVj/controlActProcess[ @classCode=CACTI]@moo dCode=EVN/j/subject/@typeCode=SUBJ/j/investigationEvent[ @classCode=INVSTGT]@moodCo de=EVN/j/outboundRelationship[ @typeCode=SPRT/j/relatedInvestigation/code[ @code=2I]@code System=2,16.840.1.113883.3.989.2.1.1.22]j/relatedInvestigation[ @classCode=INVSTGT]@mood Code=EVN/j/subjectOr2[ @typeCode=SUBJ/j/controlActEvent[ @classCode=CACTI]@moodCode= EVN/j/author[ @typeCode=AUT] /assignedEntity[ @classCode=ASSIGNED] /representedOrganizatio n[ @classCode=ORGE] /determinerCode=INSTANCE] /assignedEntity[ @classCode=ASSIGNED] /r epresentedOrganization[ @classCode=ORGE] /determinerCode=INSTANCE] /name/@nullFlavor </pre>   |
| e | C.2.r.2.2 | 報告者の部署      | 60AN  | Organization Name<br>(ON) | name=Entity Name<br>Part (ENXP)            | 値          | <pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0T]@xsi:schemaLocation='urn:h7-org:v3 MCCL_IN200100UV01.xsd'j/PORR_IN049016UVj/controlActProcess[ @classCode=CACTI]@moo dCode=EVN/j/subject/@typeCode=SUBJ/j/investigationEvent[ @classCode=INVSTGT]@moodCo de=EVN/j/outboundRelationship[ @typeCode=SPRT/j/relatedInvestigation/code[ @code=2I]@code System=2,16.840.1.113883.3.989.2.1.1.22]j/relatedInvestigation[ @classCode=INVSTGT]@mood Code=EVN/j/subjectOr2[ @typeCode=SUBJ/j/controlActEvent[ @classCode=CACTI]@moodCode= EVN/j/author[ @typeCode=AUT] /assignedEntity[ @classCode=ASSIGNED] /representedOrganizatio n[ @classCode=ORGE] /determinerCode=INSTANCE] /assignedEntity[ @classCode=ASSIGNED] /r epresentedOrganization[ @classCode=ORGE] /determinerCode=INSTANCE] /name/text() </pre>        |
| e |           |             |       |                           |  | NullFlavor | <pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0T]@xsi:schemaLocation='urn:h7-org:v3 MCCL_IN200100UV01.xsd'j/PORR_IN049016UVj/controlActProcess[ @classCode=CACTI]@moo dCode=EVN/j/subject/@typeCode=SUBJ/j/investigationEvent[ @classCode=INVSTGT]@moodCo de=EVN/j/outboundRelationship[ @typeCode=SPRT/j/relatedInvestigation/code[ @code=2I]@code System=2,16.840.1.113883.3.989.2.1.1.22]j/relatedInvestigation[ @classCode=INVSTGT]@mood Code=EVN/j/subjectOr2[ @typeCode=SUBJ/j/controlActEvent[ @classCode=CACTI]@moodCode= EVN/j/author[ @typeCode=AUT] /assignedEntity[ @classCode=ASSIGNED] /representedOrganizatio n[ @classCode=ORGE] /determinerCode=INSTANCE] /assignedEntity[ @classCode=ASSIGNED] /r epresentedOrganization[ @classCode=ORGE] /determinerCode=INSTANCE] /name/@nullFlavor </pre>   |
| e | C.2.r.2.3 | 報告者の住所 (番地) | 100AN | Postal Address (AD)       | streetAddressLine=A<br>address Part (ADXP) | 値          | <pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0T]@xsi:schemaLocation='urn:h7-org:v3 MCCL_IN200100UV01.xsd'j/PORR_IN049016UVj/controlActProcess[ @classCode=CACTI]@moo dCode=EVN/j/subject/@typeCode=SUBJ/j/investigationEvent[ @classCode=INVSTGT]@moodCo de=EVN/j/outboundRelationship[ @typeCode=SPRT/j/relatedInvestigation/code[ @code=2I]@code System=2,16.840.1.113883.3.989.2.1.1.22]j/relatedInvestigation[ @classCode=INVSTGT]@mood Code=EVN/j/subjectOr2[ @typeCode=SUBJ/j/controlActEvent[ @classCode=CACTI]@moodCode= EVN/j/author[ @typeCode=AUT] /assignedEntity[ @classCode=ASSIGNED] /representedOrganizatio n[ @classCode=ORGE] /determinerCode=INSTANCE] /name/text() </pre>  |

(別添 3)

|   |           |                |      |                     |                                   |  |  |
|---|-----------|----------------|------|---------------------|-----------------------------------|--|--|
| e |           |                |      |                     | NullFlavor                        | /MCCI_IN200100UV01@ITSVersion=XML_1.0.1/@xsi:schemaLocation=urn:hl7-org:v3<br>MCCI_IN200100UV01.xsd/PORR_IN049016UV01/controlActProcess[@classCode=CACTI]@mo<br>dCode=EVN/subject[@typeCode=SUBJ]/investigationEvent[@classCode=INVSIG]@mo<br>dCode=EVN/outboundRelationship[@typeCode=SPRT]/relatedInvestigation/@code=2I@code<br>System=2.16.840.1.113883.3.989.2.1.1.22I/relatedInvestigation/@classCode=INVSIG<br>Code=EVN/subjectOf2[@typeCode=SUBJ]/controlActEvent[@classCode=CACTI]@mo<br>dCode=EVN/author[@typeCode=AUT]/assignedEntity[@classCode=ASSIGNED]@addrf1/streetAddressLI<br>nel1/@nullFlavor |  |
| e | C.2.r.2.4 | 報告者の住所 (市町村等)  | 35AN | Postal Address (AD) | city=Address Part<br>(ADXP)       | 値  | /MCCI_IN200100UV01@ITSVersion=XML_1.0.1/@xsi:schemaLocation=urn:hl7-org:v3<br>MCCI_IN200100UV01.xsd/PORR_IN049016UV01/controlActProcess[@classCode=CACTI]@mo<br>dCode=EVN/subject[@typeCode=SUBJ]/investigationEvent[@classCode=INVSIG]@mo<br>dCode=EVN/outboundRelationship[@typeCode=SPRT]/relatedInvestigation/@code=2I@code<br>System=2.16.840.1.113883.3.989.2.1.1.22I/relatedInvestigation/@classCode=INVSIG<br>Code=EVN/subjectOf2[@typeCode=SUBJ]/controlActEvent[@classCode=CACTI]@mo<br>dCode=EVN/author[@typeCode=AUT]/assignedEntity[@classCode=ASSIGNED]@addrf1/city1/textI           |
| e |           |                |      |                     | NullFlavor                        | 値  | /MCCI_IN200100UV01@ITSVersion=XML_1.0.1/@xsi:schemaLocation=urn:hl7-org:v3<br>MCCI_IN200100UV01.xsd/PORR_IN049016UV01/controlActProcess[@classCode=CACTI]@mo<br>dCode=EVN/subject[@typeCode=SUBJ]/investigationEvent[@classCode=INVSIG]@mo<br>dCode=EVN/outboundRelationship[@typeCode=SPRT]/relatedInvestigation/@code=2I@code<br>System=2.16.840.1.113883.3.989.2.1.1.22I/relatedInvestigation/@classCode=INVSIG<br>Code=EVN/subjectOf2[@typeCode=SUBJ]/controlActEvent[@classCode=CACTI]@mo<br>dCode=EVN/author[@typeCode=AUT]/assignedEntity[@classCode=ASSIGNED]@addrf1/city1/textI<br>vor    |
| e | C.2.r.2.5 | 報告者の住所 (都道府県等) | 40AN | Postal Address (AD) | state=Address Part<br>(ADXP)      | 値  | /MCCI_IN200100UV01@ITSVersion=XML_1.0.1/@xsi:schemaLocation=urn:hl7-org:v3<br>MCCI_IN200100UV01.xsd/PORR_IN049016UV01/controlActProcess[@classCode=CACTI]@mo<br>dCode=EVN/subject[@typeCode=SUBJ]/investigationEvent[@classCode=INVSIG]@mo<br>dCode=EVN/outboundRelationship[@typeCode=SPRT]/relatedInvestigation/@code=2I@code<br>System=2.16.840.1.113883.3.989.2.1.1.22I/relatedInvestigation/@classCode=INVSIG<br>Code=EVN/subjectOf2[@typeCode=SUBJ]/controlActEvent[@classCode=CACTI]@mo<br>dCode=EVN/author[@typeCode=AUT]/assignedEntity[@classCode=ASSIGNED]@addrf1/statef1/textI         |
| e |           |                |      |                     | NullFlavor                        | NullFlavor   | /MCCI_IN200100UV01@ITSVersion=XML_1.0.1/@xsi:schemaLocation=urn:hl7-org:v3<br>MCCI_IN200100UV01.xsd/PORR_IN049016UV01/controlActProcess[@classCode=CACTI]@mo<br>dCode=EVN/subject[@typeCode=SUBJ]/investigationEvent[@classCode=INVSIG]@mo<br>dCode=EVN/outboundRelationship[@typeCode=SPRT]/relatedInvestigation/@code=2I@code<br>System=2.16.840.1.113883.3.989.2.1.1.22I/relatedInvestigation/@classCode=INVSIG<br>Code=EVN/subjectOf2[@typeCode=SUBJ]/controlActEvent[@classCode=CACTI]@mo<br>dCode=EVN/author[@typeCode=AUT]/assignedEntity[@classCode=ASSIGNED]@addrf1/statef1/textI<br>avor |
| e | C.2.r.2.6 | 報告者の住所 (郵便番号)  | 15AN | Postal Address (AD) | postalCode=Address<br>Part (ADXP) | 値  | /MCCI_IN200100UV01@ITSVersion=XML_1.0.1/@xsi:schemaLocation=urn:hl7-org:v3<br>MCCI_IN200100UV01.xsd/PORR_IN049016UV01/controlActProcess[@classCode=CACTI]@mo<br>dCode=EVN/subject[@typeCode=SUBJ]/investigationEvent[@classCode=INVSIG]@mo<br>dCode=EVN/outboundRelationship[@typeCode=SPRT]/relatedInvestigation/@code=2I@code<br>System=2.16.840.1.113883.3.989.2.1.1.22I/relatedInvestigation/@classCode=INVSIG<br>Code=EVN/subjectOf2[@typeCode=SUBJ]/controlActEvent[@classCode=CACTI]@mo<br>dCode=EVN/author[@typeCode=AUT]/assignedEntity[@classCode=ASSIGNED]@addrf1/postalCodef1/textI    |

(別添3)

|   |           |          |      |                                 |   |
|---|-----------|----------|------|---------------------------------|---|
| e |           |          |      | NullFlavor                      | <pre> /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PDRR_IN049016UVr/controlActProcess[@classCode=CACTI][@mood dCode=EVN]/subject[@typeCode=SUBJ][/investigationEvent[@classCode=INVTG][@moodCo de=EVN]/outboundRelationship[@typeCode=SPRT][relatedInvestigation/@code=2][@code System=2.16.840.1.113883.3.989.2.1.1.22][/relatedInvestigation/@classCode=INVTG][@mood Code=EVN]/subjectOr2[@typeCode=SUBJ]/controlActEvent[@classCode=CACTI][@moodCode= EVN]/author[@typeCode=AUT]/assignedEntity[@classCode=ASSIGNED][actr1][postalCode1][ @nullFlavor substring(/MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PDRR_IN049016UVr/controlActProcess[@classCode=CACTI][@mood dCode=EVN]/subject[@typeCode=SUBJ][/investigationEvent[@classCode=INVTG][@moodCo de=EVN]/outboundRelationship[@typeCode=SPRT][relatedInvestigation/@code=2][@code System=2.16.840.1.113883.3.989.2.1.1.22][/relatedInvestigation/@classCode=INVTG][@mood Code=EVN]/subjectOr2[@typeCode=SUBJ]/controlActEvent[@classCode=CACTI][@moodCode= EVN]/author[@typeCode=AUT]/assignedEntity[@classCode=ASSIGNED]/telecom[starts-with(@v alue, tel:)]][/value, 5) </pre> |
| e | C.2.r.2.7 | 報告者の電話番号 | 33AN | Telecommunication Address (TEL) | <pre> /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PDRR_IN049016UVr/controlActProcess[@classCode=CACTI][@mood dCode=EVN]/subject[@typeCode=SUBJ][/investigationEvent[@classCode=INVTG][@moodCo de=EVN]/outboundRelationship[@typeCode=SPRT][relatedInvestigation/@code=2][@code System=2.16.840.1.113883.3.989.2.1.1.22][/relatedInvestigation/@classCode=INVTG][@mood Code=EVN]/subjectOr2[@typeCode=SUBJ]/controlActEvent[@classCode=CACTI][@moodCode= EVN]/author[@typeCode=AUT]/assignedEntity[@classCode=ASSIGNED]/telecom[starts-with(@v alue, tel:)]][/value, 5) </pre>   |
| e |           |          |      | NullFlavor                      | <pre> /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PDRR_IN049016UVr/controlActProcess[@classCode=CACTI][@mood dCode=EVN]/subject[@typeCode=SUBJ][/investigationEvent[@classCode=INVTG][@moodCo de=EVN]/outboundRelationship[@typeCode=SPRT][relatedInvestigation/@code=2][@code System=2.16.840.1.113883.3.989.2.1.1.22][/relatedInvestigation/@classCode=INVTG][@mood Code=EVN]/subjectOr2[@typeCode=SUBJ]/controlActEvent[@classCode=CACTI][@moodCode= EVN]/author[@typeCode=AUT]/assignedEntity[@classCode=ASSIGNED]/telecom[starts-with(@v alue, tel:)]][/value, 5) </pre>   |
| e | C.2.r.3   | 報告者の国コード | 2A   | Concept Descriptor (CD)         | <pre> /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PDRR_IN049016UVr/controlActProcess[@classCode=CACTI][@mood dCode=EVN]/subject[@typeCode=SUBJ][/investigationEvent[@classCode=INVTG][@moodCo de=EVN]/outboundRelationship[@typeCode=SPRT][relatedInvestigation/@code=2][@code System=2.16.840.1.113883.3.989.2.1.1.22][/relatedInvestigation/@classCode=INVTG][@mood Code=EVN]/subjectOr2[@typeCode=SUBJ]/controlActEvent[@classCode=CACTI][@moodCode= EVN]/author[@typeCode=AUT]/assignedEntity[@classCode=ASSIGNED]/assignedPerson[@clas sCode=PSN][@determinerCode=INSTANCE]/asLocatedEntity[@classCode=LOC][/location[ classCode=COUNTRY][@determinerCode=INSTANCE]/code/@codeSystem=1.0.3.166.1.2.2][@c ode </pre>  |
| e |           |          |      | NullFlavor                      | <pre> /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PDRR_IN049016UVr/controlActProcess[@classCode=CACTI][@mood dCode=EVN]/subject[@typeCode=SUBJ][/investigationEvent[@classCode=INVTG][@moodCo de=EVN]/outboundRelationship[@typeCode=SPRT][relatedInvestigation/@code=2][@code System=2.16.840.1.113883.3.989.2.1.1.22][/relatedInvestigation/@classCode=INVTG][@mood Code=EVN]/subjectOr2[@typeCode=SUBJ]/controlActEvent[@classCode=CACTI][@moodCode= EVN]/author[@typeCode=AUT]/assignedEntity[@classCode=ASSIGNED]/assignedPerson[@clas sCode=PSN][@determinerCode=INSTANCE]/asLocatedEntity[@classCode=LOC][/location[ classCode=COUNTRY][@determinerCode=INSTANCE]/code/@codeSystem=1.0.3.166.1.2.2][@n ullFlavor </pre>  |

(別添3)

|   |         |                   |       |                             |                              |            |  |
|---|---------|-------------------|-------|-----------------------------|------------------------------|------------|--|
| e | C.2.r.4 | 資格                | 1N    | Coded With Equivalents (CE) | code=Character String (ST)   | 値          | /MCCL_IN200100UV01@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]JPORR_IN049016UVJ/controlActProcess[@classCode=CACTI][@moodCode=EVN]/subject[@typeCode=SUBJ]/investigationEvent[@classCode=INVSIG][@moodCode=EVN]/outboundRelationship[@typeCode=SPRT][relatedInvestigation/@code=2][@codeSystem=2.16.840.1.113883.3.989.2.1.1.22][relatedInvestigation/@classCode=INVSIG][@moodCode=EVN]/subjectOf[@typeCode=SUBJ]/controlActEvent[@classCode=CACTI][@moodCode=EVN]/author[@typeCode=AUT]/assignedEntity[@classCode=ASSIGNED]/assignedPerson[@classCode=PSN][@determinerCode=INSTANCE]/asQualifiedEntity[@classCode=QUAL][1]/code/@codeSystem=2.16.840.1.113883.3.989.2.1.1.67][@code       |
| e |         |                   |       |                             |                              | NullFlavor | /MCCL_IN200100UV01@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]JPORR_IN049016UVJ/controlActProcess[@classCode=CACTI][@moodCode=EVN]/subject[@typeCode=SUBJ]/investigationEvent[@classCode=INVSIG][@moodCode=EVN]/outboundRelationship[@typeCode=SPRT][relatedInvestigation/@code=2][@codeSystem=2.16.840.1.113883.3.989.2.1.1.22][relatedInvestigation/@classCode=INVSIG][@moodCode=EVN]/subjectOf[@typeCode=SUBJ]/controlActEvent[@classCode=CACTI][@moodCode=EVN]/author[@typeCode=AUT]/assignedEntity[@classCode=ASSIGNED]/assignedPerson[@classCode=PSN][@determinerCode=INSTANCE]/asQualifiedEntity[@classCode=QUAL][1]/code/@codeSystem=2.16.840.1.113883.3.989.2.1.1.67][@nullFlavor |
| e | C.2.r.5 | 規制目的上の第一次情報源      | 1N    | Real Number (REAL)          |                              | 値          | /MCCL_IN200100UV01@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]JPORR_IN049016UVJ/controlActProcess[@classCode=CACTI][@moodCode=EVN]/subject[@typeCode=SUBJ]/investigationEvent[@classCode=INVSIG][@moodCode=EVN]/outboundRelationship[@typeCode=SPRT][relatedInvestigation/@code=2][@codeSystem=2.16.840.1.113883.3.989.2.1.1.22][priorityNumber/@value   |
| h | C.3     | 症例安全性報告の送信者に関する情報 |       |                             |                              |            |  |
| e | C.3.1   | 送信者の種類            | 1N    | Coded With Equivalents (CE) | code=Character String (ST)   | 値          | /MCCL_IN200100UV01@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]JPORR_IN049016UVJ/controlActProcess[@classCode=CACTI][@moodCode=EVN]/subjectOf[@typeCode=SUBJ]/investigationEvent[@classCode=INVSIG][@moodCode=EVN]/subjectOf1[@typeCode=SUBJ]/controlActEvent/author/assignedEntity/@code/@codeSystem=2.16.840.1.113883.3.989.2.1.1.7][1]/controlActEvent/@classCode=CACTI][@moodCode=EVN]/author/@typeCode=AUT]/assignedEntity[@classCode=ASSIGNED]/code/@codeSystem=2.16.840.1.113883.3.989.2.1.1.7][@code  |
| e | C.3.2   | 送信者の組織            | 100AN | Organization Name (ON)      | name=Entity Name Part (ENXP) | 値          | /MCCL_IN200100UV01@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]JPORR_IN049016UVJ/controlActProcess[@classCode=CACTI][@moodCode=EVN]/subjectOf[@typeCode=SUBJ]/investigationEvent[@classCode=INVSIG][@moodCode=EVN]/subjectOf1[@typeCode=SUBJ]/controlActEvent/author/assignedEntity/@code/@codeSystem=2.16.840.1.113883.3.989.2.1.1.7][1]/controlActEvent/@classCode=CACTI][@moodCode=EVN]/author/@typeCode=AUT]/assignedEntity[@classCode=ASSIGNED]/representedOrganization/@classCode=ORG][@determinerCode=INSTANCE]/assignedEntity[@classCode=ASSIGNED]/representedOrganization/@classCode=ORG][@determinerCode=INSTANCE]/name/text()  |
| h | C.3.3   | 報告送信の責任者          |       |                             |                              |            |  |
| e | C.3.3.1 | 送信者の部署            | 60AN  | Organization Name (ON)      | name=Entity Name Part (ENXP) | 値          | /MCCL_IN200100UV01@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]JPORR_IN049016UVJ/controlActProcess[@classCode=CACTI][@moodCode=EVN]/subjectOf1[@typeCode=SUBJ]/controlActEvent/author/assignedEntity/@code/@codeSystem=2.16.840.1.113883.3.989.2.1.1.7][1]/controlActEvent/@classCode=CACTI][@moodCode=EVN]/author/@typeCode=AUT]/assignedEntity[@classCode=ASSIGNED]/representedOrganization/@classCode=ORG][@determinerCode=INSTANCE]/name/text()   |

(別添3)

|   |         |                              |       |                     |                                       |   |   |
|---|---------|------------------------------|-------|---------------------|---------------------------------------|---|---|
| e | C.3.3.2 | 送信者の職名                       | 50AN  | Person Name (PN)    | prefix=Entity Name Part (ENXP)        | 値 | /MCCL_IN200100UV01[@ITSVersion='XML_1.0']/@xsi:schemaLocation=urn:hl7-org:v3<br>MCCL_IN200100UV01.xsd/PORR_IN049016UV1/controlActProcess/@classCode=CACTI[@moodCode=EVN]/subject/@typeCode=SUBJ[1]/investigationEvent/@classCode=INVSIG[1]/moodCode=EVN/subjectOf1/@typeCode=SUBJ[1]/controlActEvent/author/assignedEntity/code/@codeSystem=2.16.840.1.113883.3.889.2.1.1.7[1]/controlActEvent/@classCode=CACTI[@moodCode=EVN]/author/@typeCode=AUT/@assignedEntity/@classCode=ASSIGNED/assignedPerson/@classCode=PSN[1]/@determinerCode=INSTANCE[1]/text |
| e | C.3.3.3 | 送信者の名前                       | 60AN  | Person Name (PN)    | given=Entity Name Part (ENXP)         | 値 | /MCCL_IN200100UV01[@ITSVersion='XML_1.0']/@xsi:schemaLocation=urn:hl7-org:v3<br>MCCL_IN200100UV01.xsd/PORR_IN049016UV1/controlActProcess/@classCode=CACTI[@moodCode=EVN]/subject/@typeCode=SUBJ[1]/investigationEvent/@classCode=INVSIG[1]/moodCode=EVN/subjectOf1/@typeCode=SUBJ[1]/controlActEvent/author/assignedEntity/code/@codeSystem=2.16.840.1.113883.3.889.2.1.1.7[1]/controlActEvent/@classCode=CACTI[@moodCode=EVN]/author/@typeCode=AUT/@assignedEntity/@classCode=ASSIGNED/assignedPerson/@classCode=PSN[1]/@determinerCode=INSTANCE[1]/text |
| e | C.3.3.4 | 送信者の中間名                      | 60AN  | Person Name (PN)    | given=Entity Name Part (ENXP)         | 値 | /MCCL_IN200100UV01[@ITSVersion='XML_1.0']/@xsi:schemaLocation=urn:hl7-org:v3<br>MCCL_IN200100UV01.xsd/PORR_IN049016UV1/controlActProcess/@classCode=CACTI[@moodCode=EVN]/subject/@typeCode=SUBJ[1]/investigationEvent/@classCode=INVSIG[1]/moodCode=EVN/subjectOf1/@typeCode=SUBJ[1]/controlActEvent/author/assignedEntity/code/@codeSystem=2.16.840.1.113883.3.889.2.1.1.7[1]/controlActEvent/@classCode=CACTI[@moodCode=EVN]/author/@typeCode=AUT/@assignedEntity/@classCode=ASSIGNED/assignedPerson/@classCode=PSN[1]/@determinerCode=INSTANCE[1]/text |
| e | C.3.3.5 | 送信者の姓                        | 60AN  | Person Name (PN)    | family=Entity Name Part (ENXP)        | 値 | /MCCL_IN200100UV01[@ITSVersion='XML_1.0']/@xsi:schemaLocation=urn:hl7-org:v3<br>MCCL_IN200100UV01.xsd/PORR_IN049016UV1/controlActProcess/@classCode=CACTI[@moodCode=EVN]/subject/@typeCode=SUBJ[1]/investigationEvent/@classCode=INVSIG[1]/moodCode=EVN/subjectOf1/@typeCode=SUBJ[1]/controlActEvent/author/assignedEntity/code/@codeSystem=2.16.840.1.113883.3.889.2.1.1.7[1]/controlActEvent/@classCode=CACTI[@moodCode=EVN]/author/@typeCode=AUT/@assignedEntity/@classCode=ASSIGNED/assignedPerson/@classCode=PSN[1]/@determinerCode=INSTANCE[1]/text |
| h | C.3.4   | 送信者の住所、FAX番号、電話番号及び電子メールアドレス |       |                     |                                       |   |   |
| e | C.3.4.1 | 送信者の住所 (番地)                  | 100AN | Postal Address (AD) | streetAddressLine=Address Part (ADXP) | 値 | /MCCL_IN200100UV01[@ITSVersion='XML_1.0']/@xsi:schemaLocation=urn:hl7-org:v3<br>MCCL_IN200100UV01.xsd/PORR_IN049016UV1/controlActProcess/@classCode=CACTI[@moodCode=EVN]/subject/@typeCode=SUBJ[1]/investigationEvent/@classCode=INVSIG[1]/moodCode=EVN/subjectOf1/@typeCode=SUBJ[1]/controlActEvent/author/assignedEntity/code/@codeSystem=2.16.840.1.113883.3.889.2.1.1.7[1]/controlActEvent/@classCode=CACTI[@moodCode=EVN]/author/@typeCode=AUT/@assignedEntity/@classCode=ASSIGNED/addr1[1]/streetAddressLine[1]/text                                |
| e | C.3.4.2 | 送信者の住所 (市町村等)                | 35AN  | Postal Address (AD) | city=Address Part (ADXP)              | 値 | /MCCL_IN200100UV01[@ITSVersion='XML_1.0']/@xsi:schemaLocation=urn:hl7-org:v3<br>MCCL_IN200100UV01.xsd/PORR_IN049016UV1/controlActProcess/@classCode=CACTI[@moodCode=EVN]/subject/@typeCode=SUBJ[1]/investigationEvent/@classCode=INVSIG[1]/moodCode=EVN/subjectOf1/@typeCode=SUBJ[1]/controlActEvent/author/assignedEntity/code/@codeSystem=2.16.840.1.113883.3.889.2.1.1.7[1]/controlActEvent/@classCode=CACTI[@moodCode=EVN]/author/@typeCode=AUT/@assignedEntity/@classCode=ASSIGNED/addr1[1]/city[1]/text   |

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|   |         |                  |       |                                 |                                |             |  |
|---|---------|------------------|-------|---------------------------------|--------------------------------|-------------|--|
| e | C.3.4.3 | 送信者の住所 (郵便番号等)   | 40AN  | Postal Address (AD)             | state=Address Part (ADXP)      | 値           | /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/PARR_IN049016UV01/controlActProcess[@classCode=CACTI][@moodCdCode=EVN]/subject[@typeCode=SUBJ]/investigationEvent[@classCode=INVSIG][@moodCdCode=EVN]/subjectOrI[@typeCode=SUBJ]/controlActEvent/author/assignedEntity/code[@codeSystem=2.16.840.1.113883.3.989.2.1.1.7][@codeSystem=CACTI][@moodCode=EVN]/author/@typeCode=AUT/assignedEntity[@classCode=ASSIGNED][addr1/state1/text0]  |
| e | C.3.4.4 | 送信者の住所 (郵便番号)    | 15AN  | Postal Address (AD)             | postalCode=Address Part (ADXP) | 値           | /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/PARR_IN049016UV01/controlActProcess[@classCode=CACTI][@moodCdCode=EVN]/subject[@typeCode=SUBJ]/investigationEvent[@classCode=INVSIG][@moodCdCode=EVN]/subjectOrI[@typeCode=SUBJ]/controlActEvent/author/assignedEntity/code[@codeSystem=2.16.840.1.113883.3.989.2.1.1.7][@codeSystem=CACTI][@moodCode=EVN]/author/@typeCode=AUT/assignedEntity[@classCode=ASSIGNED][addr1/postalCode1/text0]   |
| e | C.3.4.5 | 送信者の住所 (国コード)    | 2A    | Concept Descriptor (CD)         | code=Character String (ST)     | 値           | /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/PARR_IN049016UV01/controlActProcess[@classCode=CACTI][@moodCdCode=EVN]/subject[@typeCode=SUBJ]/investigationEvent[@classCode=INVSIG][@moodCdCode=EVN]/subjectOrI[@typeCode=SUBJ]/controlActEvent/author/assignedEntity/code[@codeSystem=2.16.840.1.113883.3.989.2.1.1.7][@codeSystem=CACTI][@moodCode=EVN]/author/@typeCode=AUT/assignedEntity[@classCode=ASSIGNED][determinerCode=LOCE1]/location/@code=PSN1/@determinerCode=INSTANCE1/instanceLocation/@codeSystem=1.0.3166.1.2.2][@code=PSN1/@value, 5] |
| e | C.3.4.6 | 送信者の電話番号         | 33AN  | Telecommunication Address (TEL) |                                | 値           | substring(MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/PARR_IN049016UV01/controlActProcess[@classCode=CACTI][@moodCdCode=EVN]/subject[@typeCode=SUBJ]/investigationEvent[@classCode=INVSIG][@moodCdCode=EVN]/subjectOrI[@typeCode=SUBJ]/controlActEvent/author/assignedEntity/code[@codeSystem=2.16.840.1.113883.3.989.2.1.1.7][@codeSystem=CACTI][@moodCode=EVN]/author/@typeCode=AUT/assignedEntity[@classCode=ASSIGNED]/telecom1starts-with/@value, 5)  |
| e | C.3.4.7 | 送信者の FAX 番号      | 33AN  | Telecommunication Address (TEL) |                                | 値           | substring(MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/PARR_IN049016UV01/controlActProcess[@classCode=CACTI][@moodCdCode=EVN]/subject[@typeCode=SUBJ]/investigationEvent[@classCode=INVSIG][@moodCdCode=EVN]/subjectOrI[@typeCode=SUBJ]/controlActEvent/author/assignedEntity/code[@codeSystem=2.16.840.1.113883.3.989.2.1.1.7][@codeSystem=CACTI][@moodCode=EVN]/author/@typeCode=AUT/assignedEntity[@classCode=ASSIGNED]/telecom1starts-with/@value, 5)  |
| e | C.3.4.8 | 送信者の電子メールアドレス    | 100AN | Telecommunication Address (TEL) |                                | 値           | substring(MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/PARR_IN049016UV01/controlActProcess[@classCode=CACTI][@moodCdCode=EVN]/subject[@typeCode=SUBJ]/investigationEvent[@classCode=INVSIG][@moodCdCode=EVN]/subjectOrI[@typeCode=SUBJ]/controlActEvent/author/assignedEntity/code[@codeSystem=2.16.840.1.113883.3.989.2.1.1.7][@codeSystem=CACTI][@moodCode=EVN]/author/@typeCode=AUT/assignedEntity[@classCode=ASSIGNED]/telecom1starts-with/@value, 8)  |
| h | C.4.f   | 引用文献 (必要に応じ繰り返し) |       |                                 |                                | 繰り返し<br>ノード | /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/PARR_IN049016UV01/controlActProcess[@classCode=CACTI][@moodCdCode=EVN]/subject[@typeCode=SUBJ]/document/code[@code=2][@codeSystem=2.16.840.1.113883.3.989.2.1.1.27]  |

(別添 3)

|   |           |                         |       |                          |             |   |
|---|-----------|-------------------------|-------|--------------------------|-------------|---|
| e | C.4.r.1   | 引用文献                    | 500AN | Encapsulated Data (ED)   | 値           | <pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/PDRR_IN049016UV01/controlActProcess[@classCode=CACTI][@moodCode=EVN]/subject/@typeCode=SUBJ11/investigationEvent[@classCode=INVESTG1][@moodCode=EVN]/reference/@typeCode=REFR1/documentCode[@code=2][@codeSystem=2.16.840.1.1.3883.3.989.2.1.1.27][document/@classCode=DOC][@moodCode=EVN]/bibliographicDesignationText/text </pre>   |
| e |           |                         |       |                          | NullFlavor  | <pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/PDRR_IN049016UV01/controlActProcess[@classCode=CACTI][@moodCode=EVN]/subject/@typeCode=SUBJ11/investigationEvent[@classCode=INVESTG1][@moodCode=EVN]/reference/@typeCode=REFR1/documentCode[@code=2][@codeSystem=2.16.840.1.1.3883.3.989.2.1.1.27][document/@classCode=DOC][@moodCode=EVN]/bibliographicDesignationText/@nullFlavor </pre>  |
| e | C.4.r.2   | 含まれる資料                  | N/A   | Encapsulated Data (ED)   | 値           | <pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/PDRR_IN049016UV01/controlActProcess[@classCode=CACTI][@moodCode=EVN]/subject/@typeCode=SUBJ11/investigationEvent[@classCode=INVESTG1][@moodCode=EVN]/reference/@typeCode=REFR1/documentCode[@code=2][@codeSystem=2.16.840.1.1.3883.3.989.2.1.1.27][document/@classCode=DOC][@moodCode=EVN]/text/text </pre>   |
| 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<br>繰り返す) |       |                          | 繰り返す<br>ノード | <pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/PDRR_IN049016UV01/controlActProcess[@classCode=CACTI][@moodCode=EVN]/component/@typeCode=COMP1/adverseEventAssessment[1]/adverseEventAssessment[@classCode=INVESTG1][@moodCode=EVN]/subject/@typeCode=SBJ11/primaryRole/@classCode=INVSBJ1/subjectOf/@typeCode=SBJ11/researchStudy/@classCode=CLINTRL1][@moodCode=EVN]/authorization/@typeCode=AUTH1 </pre>   |
| e | C.5.1.r.1 | 試験の登録番号                 | .50AN | Instance Identifier (II) | 値           | <pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/PDRR_IN049016UV01/controlActProcess[@classCode=CACTI][@moodCode=EVN]/component/@typeCode=COMP1/adverseEventAssessment[1]/adverseEventAssessment[@classCode=INVESTG1][@moodCode=EVN]/subject/@typeCode=SBJ11/primaryRole/@classCode=INVSBJ1/subjectOf/@typeCode=SBJ11/researchStudy/@classCode=CLINTRL1][@moodCode=EVN]/authorization/@typeCode=AUTH1/studyRegistration/@classCode=ACTI][@moodCode=EVN]/id/@root=2.16.840.1.1.3883.3.989.2.1.3.61/@extension </pre>  |
| e |           |                         |       |                          | NullFlavor  | <pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/PDRR_IN049016UV01/controlActProcess[@classCode=CACTI][@moodCode=EVN]/component/@typeCode=COMP1/adverseEventAssessment[1]/adverseEventAssessment[@classCode=INVESTG1][@moodCode=EVN]/subject/@typeCode=SBJ11/primaryRole/@classCode=INVSBJ1/subjectOf/@typeCode=SBJ11/researchStudy/@classCode=CLINTRL1][@moodCode=EVN]/authorization/@typeCode=AUTH1/studyRegistration/@classCode=ACTI][@moodCode=EVN]/id/@root=2.16.840.1.1.3883.3.989.2.1.3.61/@nullFlavor </pre> |



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|   |           |                     |        |                          |                                 |            |   |
|---|-----------|---------------------|--------|--------------------------|---------------------------------|------------|---|
| e | C.5.1.r.2 | 試験の登録国              | 2A     | Concept Descriptor (CD)  | code=Character String (ST)      | 値          | <pre> /MCCL_IN200100UV01@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/PDRR_IN049016UV01/controlActProcess/@classCode=CACTI][@moodCode=EVN]/subject/@typeCode=SUBJ][investigationEvent/@classCode=INVSSTG][@moodCode=EVN]/component/@typeCode=COMP][adverseEventAssessment/@classCode=INVSSTG][@moodCode=EVN]/subject/@typeCode=EVN][subject1/@typeCode=SBJ][primaryRole/@classCode=INVSBJ][subjectOf/@typeCode=SBJ][researchStudy/@classCode=CLNTRL][@moodCode=EVN]/author/@typeCode=AUTH][studyRegistration/@classCode=ACT][@moodCode=EVN]/author/@typeCode=AUT][territorialAuthority/@classCode=TERR][governingPlace/@classCode=COUNTRY][@codeSystem=1.0.3.166.1.2.2]/@code </pre> |
| e |           |                     |        |                          |                                 | NullFlavor | <pre> /MCCL_IN200100UV01@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/PDRR_IN049016UV01/controlActProcess/@classCode=CACTI][@moodCode=EVN]/subject/@typeCode=SUBJ][investigationEvent/@classCode=INVSSTG][@moodCode=EVN]/component/@typeCode=COMP][adverseEventAssessment/@classCode=INVSSTG][@moodCode=EVN]/subject/@typeCode=EVN][subject1/@typeCode=SBJ][primaryRole/@classCode=INVSBJ][subjectOf/@typeCode=SBJ][researchStudy/@classCode=CLNTRL][@moodCode=EVN]/author/@typeCode=AUT][territorialAuthority/@classCode=TERR][governingPlace/@classCode=COUNTRY][@codeSystem=1.0.3.166.1.2.2]/@code </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_IN049016UV01/controlActProcess/@classCode=CACTI][@moodCode=EVN]/subject/@typeCode=SUBJ][investigationEvent/@classCode=INVSSTG][@moodCode=EVN]/component/@typeCode=COMP][adverseEventAssessment/@classCode=INVSSTG][@moodCode=EVN]/subject/@typeCode=EVN][subject1/@typeCode=SBJ][primaryRole/@classCode=INVSBJ][subjectOf/@typeCode=SBJ][researchStudy/@classCode=CLNTRL][@moodCode=EVN]/title/text </pre>  |
| e |           |                     |        |                          |                                 | NullFlavor | <pre> /MCCL_IN200100UV01@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/PDRR_IN049016UV01/controlActProcess/@classCode=CACTI][@moodCode=EVN]/subject/@typeCode=SUBJ][investigationEvent/@classCode=INVSSTG][@moodCode=EVN]/component/@typeCode=COMP][adverseEventAssessment/@classCode=INVSSTG][@moodCode=EVN]/subject/@typeCode=EVN][subject1/@typeCode=SBJ][primaryRole/@classCode=INVSBJ][subjectOf/@typeCode=SBJ][researchStudy/@classCode=CLNTRL][@moodCode=EVN]/title/@nullFlavor </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) | 値          | <pre> /MCCL_IN200100UV01@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/PDRR_IN049016UV01/controlActProcess/@classCode=CACTI][@moodCode=EVN]/subject/@typeCode=SUBJ][investigationEvent/@classCode=INVSSTG][@moodCode=EVN]/component/@typeCode=COMP][adverseEventAssessment/@classCode=INVSSTG][@moodCode=EVN]/subject/@typeCode=EVN][subject1/@typeCode=SBJ][primaryRole/@classCode=INVSBJ][subjectOf/@typeCode=SBJ][researchStudy/@classCode=CLNTRL][@moodCode=EVN]/id/@root=2.16.840.1.113883.3.989.2.1.3.5]/@extension </pre>  |
| e |           |                     |        |                          |                                 | NullFlavor | <pre> /MCCL_IN200100UV01@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/PDRR_IN049016UV01/controlActProcess/@classCode=CACTI][@moodCode=EVN]/subject/@typeCode=SUBJ][investigationEvent/@classCode=INVSSTG][@moodCode=EVN]/component/@typeCode=COMP][adverseEventAssessment/@classCode=INVSSTG][@moodCode=EVN]/subject/@typeCode=EVN][subject1/@typeCode=SBJ][primaryRole/@classCode=INVSBJ][subjectOf/@typeCode=SBJ][researchStudy/@classCode=CLNTRL][@moodCode=EVN]/id/@root=2.16.840.1.113883.3.989.2.1.3.5]/@nullFlavor </pre>   |

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|   |         |                                 |      |                             |                                 |            |   |
|---|---------|---------------------------------|------|-----------------------------|---------------------------------|------------|---|
| 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 (OE) | code=Character String (ST)      | 値          | /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3:MCCL_IN200100UV01.xsd]/PDRR_IN049016UV1/controlActProcess[@classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUB][@investigationEvent/@classCode=INVTG][@moodCode=EVN]/component[@typeCode=COMP][@adverseEventAssessment[1]/adverseEventAssessment[@classCode=INVTG][@moodCode=EVN]/subject[@typeCode=SB][@primaryRole/@classCode=INVSBJ]/subjectOrf1[@typeCode=SB][@researchStudy/@classCode=CLNTRL][@moodCode=EVN]/code[@codeSystem=2.16.840.1.113883.3.989.2.1.1.8][@code  |
| h | D       | 患者特性                            |      |                             |                                 |            | /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3:MCCL_IN200100UV01.xsd]/PDRR_IN049016UV1/controlActProcess[@classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUB][@investigationEvent/@classCode=INVTG][@moodCode=EVN]/component[@typeCode=COMP][@adverseEventAssessment[1]/adverseEventAssessment[@classCode=INVTG][@moodCode=EVN]/subject1[@typeCode=SB][@primaryRole/@classCode=INVSBJ]/player1[@classCode=PSN][@determinerCode=INSTANCE]/namef1/text()  |
| e | D.1     | 患者 (名前又はイニシャル)                  | 60AN | Entity Name (EN)            | name=Entity Name Part (ENXP)    | 値          | /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3:MCCL_IN200100UV01.xsd]/PDRR_IN049016UV1/controlActProcess[@classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUB][@investigationEvent/@classCode=INVTG][@moodCode=EVN]/component[@typeCode=COMP][@adverseEventAssessment[1]/adverseEventAssessment[@classCode=INVTG][@moodCode=EVN]/subject1[@typeCode=SB][@primaryRole/@classCode=INVSBJ]/player1[@classCode=PSN][@determinerCode=INSTANCE]/namef1/text()  |
| e |         |                                 |      |                             |                                 | NullFlavor | /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3:MCCL_IN200100UV01.xsd]/PDRR_IN049016UV1/controlActProcess[@classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUB][@investigationEvent/@classCode=INVTG][@moodCode=EVN]/component[@typeCode=COMP][@adverseEventAssessment[1]/adverseEventAssessment[@classCode=INVTG][@moodCode=EVN]/subject1[@typeCode=SB][@primaryRole/@classCode=INVSBJ]/player1[@classCode=PSN][@determinerCode=INSTANCE]/namef1/text()  |
| h | D.1.1   | 患者の診療記録番号及びその情報源 (記載が許可されている場合) |      |                             |                                 |            | /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3:MCCL_IN200100UV01.xsd]/PDRR_IN049016UV1/controlActProcess[@classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUB][@investigationEvent/@classCode=INVTG][@moodCode=EVN]/component[@typeCode=COMP][@adverseEventAssessment[1]/adverseEventAssessment[@classCode=INVTG][@moodCode=EVN]/subject1[@typeCode=SB][@primaryRole/@classCode=INVSBJ]/player1[@classCode=PSN][@determinerCode=INSTANCE]/namef1/text()  |
| 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          | /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3:MCCL_IN200100UV01.xsd]/PDRR_IN049016UV1/controlActProcess[@classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUB][@investigationEvent/@classCode=INVTG][@moodCode=EVN]/component[@typeCode=COMP][@adverseEventAssessment[1]/adverseEventAssessment[@classCode=INVTG][@moodCode=EVN]/subject1[@typeCode=SB][@primaryRole/@classCode=INVSBJ]/player1[@classCode=PSN][@determinerCode=INSTANCE]/asIdentifiedEntity/@classCode=IDENT][@code/@code=1][@codeSystem=2.16.840.1.113883.3.989.2.1.1.4][@root=2.16.840.1.113883.3.989.2.1.3.7][@extension |
| e |         |                                 |      |                             |                                 | NullFlavor | /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3:MCCL_IN200100UV01.xsd]/PDRR_IN049016UV1/controlActProcess[@classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUB][@investigationEvent/@classCode=INVTG][@moodCode=EVN]/component[@typeCode=COMP][@adverseEventAssessment[1]/adverseEventAssessment[@classCode=INVTG][@moodCode=EVN]/subject1[@typeCode=SB][@primaryRole/@classCode=INVSBJ]/player1[@classCode=PSN][@determinerCode=INSTANCE]/asIdentifiedEntity/@classCode=IDENT][@code/@code=1][@codeSystem=2.16.840.1.113883.3.989.2.1.1.4][@root=2.16.840.1.113883.3.989.2.1.3.7][@extension |

(別添 3)

|   |         |                                 |      |                          |                                 |            |   |
|---|---------|---------------------------------|------|--------------------------|---------------------------------|------------|---|
| 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> /MCCL_IN200100UV01/@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/P/RR_IN049016UVJ/controlActProcess[@classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUBJT1]/investigationEvent[@classCode=INVSCTG][@moodCode=EVN]/component[@typeCode=COMPJ]/adverseEventAssessment[1]/adverseEventAssessment[@classCode=INVSCTG][@moodCode=EVN]/subject1[@typeCode=SBJT1]/primaryRole[@classCode=INVSBJ/player1/@classCode=PSN][@determinerCode=INSTANCE/identifiedEntity][@classCode=IDENT][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>   |
| e |         |                                 |      |                          |                                 | NullFlavor | <pre> /MCCL_IN200100UV01/@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/P/RR_IN049016UVJ/controlActProcess[@classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUBJT1]/investigationEvent[@classCode=INVSCTG][@moodCode=EVN]/component[@typeCode=COMPJ]/adverseEventAssessment[1]/adverseEventAssessment[@classCode=INVSCTG][@moodCode=EVN]/subject1[@typeCode=SBJT1]/primaryRole[@classCode=INVSBJ/player1/@classCode=PSN][@determinerCode=INSTANCE/identifiedEntity][@classCode=IDENT][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 </pre>  |
| 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          | <pre> /MCCL_IN200100UV01/@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/P/RR_IN049016UVJ/controlActProcess[@classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUBJT1]/investigationEvent[@classCode=INVSCTG][@moodCode=EVN]/component[@typeCode=COMPJ]/adverseEventAssessment[1]/adverseEventAssessment[@classCode=INVSCTG][@moodCode=EVN]/subject1[@typeCode=SBJT1]/primaryRole[@classCode=INVSBJ/player1/@classCode=PSN][@determinerCode=INSTANCE/identifiedEntity][@classCode=IDENT][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 </pre>   |
| e |         |                                 |      |                          |                                 | NullFlavor | <pre> /MCCL_IN200100UV01/@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/P/RR_IN049016UVJ/controlActProcess[@classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUBJT1]/investigationEvent[@classCode=INVSCTG][@moodCode=EVN]/component[@typeCode=COMPJ]/adverseEventAssessment[1]/adverseEventAssessment[@classCode=INVSCTG][@moodCode=EVN]/subject1[@typeCode=SBJT1]/primaryRole[@classCode=INVSBJ/player1/@classCode=PSN][@determinerCode=INSTANCE/identifiedEntity][@classCode=IDENT][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 </pre>  |
| 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          | <pre> /MCCL_IN200100UV01/@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/P/RR_IN049016UVJ/controlActProcess[@classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUBJT1]/investigationEvent[@classCode=INVSCTG][@moodCode=EVN]/component[@typeCode=COMPJ]/adverseEventAssessment[1]/adverseEventAssessment[@classCode=INVSCTG][@moodCode=EVN]/subject1[@typeCode=SBJT1]/primaryRole[@classCode=INVSBJ/player1/@classCode=PSN][@determinerCode=INSTANCE/identifiedEntity][@classCode=IDENT][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 </pre>  |
| e |         |                                 |      |                          |                                 | NullFlavor | <pre> /MCCL_IN200100UV01/@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/P/RR_IN049016UVJ/controlActProcess[@classCode=CACT][@moodCode=EVN]/subject[@typeCode=SUBJT1]/investigationEvent[@classCode=INVSCTG][@moodCode=EVN]/component[@typeCode=COMPJ]/adverseEventAssessment[1]/adverseEventAssessment[@classCode=INVSCTG][@moodCode=EVN]/subject1[@typeCode=SBJT1]/primaryRole[@classCode=INVSBJ/player1/@classCode=PSN][@determinerCode=INSTANCE/identifiedEntity][@classCode=IDENT][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 </pre> |
| h | D.2     | 年齢情報                            |      |                          |                                 |            |   |

(別添 3)

|   |          |                          |       |                        |                              |   |
|---|----------|--------------------------|-------|------------------------|------------------------------|---|
| e | D.2.1    | 生年月日                     | 日付/時間 | Point in Time (TS)     | 値                            | <pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0T][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/P/RR_IN049016UVJ/controlActProcess[@classCode=CACTI][@moo dCode=EVN]/subject/@typeCode=SUBJ11/investigationEvent[@classCode=INVESTG1][@moodCo de=EVN]/component/@typeCode=COMP11/adverseEventAssessment11/adverseEventAssessment 11/@classCode=INVESTG11/@moodCode=EVN]/subject/@typeCode=SBJ11/primaryRole/@classC ode=INVSBJ11/player1/@classCode=PSN11/@determinerCode=INSTANCE/dateTime/@value /MCCL_IN200100UV01[@ITSVersion=XML_1.0T][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/P/RR_IN049016UVJ/controlActProcess[@classCode=CACTI][@moo dCode=EVN]/subject/@typeCode=SUBJ11/investigationEvent[@classCode=INVESTG1][@moodCo de=EVN]/component/@typeCode=COMP11/adverseEventAssessment11/adverseEventAssessment 11/@classCode=INVESTG11/@moodCode=EVN]/subject/@typeCode=SBJ11/primaryRole/@classC ode=INVSBJ11/player1/@classCode=PSN11/@determinerCode=INSTANCE/dateTime/@nullFlavor </pre> |
| e | D.2.2    | 副作用/有害事象発現時の年齢           |       |                        | NullFlavor                   | <pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0T][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/P/RR_IN049016UVJ/controlActProcess[@classCode=CACTI][@moo dCode=EVN]/subject/@typeCode=SUBJ11/investigationEvent[@classCode=INVESTG1][@moodCo de=EVN]/component/@typeCode=COMP11/adverseEventAssessment11/adverseEventAssessment 11/@classCode=INVESTG11/@moodCode=EVN]/subject/@typeCode=SBJ11/primaryRole/@classC ode=INVSBJ11/player1/@classCode=PSN11/@determinerCode=INSTANCE/dateTime/@nullFlavor </pre>   |
| e | D.2.2a   | 副作用/有害事象発現時の年齢(数)        | 5N    | Physical Quantity (PQ) | value=Real Number (REAL)     | <pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0T][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/P/RR_IN049016UVJ/controlActProcess[@classCode=CACTI][@moo dCode=EVN]/subject/@typeCode=SUBJ11/investigationEvent[@classCode=INVESTG1][@moodCo de=EVN]/component/@typeCode=COMP11/adverseEventAssessment11/adverseEventAssessment 11/@classCode=INVESTG11/@moodCode=EVN]/subject/@typeCode=SBJ11/primaryRole/@classC ode=INVSBJ11/player1/@typeCode=SBJ11/observation/@code=311/@codeSystem=2.16.84 0.1.113883.3.989.2.1.1.19111/observation/@classCode=OBS11/@moodCode=EVN]/value/@xsi:typ e=PQ11/@unit </pre>   |
| e | D.2.2b   | 副作用/有害事象発現時の年齢(単位)       | 50AN  | Physical Quantity (PQ) | unit=Coded Simple Value (CS) | <pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0T][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/P/RR_IN049016UVJ/controlActProcess[@classCode=CACTI][@moo dCode=EVN]/subject/@typeCode=SUBJ11/investigationEvent[@classCode=INVESTG1][@moodCo de=EVN]/component/@typeCode=COMP11/adverseEventAssessment11/adverseEventAssessment 11/@classCode=INVESTG11/@moodCode=EVN]/subject/@typeCode=SBJ11/primaryRole/@classC ode=INVSBJ11/player1/@typeCode=SBJ11/observation/@code=311/@codeSystem=2.16.84 0.1.113883.3.989.2.1.1.19111/observation/@classCode=OBS11/@moodCode=EVN]/value/@xsi:typ e=PQ11/@unit </pre>   |
| e | D.2.2.1a | 胎児での副作用/有害事象発現時の妊娠期間(数)  | 3N    | Physical Quantity (PQ) | value=Real Number (REAL)     | <pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0T][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/P/RR_IN049016UVJ/controlActProcess[@classCode=CACTI][@moo dCode=EVN]/subject/@typeCode=SUBJ11/investigationEvent[@classCode=INVESTG1][@moodCo de=EVN]/component/@typeCode=COMP11/adverseEventAssessment11/adverseEventAssessment 11/@classCode=INVESTG11/@moodCode=EVN]/subject/@typeCode=SBJ11/primaryRole/@classC ode=INVSBJ11/player1/@typeCode=SBJ11/observation/@code=1611/@codeSystem=2.16.84 0.1.113883.3.989.2.1.1.19111/observation/@classCode=OBS11/@moodCode=EVN]/value/@xsi:ty pe=PQ11/@unit </pre>  |
| e | D.2.2.1b | 胎児での副作用/有害事象発現時の妊娠期間(単位) | 50AN  | Physical Quantity (PQ) | unit=Coded Simple Value (CS) | <pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0T][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/P/RR_IN049016UVJ/controlActProcess[@classCode=CACTI][@moo dCode=EVN]/subject/@typeCode=SUBJ11/investigationEvent[@classCode=INVESTG1][@moodCo de=EVN]/component/@typeCode=COMP11/adverseEventAssessment11/adverseEventAssessment 11/@classCode=INVESTG11/@moodCode=EVN]/subject/@typeCode=SBJ11/primaryRole/@classC ode=INVSBJ11/player1/@typeCode=SBJ11/observation/@code=1611/@codeSystem=2.16.84 0.1.113883.3.989.2.1.1.19111/observation/@classCode=OBS11/@moodCode=EVN]/value/@xsi:ty pe=PQ11/@unit </pre>  |

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|   |       |                    |       |                             |                            |   |   |
|---|-------|--------------------|-------|-----------------------------|----------------------------|---|---|
| e | D.2.3 | 患者の年齢群 (報告者の表現による) | 1N    | Coded With Equivalents (CE) | code=Character String (ST) | 値 | /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PDRR_IN049016UV01/controlActProcess[@classCode=CACTI][@moodCode=EVN]/subject[@typeCode=SUBJ]/investigationEvent[@classCode=INVSIG][@moodCode=EVN]/component[@typeCode=COMP]/adverseEventAssessment[1]/adverseEventAssessment[@classCode=INVSIG][@moodCode=EVN]/subject[1]/primaryRole[@classCode=INVSBJ]/subjectOf2[@typeCode=SBJ]/observation/code[@code=4][@codeSystem=2.16.84 0.1.113883.3.989.2.1.1.19][1]/observation[@classCode=OBS][@moodCode=EVN]/value[@xsi:type=CE][@codeSystem=2.16.840.1.113883.3.989.2.1.1.9][1]/@code |
| e | D.3   | 体重 (kg)            | 6N    | Physical Quantity (PQ)      | value=Real Number (REAL)   | 値 | /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PDRR_IN049016UV01/controlActProcess[@classCode=CACTI][@moodCode=EVN]/subject[@typeCode=SUBJ]/investigationEvent[@classCode=INVSIG][@moodCode=EVN]/component[@typeCode=COMP]/adverseEventAssessment[1]/adverseEventAssessment[@classCode=INVSIG][@moodCode=EVN]/subject[1]/primaryRole[@classCode=INVSBJ]/subjectOf2[@typeCode=SBJ]/observation/code[@code=7][@codeSystem=2.16.84 0.1.113883.3.989.2.1.1.19][1]/observation[@classCode=OBS][@moodCode=EVN]/value[@xsi:type=PQ][@unit=kg][1]/@value                                   |
| e | D.4   | 身長 (cm)            | 3N    | Physical Quantity (PQ)      | value=Real Number (REAL)   | 値 | /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PDRR_IN049016UV01/controlActProcess[@classCode=CACTI][@moodCode=EVN]/subject[@typeCode=SUBJ]/investigationEvent[@classCode=INVSIG][@moodCode=EVN]/component[@typeCode=COMP]/adverseEventAssessment[1]/adverseEventAssessment[@classCode=INVSIG][@moodCode=EVN]/subject[1]/primaryRole[@classCode=INVSBJ]/subjectOf2[@typeCode=SBJ]/observation/code[@code=17][@codeSystem=2.16.84 0.1.113883.3.989.2.1.1.19][1]/observation[@classCode=OBS][@moodCode=EVN]/value[@xsi:type=PQ][@unit=cm][1]/@value                                  |
| e | D.5   | 性別                 | 1N    | Coded With Equivalents (CE) | code=Character String (ST) | 値 | /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PDRR_IN049016UV01/controlActProcess[@classCode=CACTI][@moodCode=EVN]/subject[@typeCode=SUBJ]/investigationEvent[@classCode=INVSIG][@moodCode=EVN]/component[@typeCode=COMP]/adverseEventAssessment[1]/adverseEventAssessment[@classCode=INVSIG][@moodCode=EVN]/subject[1]/primaryRole[@classCode=INVSBJ]/player[1]/classCode=PSN][@determinerCode=INSTANCE]/administrativeGenderCode[@codeSystem=1.0.52181]/@code   |
| e | D.6   | 最終月経日              | 日付/時間 | Point in Time (TS)          | NullFlavor                 | 値 | /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]/PDRR_IN049016UV01/controlActProcess[@classCode=CACTI][@moodCode=EVN]/subject[@typeCode=SUBJ]/investigationEvent[@classCode=INVSIG][@moodCode=EVN]/component[@typeCode=COMP]/adverseEventAssessment[1]/adverseEventAssessment[@classCode=INVSIG][@moodCode=EVN]/subject[1]/primaryRole[@classCode=INVSBJ]/subjectOf2[@typeCode=SBJ]/observation/code[@code=22][@codeSystem=2.16.84 0.1.113883.3.989.2.1.1.19][1]/observation[@classCode=OBS][@moodCode=EVN]/value[@xsi:type=TS][1]/@value  |

(別添 3)

|   |            |  |       |                                    |  |  |  |             |   |
|---|------------|--|-------|------------------------------------|--|--|--|-------------|---|
| e |            |  |       |                                    |  |  |  | NullFlavor  | /MCCL_IN200100UV01[0]@ITSVersion=XML_1.0T[0]@xsi:schemaLocation=urn:hl7-org:v3<br>MCCL_IN200100UV01.xsd[/P/RR_IN049016UV/r/controlActProcess/@classCode=CACTI][@moodCode=EVN]/subject/@typeCode=SUBJ[1]/investigationEvent/@classCode=INVESTG[1][@moodCode=EVN]/component/@typeCode=COMP[1]/adverseEventAssessment[1]/adverseEventAssessment/@classCode=INVESTG[1][@moodCode=EVN]/subject1/@typeCode=SBJ[1]/primaryRole/@classCode=INVSBJ[1]/subjectOr2/@typeCode=SBJ[1]/observation/code/@code=22[1][@codeSystem=2.16.840.1.113883.3.989.2.1.1.20T[1]]/observation/@classCode=OBS[1][@moodCode=EVN]/value/@xsi:type=TS[1]@nullFlavor   |
| h | D.7        | 関連する治療歴及び随伴症状 (副作用/有害事象を除く)              |       |                                    |  |  |  |             | /MCCL_IN200100UV01[0]@ITSVersion=XML_1.0T[0]@xsi:schemaLocation=urn:hl7-org:v3<br>MCCL_IN200100UV01.xsd[/P/RR_IN049016UV/r/controlActProcess/@classCode=CACTI][@moodCode=EVN]/subject/@typeCode=SUBJ[1]/investigationEvent/@classCode=INVESTG[1][@moodCode=EVN]/component/@typeCode=COMP[1]/adverseEventAssessment[1]/adverseEventAssessment/@classCode=INVESTG[1][@moodCode=EVN]/subject1/@typeCode=SBJ[1]/primaryRole/@classCode=INVSBJ[1]/subjectOr2/@typeCode=SBJ[1]/organizer/code/@code=1[1][@codeSystem=2.16.840.113883.3.989.2.1.1.20T[1]]/organizer/@classCode=CATEGORY[1][@moodCode=EVN]/component/@typeCode=COMP[1]/observation/code/@codeSystem=2.16.840.1.113883.6.163[1]  |
| h | D.7.1.r    | 関連する治療歴及び随伴症状の標準化された情報 (必要に応じて繰り返す)      |       |                                    |  |  |  | 繰り返し<br>ノード | /MCCL_IN200100UV01[0]@ITSVersion=XML_1.0T[0]@xsi:schemaLocation=urn:hl7-org:v3<br>MCCL_IN200100UV01.xsd[/P/RR_IN049016UV/r/controlActProcess/@classCode=CACTI][@moodCode=EVN]/subject/@typeCode=SUBJ[1]/investigationEvent/@classCode=INVESTG[1][@moodCode=EVN]/component/@typeCode=COMP[1]/adverseEventAssessment[1]/adverseEventAssessment/@classCode=INVESTG[1][@moodCode=EVN]/subject1/@typeCode=SBJ[1]/primaryRole/@classCode=INVSBJ[1]/subjectOr2/@typeCode=SBJ[1]/organizer/code/@code=1[1][@codeSystem=2.16.840.113883.3.989.2.1.1.20T[1]]/organizer/@classCode=CATEGORY[1][@moodCode=EVN]/component/@typeCode=COMP[1]/observation/code/@codeSystem=2.16.840.1.113883.6.163[1]  |
| e | D.7.1.r.1a | 関連する治療歴及び随伴症状の MedDRA パージョン              | 4AN   | Concept Descriptor (CD)            |  |  |  | 値           | /MCCL_IN200100UV01[0]@ITSVersion=XML_1.0T[0]@xsi:schemaLocation=urn:hl7-org:v3<br>MCCL_IN200100UV01.xsd[/P/RR_IN049016UV/r/controlActProcess/@classCode=CACTI][@moodCode=EVN]/subject/@typeCode=SUBJ[1]/investigationEvent/@classCode=INVESTG[1][@moodCode=EVN]/component/@typeCode=COMP[1]/adverseEventAssessment[1]/adverseEventAssessment/@classCode=INVESTG[1][@moodCode=EVN]/subject1/@typeCode=SBJ[1]/primaryRole/@classCode=INVSBJ[1]/subjectOr2/@typeCode=SBJ[1]/organizer/code/@code=1[1][@codeSystem=2.16.840.113883.3.989.2.1.1.20T[1]]/organizer/@classCode=CATEGORY[1][@moodCode=EVN]/component/@typeCode=COMP[1]/observation/code/@codeSystem=2.16.840.1.113883.6.163[1]/observation/@classCode=OBS[1][@moodCode=EVN]/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)            |  |  |  | 値           | /MCCL_IN200100UV01[0]@ITSVersion=XML_1.0T[0]@xsi:schemaLocation=urn:hl7-org:v3<br>MCCL_IN200100UV01.xsd[/P/RR_IN049016UV/r/controlActProcess/@classCode=CACTI][@moodCode=EVN]/subject/@typeCode=SUBJ[1]/investigationEvent/@classCode=INVESTG[1][@moodCode=EVN]/component/@typeCode=COMP[1]/adverseEventAssessment[1]/adverseEventAssessment/@classCode=INVESTG[1][@moodCode=EVN]/subject1/@typeCode=SBJ[1]/primaryRole/@classCode=INVSBJ[1]/subjectOr2/@typeCode=SBJ[1]/organizer/code/@code=1[1][@codeSystem=2.16.840.113883.3.989.2.1.1.20T[1]]/organizer/@classCode=CATEGORY[1][@moodCode=EVN]/component/@typeCode=COMP[1]/observation/code/@codeSystem=2.16.840.1.113883.6.163[1]/observation/@classCode=OBS[1][@moodCode=EVN]/code/@code                              |
| e | D.7.1.r.2  | 開始日                                      | 日付/時間 | Interval of Point in Time (IVL-TS) |  |  |  | 値           | /MCCL_IN200100UV01[0]@ITSVersion=XML_1.0T[0]@xsi:schemaLocation=urn:hl7-org:v3<br>MCCL_IN200100UV01.xsd[/P/RR_IN049016UV/r/controlActProcess/@classCode=CACTI][@moodCode=EVN]/subject/@typeCode=SUBJ[1]/investigationEvent/@classCode=INVESTG[1][@moodCode=EVN]/component/@typeCode=COMP[1]/adverseEventAssessment[1]/adverseEventAssessment/@classCode=INVESTG[1][@moodCode=EVN]/subject1/@typeCode=SBJ[1]/primaryRole/@classCode=INVSBJ[1]/subjectOr2/@typeCode=SBJ[1]/organizer/code/@code=1[1][@codeSystem=2.16.840.113883.3.989.2.1.1.20T[1]]/organizer/@classCode=CATEGORY[1][@moodCode=EVN]/component/@typeCode=COMP[1]/observation/code/@codeSystem=2.16.840.1.113883.6.163[1]/observation/@classCode=OBS[1][@moodCode=EVN]/effectiveTime/@xsi:type=IVL-TS[1]/value |

(別添3)

|   |            |                               |                                     |       |           |
|---|------------|-------------------------------|-------------------------------------|-------|-----------|
| <p>/MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]P/PORR_IN049016UVJ/controlActProcess[@classCode=CACTI][@moodCode=EVN]/subject/@typeCode=SUBJT/InvestigationEvent[@classCode=INVSSTG][@moodCode=EVN]/component/@typeCode=COMP/AdverseEventAssessment[AdverseEventAssessmentI[@classCode=INVSSTG][@moodCode=EVN]/subject/@typeCode=SBJ/primaryRole[classCode=INVSBJ/subjectOf/@typeCode=SBJ/organizer/@code=1][@codeSystem=2.16.840.1.113883.3.989.2.1.1.20][/organizer/@classCode=CATEGORY][@moodCode=EVN]/component/@typeCode=COMP/observation/code/@codeSystem=2.16.840.1.113883.6.163/observation/@classCode=OBS][@moodCode=EVN]/effectiveTime[@xsi:type=IVL_TS]/low/@nullFlavor</p>  | NullFlavor |                               |                                     |       |           |
| <p>/MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]P/PORR_IN049016UVJ/controlActProcess[@classCode=CACTI][@moodCode=EVN]/subject/@typeCode=SUBJT/InvestigationEvent[@classCode=INVSSTG][@moodCode=EVN]/component/@typeCode=COMP/AdverseEventAssessment[AdverseEventAssessmentI[@classCode=INVSSTG][@moodCode=EVN]/subject/@typeCode=SBJ/primaryRole[classCode=INVSBJ/subjectOf/@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]/value[@xsi:type=BL]/@value</p>   | 値          | Boolean (BL)                  | ブール型                                | 継続    | D.7.1.r.3 |
| <p>/MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]P/PORR_IN049016UVJ/controlActProcess[@classCode=CACTI][@moodCode=EVN]/subject/@typeCode=SUBJT/InvestigationEvent[@classCode=INVSSTG][@moodCode=EVN]/component/@typeCode=COMP/AdverseEventAssessment[AdverseEventAssessmentI[@classCode=INVSSTG][@moodCode=EVN]/subject/@typeCode=SBJ/primaryRole[classCode=INVSBJ/subjectOf/@typeCode=SBJ/organizer/@code=1][@codeSystem=2.16.840.1.113883.3.989.2.1.1.20][/organizer/@classCode=CATEGORY][@moodCode=EVN]/component/@typeCode=COMP/observation/code/@codeSystem=2.16.840.1.113883.6.163/observation/@classCode=OBS][@moodCode=EVN]/inboundRelationship[@typeCode=REFR/observation/code/@code=13][@codeSystem=2.16.840.1.113883.3.989.2.1.1.19][/observation/@classCode=OBS][@moodCode=EVN]/value[@xsi:type=BL]/@value</p> | NullFlavor |                               |                                     |       |           |
| <p>/MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]P/PORR_IN049016UVJ/controlActProcess[@classCode=CACTI][@moodCode=EVN]/subject/@typeCode=SUBJT/InvestigationEvent[@classCode=INVSSTG][@moodCode=EVN]/component/@typeCode=COMP/AdverseEventAssessment[AdverseEventAssessmentI[@classCode=INVSSTG][@moodCode=EVN]/subject/@typeCode=SBJ/primaryRole[classCode=INVSBJ/subjectOf/@typeCode=SBJ/organizer/@code=1][@codeSystem=2.16.840.1.113883.3.989.2.1.1.20][/organizer/@classCode=CATEGORY][@moodCode=EVN]/component/@typeCode=COMP/observation/code/@codeSystem=2.16.840.1.113883.6.163/observation/@classCode=OBS][@moodCode=EVN]/effectiveTime[@xsi:type=IVL_TS]/high/@value</p>  | 値          | high=Interval Boundary (IVXB) | Interval of Point in Time (IVL<TS>) | 日付/時間 | D.7.1.r.4 |
| <p>/MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]P/PORR_IN049016UVJ/controlActProcess[@classCode=CACTI][@moodCode=EVN]/subject/@typeCode=SUBJT/InvestigationEvent[@classCode=INVSSTG][@moodCode=EVN]/component/@typeCode=COMP/AdverseEventAssessment[AdverseEventAssessmentI[@classCode=INVSSTG][@moodCode=EVN]/subject/@typeCode=SBJ/primaryRole[classCode=INVSBJ/subjectOf/@typeCode=SBJ/organizer/@code=1][@codeSystem=2.16.840.1.113883.3.989.2.1.1.20][/organizer/@classCode=CATEGORY][@moodCode=EVN]/component/@typeCode=COMP/observation/code/@codeSystem=2.16.840.1.113883.6.163/observation/@classCode=OBS][@moodCode=EVN]/effectiveTime[@xsi:type=IVL_TS]/high/@value</p>  | NullFlavor |                               |                                     |       |           |

(別添 3)

|   |           |   |         |                        |            |  |
|---|-----------|---|---------|------------------------|------------|--|
| e | D.7.1.r.5 | 備考                                      | 2000AN  | Encapsulated Data (ED) | 値          | <pre> /MCCL_IN200100UV01[@ITSVersion='XML_1.0']@xsi:schemaLocation='urn:hl7-org:v3 MCCL_IN200100UV01.xsd'P/OPRR_IN049016UVI/controlActProcess[@classCode='CACTI']@moodCo dCode='EVN']/subject[@typeCode='SUBJ']/investigationEvent[@classCode='INVSCTG']@moodCo de='EVN']/component[@typeCode='COMP']/adverseEventAssessment[1]/adverseEventAssessment [@classCode='INVSCTG']@moodCode='EVN']/subject[1]/typeCode='SBJ']/primaryRole[@classC ode='INVSBJ']/subjectOf2[@typeCode='SBJ']/organizer/code[@code='1']/@codeSystem='2.16.840.1 .113883.3.989.2.1.1.20'[]/organizer[@classCode='CATEGORY']@moodCode='EVN']/component[ @typeCode='COMP']/observation/code/@codeSystem='2.16.840.1.113883.6.163'[]/observation/@ classCode='OBS']@moodCode='EVN']/outboundRelationship2[@typeCode='COMP']/observation/co de/@code='10T']@codeSystem='2.16.840.1.113883.3.989.2.1.1.19'[]/observation/@classCode='O BS']@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> /MCCL_IN200100UV01[@ITSVersion='XML_1.0']@xsi:schemaLocation='urn:hl7-org:v3 MCCL_IN200100UV01.xsd'P/OPRR_IN049016UVI/controlActProcess[@classCode='CACTI']@moodCo dCode='EVN']/subject[@typeCode='SUBJ']/investigationEvent[@classCode='INVSCTG']@moodCo de='EVN']/component[@typeCode='COMP']/adverseEventAssessment[1]/adverseEventAssessment [@classCode='INVSCTG']@moodCode='EVN']/subject[1]/typeCode='SBJ']/primaryRole[@classC ode='INVSBJ']/subjectOf2[@typeCode='SBJ']/organizer/code[@code='1']/@codeSystem='2.16.840.1 .113883.3.989.2.1.1.20'[]/organizer[@classCode='CATEGORY']@moodCode='EVN']/component[ @typeCode='COMP']/observation/code/@codeSystem='2.16.840.1.113883.6.163'[]/observation/@ classCode='OBS']@moodCode='EVN']/outboundRelationship2[@typeCode='EXPL']/observation/co de/@code='38']@codeSystem='2.16.840.1.113883.3.989.2.1.1.19'[]/observation/@classCode='O BS']@moodCode='EVN']/value[@xsi:type='BL']/value </pre>   |
| e | D.7.2     | 関連する治療歴及び副作用<br>状（副作用／有害事象を除<br>く）の記述情報 | 10000AN | Encapsulated Data (ED) | 値          | <pre> /MCCL_IN200100UV01[@ITSVersion='XML_1.0']@xsi:schemaLocation='urn:hl7-org:v3 MCCL_IN200100UV01.xsd'P/OPRR_IN049016UVI/controlActProcess[@classCode='CACTI']@moodCo dCode='EVN']/subject[@typeCode='SUBJ']/investigationEvent[@classCode='INVSCTG']@moodCo de='EVN']/component[@typeCode='COMP']/adverseEventAssessment[1]/adverseEventAssessment [@classCode='INVSCTG']@moodCode='EVN']/subject[1]/typeCode='SBJ']/primaryRole[@classC ode='INVSBJ']/subjectOf2[@typeCode='SBJ']/organizer/code[@code='1']/@codeSystem='2.16.840.1 .113883.3.989.2.1.1.20'[]/organizer[@classCode='CATEGORY']@moodCode='EVN']/component[ @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             | NullFlavor | <pre> /MCCL_IN200100UV01[@ITSVersion='XML_1.0']@xsi:schemaLocation='urn:hl7-org:v3 MCCL_IN200100UV01.xsd'P/OPRR_IN049016UVI/controlActProcess[@classCode='CACTI']@moodCo dCode='EVN']/subject[@typeCode='SUBJ']/investigationEvent[@classCode='INVSCTG']@moodCo de='EVN']/component[@typeCode='COMP']/adverseEventAssessment[1]/adverseEventAssessment [@classCode='INVSCTG']@moodCode='EVN']/subject[1]/typeCode='SBJ']/primaryRole[@classC ode='INVSBJ']/subjectOf2[@typeCode='SBJ']/organizer/code[@code='1']/@codeSystem='2.16.840.1 .113883.3.989.2.1.1.20'[]/organizer[@classCode='CATEGORY']@moodCode='EVN']/component[ @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']/value </pre>  |
| e | D.7.3     | 併用療法                                    | ブール型    | Boolean (BL)           | 値          | <pre> /MCCL_IN200100UV01[@ITSVersion='XML_1.0']@xsi:schemaLocation='urn:hl7-org:v3 MCCL_IN200100UV01.xsd'P/OPRR_IN049016UVI/controlActProcess[@classCode='CACTI']@moodCo dCode='EVN']/subject[@typeCode='SUBJ']/investigationEvent[@classCode='INVSCTG']@moodCo de='EVN']/component[@typeCode='COMP']/adverseEventAssessment[1]/adverseEventAssessment [@classCode='INVSCTG']@moodCode='EVN']/subject[1]/typeCode='SBJ']/primaryRole[@classC ode='INVSBJ']/subjectOf2[@typeCode='SBJ']/organizer/code[@code='1']/@codeSystem='2.16.840.1 .113883.3.989.2.1.1.20'[]/organizer[@classCode='CATEGORY']@moodCode='EVN']/component[ @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)

|   |          |                                |               |                                |             |  |
|---|----------|--------------------------------|---------------|--------------------------------|-------------|--|
| h | D.8.r    | 関連する過去の医薬品使用<br>歴 (必要に応じて繰り返す) |               |                                | 繰り返し<br>ノード | /MCCI_IN200100UV01@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3<br>MCCI_IN200100UV01.xsd]/PORR_IN049016UV01/controlActProcess[@classCode=CACTI][@moodCo<br>dCode=EVEN]/subject[@typeCode=SUBJ]/investigationEvent[@classCode=INVSIG][@moodCo<br>dCode=EVEN]/component[@typeCode=COMP]/adverseEventAssessment[1]/adverseEventAssessment<br>[1]/@classCode=INVSIG][@moodCode=EVN]/subject[1]/@typeCode=SBJ][1]/primaryRole[@classC<br>ode=INVSBJ]/subjectC2[1]/@typeCode=SBJ][organizerCode=@code=2][@codeSystem=2.16.840.1<br>.113883.3.989.2.1.1.20][1]/organizer[1]/instanceOfKind[@classCode=EVN]/component[<br>@typeCode=COMP][substanceAdministration]   |
| e | D.8.r.1  | 医薬品名 (報告された薬類)                 | 250AN         | Entity Name (EN)               | 値           | /MCCI_IN200100UV01@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3<br>MCCI_IN200100UV01.xsd]/PORR_IN049016UV01/controlActProcess[@classCode=CACTI][@moodCo<br>dCode=EVEN]/subject[@typeCode=SUBJ]/investigationEvent[@classCode=INVSIG][@moodCo<br>dCode=EVEN]/component[@typeCode=COMP]/adverseEventAssessment[1]/adverseEventAssessment<br>[1]/@classCode=INVSIG][@moodCode=EVN]/subject[1]/@typeCode=SBJ][1]/primaryRole[@classC<br>ode=INVSBJ]/subjectC2[1]/@typeCode=SBJ][organizerCode=@code=2][@codeSystem=2.16.840.1<br>.113883.3.989.2.1.1.20][1]/organizer[1]/instanceOfKind[@classCode=EVN]/component[<br>@typeCode=COMP][substanceAdministration][@typeCode=CSMT][1]/instanceOfKind[@classCode=SBADM][<br>@moodCode=EVN]/consumable[1]/@determinerCode=KIND][name]/text]  |
| e | D.8.r.2a | MPID パージョン日付/番号                | M5 ガイド<br>を参照 | Coded With<br>Equivalents (CE) | 値           | /MCCI_IN200100UV01@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3<br>MCCI_IN200100UV01.xsd]/PORR_IN049016UV01/controlActProcess[@classCode=CACTI][@moodCo<br>dCode=EVEN]/subject[@typeCode=SUBJ]/investigationEvent[@classCode=INVSIG][@moodCo<br>dCode=EVEN]/component[@typeCode=COMP]/adverseEventAssessment[1]/adverseEventAssessment<br>[1]/@classCode=INVSIG][@moodCode=EVN]/subject[1]/@typeCode=SBJ][1]/primaryRole[@classC<br>ode=INVSBJ]/subjectC2[1]/@typeCode=SBJ][organizerCode=@code=2][@codeSystem=2.16.840.1<br>.113883.3.989.2.1.1.20][1]/organizer[1]/instanceOfKind[@classCode=EVN]/component[<br>@typeCode=COMP][substanceAdministration][@typeCode=CSMT][1]/instanceOfKind[@classCode=SBADM][<br>@moodCode=EVN]/consumable[1]/@determinerCode=KIND][name]/text]  |
| e | D.8.r.2b | 医薬品製品識別子 (MPID)                | M5 ガイド<br>を参照 | Coded With<br>Equivalents (CE) | 値           | /MCCI_IN200100UV01@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3<br>MCCI_IN200100UV01.xsd]/PORR_IN049016UV01/controlActProcess[@classCode=CACTI][@moodCo<br>dCode=EVEN]/subject[@typeCode=SUBJ]/investigationEvent[@classCode=INVSIG][@moodCo<br>dCode=EVEN]/component[@typeCode=COMP]/adverseEventAssessment[1]/adverseEventAssessment<br>[1]/@classCode=INVSIG][@moodCode=EVN]/subject[1]/@typeCode=SBJ][1]/primaryRole[@classC<br>ode=INVSBJ]/subjectC2[1]/@typeCode=SBJ][organizerCode=@code=2][@codeSystem=2.16.840.1<br>.113883.3.989.2.1.1.20][1]/organizer[1]/instanceOfKind[@classCode=EVN]/component[<br>@typeCode=COMP][substanceAdministration][@typeCode=CSMT][1]/instanceOfKind[@classCode=SBADM][<br>@moodCode=EVN]/consumable[1]/@typeCode=CSMT][1]/instanceOfKind[@classCode=INST]/kindO<br>fProduct[@classCode=MMA][1]/@determinerCode=KIND][code]/codeSystem=TBD-MPID]/@cod<br>eSystemVersion] |

(別添 3)

|   |          |                  |               |  |   |   |
|---|----------|------------------|---------------|--|---|---|
| e | D.8.r.3a | PhPID パージョン日付/番号 | M5 ガイド<br>を参照 | Coded With<br>Equivalents (CE)         | codeSystemVersion=<br>Character String (ST) | /MCCI_IN200100UV01[@ITSVersion=XML_1.0T][@xsi:schemaLocation=urn:hl7-org:v3<br>MCCI_IN200100UV01.xsd]/P/RR_IN049016UV1/controlActProcess[@classCode=CACTI][@moo<br>dCode=EVN]/subject/@typeCode=SUBJ11/investigationEvent/@classCode=INVESTG11/@moodCo<br>de=EVN/component/@typeCode=COMP11/adverseEventAssessment[1]/adverseEventAssessment<br>[1]/classCode=INVESTG11/@moodCode=EVN/subject/@typeCode=SBJ11/primaryRole/@classC<br>ode=INVSBJ1/subjectOf2/@typeCode=SBJ1/organizer/code/@code=21/@codeSystem=2.16.840.1<br>.113883.3.989.2.1.1.2011/organizer/@classCode=CATEGORY11/@moodCode=EVN/component<br>[1]/typeCode=COMP11/substanceAdministration[1]/substanceAdministration/@classCode=SBADM11<br>/@moodCode=EVN/consumable/@typeCode=CSM11/@instanceOfKindOf/@classCode=INST11/kinD<br>OfProduct/@classCode=MMA11/@determinerCode=KIND11/code/@codeSystem=TBD-PHPID11/@cod<br>eSystemVersion |
| e | D.8.r.3b | 薬剤識別子 (PhPID)    | M5 ガイド<br>を参照 | Coded With<br>Equivalents (CE)         | code=Character<br>String (ST)               | /MCCI_IN200100UV01[@ITSVersion=XML_1.0T][@xsi:schemaLocation=urn:hl7-org:v3<br>MCCI_IN200100UV01.xsd]/P/RR_IN049016UV1/controlActProcess[@classCode=CACTI][@moo<br>dCode=EVN]/subject/@typeCode=SUBJ11/investigationEvent/@classCode=INVESTG11/@moodCo<br>de=EVN/component/@typeCode=COMP11/adverseEventAssessment[1]/adverseEventAssessment<br>[1]/classCode=INVESTG11/@moodCode=EVN/subject/@typeCode=SBJ11/primaryRole/@classC<br>ode=INVSBJ1/subjectOf2/@typeCode=SBJ1/organizer/code/@code=21/@codeSystem=2.16.840.1<br>.113883.3.989.2.1.1.2011/organizer/@classCode=CATEGORY11/@moodCode=EVN/component<br>[1]/typeCode=COMP11/substanceAdministration[1]/substanceAdministration/@classCode=SBADM11<br>/@moodCode=EVN/consumable/@typeCode=CSM11/@instanceOfKindOf/@classCode=INST11/kinD<br>OfProduct/@classCode=MMA11/@determinerCode=KIND11/code/@codeSystem=TBD-PHPID11/@cod<br>eSystemVersion |
| e | D.8.r.4  | 開始日              | 日付/時間         | Interval of Point in<br>Time (IVL<TS>) | low=Interval<br>Boundary (IVXB)             | /MCCI_IN200100UV01[@ITSVersion=XML_1.0T][@xsi:schemaLocation=urn:hl7-org:v3<br>MCCI_IN200100UV01.xsd]/P/RR_IN049016UV1/controlActProcess[@classCode=CACTI][@moo<br>dCode=EVN]/subject/@typeCode=SUBJ11/investigationEvent/@classCode=INVESTG11/@moodCo<br>de=EVN/component/@typeCode=COMP11/adverseEventAssessment[1]/adverseEventAssessment<br>[1]/classCode=INVESTG11/@moodCode=EVN/subject/@typeCode=SBJ11/primaryRole/@classC<br>ode=INVSBJ1/subjectOf2/@typeCode=SBJ1/organizer/code/@code=21/@codeSystem=2.16.840.1<br>.113883.3.989.2.1.1.2011/organizer/@classCode=CATEGORY11/@moodCode=EVN/component<br>[1]/typeCode=COMP11/substanceAdministration[1]/substanceAdministration/@classCode=SBADM11<br>/@moodCode=EVN/reflectiveTime/@xsi:type=IVL_TS11/low/@value   |
| e |          |                  |               |  | NullFlavor                                  | /MCCI_IN200100UV01[@ITSVersion=XML_1.0T][@xsi:schemaLocation=urn:hl7-org:v3<br>MCCI_IN200100UV01.xsd]/P/RR_IN049016UV1/controlActProcess[@classCode=CACTI][@moo<br>dCode=EVN]/subject/@typeCode=SUBJ11/investigationEvent/@classCode=INVESTG11/@moodCo<br>de=EVN/component/@typeCode=COMP11/adverseEventAssessment[1]/adverseEventAssessment<br>[1]/classCode=INVESTG11/@moodCode=EVN/subject/@typeCode=SBJ11/primaryRole/@classC<br>ode=INVSBJ1/subjectOf2/@typeCode=SBJ1/organizer/code/@code=21/@codeSystem=2.16.840.1<br>.113883.3.989.2.1.1.2011/organizer/@classCode=CATEGORY11/@moodCode=EVN/component<br>[1]/typeCode=COMP11/substanceAdministration[1]/substanceAdministration/@classCode=SBADM11<br>/@moodCode=EVN/reflectiveTime/@xsi:type=IVL_TS11/low/@value   |
| e | D.8.r.5  | 終了日              | 日付/時間         | Interval of Point in<br>Time (IVL<TS>) | high=Interval<br>Boundary (IVXB)            | /MCCI_IN200100UV01[@ITSVersion=XML_1.0T][@xsi:schemaLocation=urn:hl7-org:v3<br>MCCI_IN200100UV01.xsd]/P/RR_IN049016UV1/controlActProcess[@classCode=CACTI][@moo<br>dCode=EVN]/subject/@typeCode=SUBJ11/investigationEvent/@classCode=INVESTG11/@moodCo<br>de=EVN/component/@typeCode=COMP11/adverseEventAssessment[1]/adverseEventAssessment<br>[1]/classCode=INVESTG11/@moodCode=EVN/subject/@typeCode=SBJ11/primaryRole/@classC<br>ode=INVSBJ1/subjectOf2/@typeCode=SBJ1/organizer/code/@code=21/@codeSystem=2.16.840.1<br>.113883.3.989.2.1.1.2011/organizer/@classCode=CATEGORY11/@moodCode=EVN/component<br>[1]/typeCode=COMP11/substanceAdministration[1]/substanceAdministration/@classCode=SBADM11<br>/@moodCode=EVN/reflectiveTime/@xsi:type=IVL_TS11/high/@value  |

(別添3)

|   |          |                    |     |   |  |   |
|---|----------|--------------------|-----|---|--|---|
| e |          |                    |     | NullFlavor  | <pre> /MCCL_IN200100UV01@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 /MCCL_IN200100UV01.xsd]/PDRR_IN049016UV01/controlActProcess/@classCode=CACTI][@moodCode=EVN]/subject/@typeCode=SUBJ][/investigationEvent/@classCode=INVSSTG][@moodCode=EVN]/component/@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment[1]/classCode=INVSSTG][@moodCode=EVN]/subject/@typeCode=EVN]/organizer/@code=2][@codeSystem=2.16.840.1.113883.3.989.2.1.1.20][/organizer/@classCode=CATEGORY][@moodCode=EVN]/component/@typeCode=COMP][substanceAdministration[1]/substanceAdministration/@classCode=SBADM][@moodCode=EVN]/effectiveTime/@xsi:type=IVL_TS][high/@nullFlavor </pre> |   |
| e | D.8.r.6a | 使用理由の MedDRA パージョン | 4AN | Coded With Equivalents (CE)<br>codeSystemVersion= Character String (ST) | 値  | <pre> /MCCL_IN200100UV01@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 /MCCL_IN200100UV01.xsd]/PDRR_IN049016UV01/controlActProcess/@classCode=CACTI][@moodCode=EVN]/subject/@typeCode=SUBJ][/investigationEvent/@classCode=INVSSTG][@moodCode=EVN]/component/@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment[1]/classCode=INVSSTG][@moodCode=EVN]/subject1/@typeCode=SBJ][/primaryRole/@classCode=INVSSTG][@moodCode=EVN]/organizer/@code=2][@codeSystem=2.16.840.1.113883.3.989.2.1.1.20][/organizer/@classCode=CATEGORY][@moodCode=EVN]/component/@typeCode=COMP][substanceAdministration[1]/substanceAdministration/@classCode=SBADM][@moodCode=EVN]/outboundRelationship2/@typeCode=RSON][observation/@code=19][@codeSystem=2.16.840.1.113883.3.989.2.1.1.19][/observation/@classCode=OBS][@moodCode=EVN]/value/@xsi:type=CE][@codeSystem=2.16.840.1.113883.6.163][/][@codeSystemVersion </pre> |
| e | D.8.r.6b | 使用理由 (MedDRA コード)  | 8N  | Coded With Equivalents (CE)<br>code=Character String (ST)               | 値  | <pre> /MCCL_IN200100UV01@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 /MCCL_IN200100UV01.xsd]/PDRR_IN049016UV01/controlActProcess/@classCode=CACTI][@moodCode=EVN]/subject/@typeCode=SUBJ][/investigationEvent/@classCode=INVSSTG][@moodCode=EVN]/component/@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment[1]/classCode=INVSSTG][@moodCode=EVN]/subject/@typeCode=SBJ][/primaryRole/@classCode=INVSSTG][@moodCode=EVN]/organizer/@code=2][@codeSystem=2.16.840.1.113883.3.989.2.1.1.20][/organizer/@classCode=CATEGORY][@moodCode=EVN]/component/@typeCode=COMP][substanceAdministration[1]/substanceAdministration/@classCode=SBADM][@moodCode=EVN]/outboundRelationship2/@typeCode=RSON][observation/@code=19][@codeSystem=2.16.840.1.113883.3.989.2.1.1.19][/observation/@classCode=OBS][@moodCode=EVN]/value/@xsi:type=CE][@codeSystem=2.16.840.1.113883.6.163][/][@codeSystemVersion </pre>  |
| e | D.8.r.7a | 副作用の MedDRA パージョン  | 4AN | Coded With Equivalents (CE)<br>codeSystemVersion= Character String (ST) | 値  | <pre> /MCCL_IN200100UV01@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 /MCCL_IN200100UV01.xsd]/PDRR_IN049016UV01/controlActProcess/@classCode=CACTI][@moodCode=EVN]/subject/@typeCode=SUBJ][/investigationEvent/@classCode=INVSSTG][@moodCode=EVN]/component/@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment[1]/classCode=INVSSTG][@moodCode=EVN]/subject1/@typeCode=SBJ][/primaryRole/@classCode=INVSSTG][@moodCode=EVN]/organizer/@code=2][@codeSystem=2.16.840.1.113883.3.989.2.1.1.20][/organizer/@classCode=CATEGORY][@moodCode=EVN]/component/@typeCode=COMP][substanceAdministration[1]/substanceAdministration/@classCode=SBADM][@moodCode=EVN]/outboundRelationship2/@typeCode=RSON][observation/@code=29][@codeSystem=2.16.840.1.113883.3.989.2.1.1.19][/observation/@classCode=OBS][@moodCode=EVN]/value/@xsi:type=CE][@codeSystem=2.16.840.1.113883.6.163][/][@codeSystemVersion </pre> |

(別添 3)

|   |            |                       |       |                             |   |             |  |
|---|------------|-----------------------|-------|-----------------------------|---|-------------|--|
| e | D.8.r.7b   | 副作用 (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'/P/PORR_IN049016UV01/controlActProcess[@classCode='CACTI']/@moodCode='EVN']/subject/@typeCode='SUBJ']/investigationEvent[@classCode='INVSIG']/@moodCode='EVN']/component/@typeCode='COMP']/adverseEventAssessment[1]/adverseEventAssessment[@classCode='INVSIG']/@moodCode='EVN']/subject[1]/@typeCode='SBJ']/primaryRole[1]/@classCode='INVSBJ']/subjectOf2/@typeCode='SBJ']/organizer/@code='2.16.840.1.113883.3.989.2.1.1.20']/organizer/@classCode='CAIEGORY']/@moodCode='EVN']/component[1]/@typeCode='COMP']/substanceAdministration[1]/substanceAdministration[@classCode='SBADM']/@moodCode='EVN']/boundRelationship[2]/@typeCode='CAUS']/observation/@code='29']/@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']/observation/@classCode='OBS']/@moodCode='EVN']/value/@xsi:type='CE']/@codeSystem='2.16.840.1.113883.6.163']]/@code         </pre> |
| h | D.9        | 死亡の場合                 |       |                             |   |             |  |
| e | D.9.1      | 死亡日                   | 日付/時間 | Point in Time (TS)          |   | 値           | <pre> /MCCL_IN200100UV01[@ITSVersion='XML_1.0']/@xsi:schemaLocation='urn:hl7-org:v3 /MCCL_IN200100UV01.xsd'/P/PORR_IN049016UV01/controlActProcess[@classCode='CACTI']/@moodCode='EVN']/subject/@typeCode='SUBJ']/investigationEvent[@classCode='INVSIG']/@moodCode='EVN']/component/@typeCode='COMP']/adverseEventAssessment[1]/adverseEventAssessment[@classCode='INVSIG']/@moodCode='EVN']/subject[1]/@typeCode='SBJ']/primaryRole[1]/@classCode='INVSBJ']/player[1]/@classCode='PSN']/@determinerCode='INSTANCE']/deceasedTime/@value         </pre>  |
| e |            |                       |       |                             |   | NullFlavor  | <pre> /MCCL_IN200100UV01[@ITSVersion='XML_1.0']/@xsi:schemaLocation='urn:hl7-org:v3 /MCCL_IN200100UV01.xsd'/P/PORR_IN049016UV01/controlActProcess[@classCode='CACTI']/@moodCode='EVN']/subject/@typeCode='SUBJ']/investigationEvent[@classCode='INVSIG']/@moodCode='EVN']/component/@typeCode='COMP']/adverseEventAssessment[1]/adverseEventAssessment[@classCode='INVSIG']/@moodCode='EVN']/subject[1]/@typeCode='SBJ']/primaryRole[1]/@classCode='INVSBJ']/player[1]/@classCode='PSN']/@determinerCode='INSTANCE']/deceasedTime/@value         </pre>  |
| h | D.9.2.r    | 報告された死因 (必要に応じて繰り返す)  |       |                             |   | 繰り返し<br>ノード | <pre> /MCCL_IN200100UV01[@ITSVersion='XML_1.0']/@xsi:schemaLocation='urn:hl7-org:v3 /MCCL_IN200100UV01.xsd'/P/PORR_IN049016UV01/controlActProcess[@classCode='CACTI']/@moodCode='EVN']/subject/@typeCode='SUBJ']/investigationEvent[@classCode='INVSIG']/@moodCode='EVN']/component/@typeCode='COMP']/adverseEventAssessment[1]/adverseEventAssessment[@classCode='INVSIG']/@moodCode='EVN']/subject[1]/@typeCode='SBJ']/primaryRole[1]/@classCode='INVSBJ']/subjectOf2/@typeCode='SBJ']/jobObservation/@code='32']/@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']         </pre>   |
| e | D.9.2.r.1a | 報告された死因の 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:hl7-org:v3 /MCCL_IN200100UV01.xsd'/P/PORR_IN049016UV01/controlActProcess[@classCode='CACTI']/@moodCode='EVN']/subject/@typeCode='SUBJ']/investigationEvent[@classCode='INVSIG']/@moodCode='EVN']/component/@typeCode='COMP']/adverseEventAssessment[1]/adverseEventAssessment[@classCode='INVSIG']/@moodCode='EVN']/subject[1]/@typeCode='SBJ']/primaryRole[1]/@classCode='INVSBJ']/subjectOf2/@typeCode='SBJ']/jobObservation/@code='32']/@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']/jobObservation/@classCode='OBS']/@moodCode='EVN']/value/@xsi:type='CE']/@codeSystem='2.16.840.1.113883.6.163']]/@codeSystemVersion         </pre>  |
| e | D.9.2.r.1b | 報告された死因 (MedDRA コード)  | 8N    | Coded With Equivalents (CE) | code=Character String (ST)              | 値           | <pre> /MCCL_IN200100UV01[@ITSVersion='XML_1.0']/@xsi:schemaLocation='urn:hl7-org:v3 /MCCL_IN200100UV01.xsd'/P/PORR_IN049016UV01/controlActProcess[@classCode='CACTI']/@moodCode='EVN']/subject/@typeCode='SUBJ']/investigationEvent[@classCode='INVSIG']/@moodCode='EVN']/component/@typeCode='COMP']/adverseEventAssessment[1]/adverseEventAssessment[@classCode='INVSIG']/@moodCode='EVN']/subject[1]/@typeCode='SBJ']/primaryRole[1]/@classCode='INVSBJ']/subjectOf2/@typeCode='SBJ']/jobObservation/@code='32']/@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']/jobObservation/@classCode='OBS']/@moodCode='EVN']/value/@xsi:type='CE']/@codeSystem='2.16.840.1.113883.6.163']]/@code         </pre>   |

(別添3)

|   |   |  |  |  |  |  |  |
|---|---|--|--|--|--|--|--|
| <p>e</p> <p>D.9.2.r.2</p> <p>報告された死因 (自由記載)</p> <p>250AN</p> <p>Coded With Equivalents (CE)</p> <p>originalText = Encapsulated Data (ED)</p> <p>値</p>               | <pre>/MCCL_IN200100UV01@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]PDRR_IN049016UV[controlActProcess @classCode=CACTI][@moo dCode=EVN]/subject/@typeCode=SUBJ[adverseEventAssessment @classCode=INVSIG][@moodCo de=EVN]/component/@typeCode=COMP[adverseEventAssessment 1/adverseEventAssessment  @classCode=INVSIG][@moodCode=EVN]/subject1/@typeCode=SBJ[1/primaryRole @classC ode=INVSBJ]/subjectOrZ/@typeCode=SBJ[observation/code @code=5][@codeSystem=2.16.8 40.1.113883.3.989.2.1.1.19][1/observation @classCode=OBS][@moodCode=EVN]/value/@xsi:ty pe=CE][@codeSystem=2.16.840.1.113883.6.163][1]originalText&lt;/pre&gt; </pre> |  |  |  |  |  |  |
| <p>e</p> <p>D.9.3</p> <p>割検は実施されたか?</p> <p>ブール型</p> <p>Boolean (BL)</p> <p>値</p>  | <pre>/MCCL_IN200100UV01@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]PDRR_IN049016UV[controlActProcess @classCode=CACTI][@moo dCode=EVN]/subject/@typeCode=SUBJ[1/investigationEvent @classCode=INVSIG][@moodCo de=EVN]/component/@typeCode=COMP[adverseEventAssessment 1/adverseEventAssessment  @classCode=INVSIG][@moodCode=EVN]/subject1/@typeCode=SBJ[1/primaryRole @classC ode=INVSBJ]/subjectOrZ/@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:ty pe=BL][1]/value&lt;/pre&gt; </pre>  |  |  |  |  |  |  |
| <p>e</p> <p>D.9.4.r</p> <p>割検による死因 (必要に依り<br/>繰り返す)</p> <p>ブール型</p> <p>Boolean (BL)</p> <p>NullFlavor</p> <p>値</p>  | <pre>/MCCL_IN200100UV01@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]PDRR_IN049016UV[controlActProcess @classCode=CACTI][@moo dCode=EVN]/subject/@typeCode=SUBJ[1/investigationEvent @classCode=INVSIG][@moodCo de=EVN]/component/@typeCode=COMP[adverseEventAssessment 1/adverseEventAssessment  @classCode=INVSIG][@moodCode=EVN]/subject1/@typeCode=SBJ[1/primaryRole @classC ode=INVSBJ]/subjectOrZ/@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:ty pe=BL][1]/nullFlavor&lt;/pre&gt; </pre>   |  |  |  |  |  |  |
| <p>h</p> <p>D.9.4.r.1a</p> <p>割検による死因 (必要に依り<br/>繰り返す)</p> <p>ブール型</p> <p>Boolean (BL)</p> <p>繰り返し<br/>ノード</p> <p>値</p>   | <pre>/MCCL_IN200100UV01@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]PDRR_IN049016UV[controlActProcess @classCode=CACTI][@moo dCode=EVN]/subject/@typeCode=SUBJ[1/investigationEvent @classCode=INVSIG][@moodCo de=EVN]/component/@typeCode=COMP[adverseEventAssessment 1/adverseEventAssessment  @classCode=INVSIG][@moodCode=EVN]/subject1/@typeCode=SBJ[1/primaryRole @classC ode=INVSBJ]/subjectOrZ/@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:ty pe=BL][1]/value&lt;/pre&gt; </pre>  |  |  |  |  |  |  |
| <p>e</p> <p>D.9.4.r.1a</p> <p>割検による死因の MedDRA<br/>バージョン</p> <p>4AN</p> <p>Coded With Equivalents (CE)</p> <p>codeSystemVersion = Character String (ST)</p> <p>値</p> | <pre>/MCCL_IN200100UV01@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]PDRR_IN049016UV[controlActProcess @classCode=CACTI][@moo dCode=EVN]/subject/@typeCode=SUBJ[1/investigationEvent @classCode=INVSIG][@moodCo de=EVN]/component/@typeCode=COMP[adverseEventAssessment 1/adverseEventAssessment  @classCode=INVSIG][@moodCode=EVN]/subject1/@typeCode=SBJ[1/primaryRole @classC ode=INVSBJ]/subjectOrZ/@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:ty pe=CE][@codeSystem=2.16.840.1.113883.6.163][1]originalText&lt;/pre&gt; </pre>   |  |  |  |  |  |  |

(別添3)

|   |            |                       |       |                             |                                       |            |   |
|---|------------|-----------------------|-------|-----------------------------|---------------------------------------|------------|---|
| e | D.9.4.r.1b | 剖検による死因 (MedDRA コード)  | 8N    | Coded With Equivalents (OE) | code=Character String (ST)            | 値          | /MCC1_IN200100UV01[@ITSVersion='XML_1.0']/@xsi:schemaLocation='urn:hl7-org:v3:MCC1_IN200100UV01.xsd'  P ORR_IN049016UV01[controlActProcess/@classCode='CACTI']  @moodCode='EVN'  subject[ @typeCode='SUBJ']  investigationEvent[ @classCode='INVESTG']  @moodCode='EVN'  component[ @typeCode='COMP']  adverseEventAssessment[1]  adverseEventAssessment[ @classCode='INVESTG']  @moodCode='EVN'  subject[ @typeCode='SUBJ']  primaryRole[ @classCode='INVSBJ']  subject[ @typeCode='SUBJ']  observation[ @code='5']  @codeSystem='2.16.84.0.1.113883.3.999.2.1.1.19'  observation[ @classCode='OBS']  @moodCode='EVN'  youthboundRelationship2[ @typeCode='DRIV']  observation[ @code='8']  @codeSystem='2.16.84.0.1.113883.3.999.2.1.1.19'  observation[ @classCode='OBS']  @moodCode='EVN'  value[ @xsi:type='CE']  @codeSystem='2.16.84.0.1.113883.6.163']  @code               |
| e | D.9.4.r.2  | 剖検による死因 (自由記載)        | 250AN | Coded With Equivalents (OE) | originalText = Encapsulated Data (ED) | 値          | /MCC1_IN200100UV01[@ITSVersion='XML_1.0']/@xsi:schemaLocation='urn:hl7-org:v3:MCC1_IN200100UV01.xsd'  P ORR_IN049016UV01[controlActProcess/@classCode='CACTI']  @moodCode='EVN'  subject[ @typeCode='SUBJ']  investigationEvent[ @classCode='INVESTG']  @moodCode='EVN'  component[ @typeCode='COMP']  adverseEventAssessment[1]  adverseEventAssessment[ @classCode='INVESTG']  @moodCode='EVN'  subject[ @typeCode='SUBJ']  primaryRole[ @classCode='INVSBJ']  subject[ @typeCode='SUBJ']  observation[ @code='5']  @codeSystem='2.16.84.0.1.113883.3.999.2.1.1.19'  observation[ @classCode='OBS']  @moodCode='EVN'  youthboundRelationship2[ @typeCode='DRIV']  observation[ @code='8']  @codeSystem='2.16.84.0.1.113883.3.999.2.1.1.19'  observation[ @classCode='OBS']  @moodCode='EVN'  value[ @xsi:type='CE']  @codeSystem='2.16.84.0.1.113883.6.163']  @originalText(text) |
| h | D.10       | 第一子/胎児報告における、 妻に関する情報 |       |                             |                                       |            |   |
| e | D.10.1     | 妻の識別                  | 60AN  | Entity Name (EN)            | name=Entity Name Part (ENXP)          | 値          | /MCC1_IN200100UV01[@ITSVersion='XML_1.0']/@xsi:schemaLocation='urn:hl7-org:v3:MCC1_IN200100UV01.xsd'  P ORR_IN049016UV01[controlActProcess/@classCode='CACTI']  @moodCode='EVN'  subject[ @typeCode='SUBJ']  investigationEvent[ @classCode='INVESTG']  @moodCode='EVN'  component[ @typeCode='COMP']  adverseEventAssessment[1]  adverseEventAssessment[ @classCode='INVESTG']  @moodCode='EVN'  subject[ @typeCode='SUBJ']  primaryRole[ @classCode='INVSBJ']  player1[ @classCode='PSNI']  @determinerCode='INSTANCE'  role[ @classCode='PR S']  associatedPerson[ @classCode='PSNI']  @determinerCode='INSTANCE'  name[1]  text()   |
| e |            |                       |       |                             |                                       | NullFlavor | /MCC1_IN200100UV01[@ITSVersion='XML_1.0']/@xsi:schemaLocation='urn:hl7-org:v3:MCC1_IN200100UV01.xsd'  P ORR_IN049016UV01[controlActProcess/@classCode='CACTI']  @moodCode='EVN'  subject[ @typeCode='SUBJ']  investigationEvent[ @classCode='INVESTG']  @moodCode='EVN'  component[ @typeCode='COMP']  adverseEventAssessment[1]  adverseEventAssessment[ @classCode='INVESTG']  @moodCode='EVN'  subject[ @typeCode='SUBJ']  primaryRole[ @classCode='INVSBJ']  player1[ @classCode='PSNI']  @determinerCode='INSTANCE'  role[ @classCode='PR S']  associatedPerson[ @classCode='PSNI']  @determinerCode='INSTANCE'  name[1]  @nullFlavor  |
| h | D.10.2     | 妻の年齢情報                |       |                             |                                       |            |   |
| e | D.10.2.1   | 妻の生年月日                | 日付/時間 | Point in Time (TS)          |                                       | 値          | /MCC1_IN200100UV01[@ITSVersion='XML_1.0']/@xsi:schemaLocation='urn:hl7-org:v3:MCC1_IN200100UV01.xsd'  P ORR_IN049016UV01[controlActProcess/@classCode='CACTI']  @moodCode='EVN'  subject[ @typeCode='SUBJ']  investigationEvent[ @classCode='INVESTG']  @moodCode='EVN'  component[ @typeCode='COMP']  adverseEventAssessment[1]  adverseEventAssessment[ @classCode='INVESTG']  @moodCode='EVN'  subject[ @typeCode='SUBJ']  primaryRole[ @classCode='INVSBJ']  player1[ @classCode='PSNI']  @determinerCode='INSTANCE'  role[ @classCode='PR S']  associatedPerson[ @classCode='PSNI']  @determinerCode='INSTANCE'  birthTime[ @value   |

(別添3)

|   |           |           |       |  |   |            |   |
|---|-----------|-----------|-------|--|---|------------|---|
| e |           |           |       | Physical Quantity (PQ)                                 | 値 | NullFlavor | /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]JPORR_IN049076UVJ/controlActProcess[@classCode=CACTI][@moodCode=EVN]/subject/@typeCode=SUBJ/InvestigationEvent[@classCode=INVTG][@moodCode=EVN]/component/@typeCode=COMP/AdverseEventAssessment[1]/AdverseEventAssessment[@classCode=INVTG][@moodCode=EVN]/subject[1]/typeCode=SBJ/primaryRole/@classCode=INVSBJ/player[1]/classCode=PSN/@determinerCode=INSTANCE/role/@classCode=PRST/associatedPerson/@classCode=PSN/@determinerCode=INSTANCE/dateTime/@nullFlavor   |
| e | D.10.2.2a | 親の年齢 (歳)  | 3N    | Physical Quantity (PQ)<br>value=Real Number (REAL)     | 値 | NullFlavor | /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]JPORR_IN049076UVJ/controlActProcess[@classCode=CACTI][@moodCode=EVN]/subject/@typeCode=SUBJ/InvestigationEvent[@classCode=INVTG][@moodCode=EVN]/component/@typeCode=COMP/AdverseEventAssessment[1]/AdverseEventAssessment[@classCode=INVTG][@moodCode=EVN]/subject[1]/typeCode=SBJ/primaryRole/@classCode=INVSBJ/player[1]/classCode=PSN/@determinerCode=INSTANCE/role/@classCode=PRST/subjectOf2/@typeCode=SBJ/observation/code/@code=3/@codeSystem=2.16.840.1.11388.3.3.989.2.1.1.19/observation/@classCode=OBS/@moodCode=EVN/value/@xsi:type=PQ[1]/@value       |
| e | D.10.2.2b | 親の年齢 (単位) | 50AN  | Physical Quantity (PQ)<br>unit=Coded Simple Value (CS) | 値 | NullFlavor | /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]JPORR_IN049076UVJ/controlActProcess[@classCode=CACTI][@moodCode=EVN]/subject/@typeCode=SUBJ/InvestigationEvent[@classCode=INVTG][@moodCode=EVN]/component/@typeCode=COMP/AdverseEventAssessment[1]/AdverseEventAssessment[@classCode=INVTG][@moodCode=EVN]/subject[1]/typeCode=SBJ/primaryRole/@classCode=INVSBJ/player[1]/classCode=PSN/@determinerCode=INSTANCE/role/@classCode=PRST/subjectOf2/@typeCode=SBJ/observation/code/@code=3/@codeSystem=2.16.840.1.11388.3.3.989.2.1.1.19/observation/@classCode=OBS/@moodCode=EVN/value/@xsi:type=PQ[1]/@unit        |
| e | D.10.3    | 親の最終月経日   | 日付/時間 | Point in Time (TS)                                     | 値 | NullFlavor | /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]JPORR_IN049076UVJ/controlActProcess[@classCode=CACTI][@moodCode=EVN]/subject/@typeCode=SUBJ/InvestigationEvent[@classCode=INVTG][@moodCode=EVN]/component/@typeCode=COMP/AdverseEventAssessment[1]/AdverseEventAssessment[@classCode=INVTG][@moodCode=EVN]/subject[1]/typeCode=SBJ/primaryRole/@classCode=INVSBJ/player[1]/classCode=PSN/@determinerCode=INSTANCE/role/@classCode=PRST/subjectOf2/@typeCode=SBJ/observation/code/@code=22/@codeSystem=2.16.840.1.11388.3.3.989.2.1.1.19/observation/@classCode=OBS/@moodCode=EVN/value/@xsi:type=TS[1]/@value      |
| e |           |           |       | Physical Quantity (PQ)                                 | 値 | NullFlavor | /MCCI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCI_IN200100UV01.xsd]JPORR_IN049076UVJ/controlActProcess[@classCode=CACTI][@moodCode=EVN]/subject/@typeCode=SUBJ/InvestigationEvent[@classCode=INVTG][@moodCode=EVN]/component/@typeCode=COMP/AdverseEventAssessment[1]/AdverseEventAssessment[@classCode=INVTG][@moodCode=EVN]/subject[1]/typeCode=SBJ/primaryRole/@classCode=INVSBJ/player[1]/classCode=PSN/@determinerCode=INSTANCE/role/@classCode=PRST/subjectOf2/@typeCode=SBJ/observation/code/@code=22/@codeSystem=2.16.840.1.11388.3.3.989.2.1.1.19/observation/@classCode=OBS/@moodCode=EVN/value/@xsi:type=TS[1]/@nullFlavor |

(別添 3)

|   |            |                              |    |                             |                            |             |  |
|---|------------|------------------------------|----|-----------------------------|----------------------------|-------------|--|
| e | D.10.4     | 親の体重 (kg)                    | 6N | Physical Quantity (PQ)      | value=Real Number (REAL)   | 値           | <pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/P/RR_IN049016UV1/controlAct/process[@classCode=CACTI][@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 ST1]/subjectOf2[@typeCode=SBJ]/observation/code[@code=7][@codeSystem=2.16.840.1.11388 3.3.989.2.1.1.19][@value] @unit=kg][@value </pre>                   |
| e | D.10.5     | 親の身長 (cm)                    | 3N | Physical Quantity (PQ)      | value=Real Number (REAL)   | 値           | <pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/P/RR_IN049016UV1/controlAct/process[@classCode=CACTI][@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 ST1]/subjectOf2[@typeCode=SBJ]/observation/code[@code=17][@codeSystem=2.16.840.1.11388 3.3.989.2.1.1.19][@value] @unit=cm][@value </pre>                  |
| e | D.10.6     | 親の性別                         | 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]/P/RR_IN049016UV1/controlAct/process[@classCode=CACTI][@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 ST1]/associatedPerson[@classCode=PSN][@determinerCode=INSTANCE]/administrativeGender Code[@codeSystem=1.0.5218][@value] </pre>                            |
| e |            |                              |    |                             | NullFlavor                 |             | <pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/P/RR_IN049016UV1/controlAct/process[@classCode=CACTI][@moo dCode=EVN]/component[@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 ST1]/associatedPerson[@classCode=PSN][@determinerCode=INSTANCE]/administrativeGender Code[@codeSystem=1.0.5218][@nullFlavor] </pre>                     |
| h | D.10.7     | 親の関連する治療歴及び随<br>件症状          |    |                             |                            |             |  |
| h | D.10.7.1.r | 親の構造化された情報 (必要<br>に応じ繰り返し返す) |    |                             |                            | 繰り返し<br>ノード | <pre> /MCCL_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCL_IN200100UV01.xsd]/P/RR_IN049016UV1/controlAct/process[@classCode=CACTI][@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 ST1]/subjectOf2[@typeCode=SBJ]/organizer/code[@code=1][@codeSystem=2.16.840.1.113883. 3.989.2.1.1.20][@value] @codeSystem=2.16.840.1.113883.6.163] </pre> |



(別添3)

|   |               |  |       |                                    |   |   |  |
|---|---------------|--|-------|------------------------------------|---|---|--|
| e | D.10.7.1.r.1a | 病の関連する治療歴及び随伴症状の MedDRA パージョン              | 4AN   | Concept Descriptor (CD)            | codeSystemVersion=Character String (ST) | 値 | /MCCLI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCLI_IN200100UV01.xsd]/PDRR_IN049016UVI/controlActProcess[@classCode=CACTI][@moodCode=EVN]/component[@typeCode=COMP][adverseEventAssessment][adverseEventAssessment][@classCode=INVSSTG][@moodCode=SUBJ][investigationEvent][@classCode=INVSSTG][@moodCode=EVN]/subject[@typeCode=EVN]/subject[@typeCode=SBJ][primaryRole][@classCode=INVSBJ/player][@classCode=PSN][determinerCode=INSTANCE]/role[@classCode=PR ST]/subjectOf2[@typeCode=SBJ]/organizer/code[@code=1][@codeSystem=2.16.840.1.113883.3.989.2.1.1.20][organizer/@classCode=CATEGORY][@moodCode=EVN]/component[@typeCode=COMP][observation/code][@codeSystem=2.16.840.1.113883.6.163][observation/@classCode=OBS][@moodCode=EVN]/code/@code |
| e | D.10.7.1.r.1b | 病の関連する治療歴及び随伴症状 (疾病/手術処置/その他) (MedDRA コード) | 8N    | Concept Descriptor (CD)            | code=Character String (ST)              | 値 | /MCCLI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCLI_IN200100UV01.xsd]/PDRR_IN049016UVI/controlActProcess[@classCode=CACTI][@moodCode=EVN]/subject[@typeCode=SUBJ][investigationEvent][@classCode=INVSSTG][@moodCode=EVN]/component[@typeCode=COMP][adverseEventAssessment][adverseEventAssessment][@classCode=INVSSTG][@moodCode=SUBJ][primaryRole][@classCode=INVSBJ/player][@classCode=PSN][determinerCode=INSTANCE]/role[@classCode=PR ST]/subjectOf2[@typeCode=SBJ]/organizer/code[@code=1][@codeSystem=2.16.840.1.113883.3.989.2.1.1.20][organizer/@classCode=CATEGORY][@moodCode=EVN]/component[@typeCode=COMP][observation/code][@codeSystem=2.16.840.1.113883.6.163][observation/@classCode=OBS][@moodCode=EVN]/code/@code                       |
| e | D.10.7.1.r.2  | 開始日  | 日付/時間 | Interval of Point in Time (VL<TS>) | low=Interval Boundary (VXB)             | 値 | /MCCLI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCLI_IN200100UV01.xsd]/PDRR_IN049016UVI/controlActProcess[@classCode=CACTI][@moodCode=EVN]/component[@typeCode=COMP][adverseEventAssessment][adverseEventAssessment][@classCode=INVSSTG][@moodCode=SUBJ][primaryRole][@classCode=INVSBJ/player][@classCode=PSN][determinerCode=INSTANCE]/role[@classCode=PR ST]/subjectOf2[@typeCode=SBJ]/organizer/code[@code=1][@codeSystem=2.16.840.1.113883.3.989.2.1.1.20][organizer/@classCode=CATEGORY][@moodCode=EVN]/component[@typeCode=COMP][observation/code][@codeSystem=2.16.840.1.113883.6.163][observation/@classCode=OBS][@moodCode=EVN]/effectiveTime/@xsi:type=IVL_TS/low/@value   |
| e |               |  |       |                                    | NullFlavor                              | 値 | /MCCLI_IN200100UV01[@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 MCCLI_IN200100UV01.xsd]/PDRR_IN049016UVI/controlActProcess[@classCode=CACTI][@moodCode=EVN]/component[@typeCode=COMP][adverseEventAssessment][adverseEventAssessment][@classCode=INVSSTG][@moodCode=SUBJ][primaryRole][@classCode=INVSBJ/player][@classCode=PSN][determinerCode=INSTANCE]/role[@classCode=PR ST]/subjectOf2[@typeCode=SBJ]/organizer/code[@code=1][@codeSystem=2.16.840.1.113883.3.989.2.1.1.20][organizer/@classCode=CATEGORY][@moodCode=EVN]/component[@typeCode=COMP][observation/code][@codeSystem=2.16.840.1.113883.6.163][observation/@classCode=OBS][@moodCode=EVN]/effectiveTime/@xsi:type=IVL_TS/low/@nullFlavor  |

(別添3)

|   |  |          |  |          |  |
|---|--|----------|--|----------|--|
| <p>e</p> <p>D.10.7.1.r.3</p> <p>継続</p> <p>ブール型</p> <p>Boolean (BL)</p> <p>値</p>   | <pre> /MCCJ_IN200100UV01/@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 /MCCJ_IN200100UV01.xsd]/P/RR_IN049016UV/]/controlActProcess/@classCode=CACT][@moodCo dCode=EVN]/subject/@typeCode=SUBJ][1]/investigationEvent/@classCode=INVSIG][@moodCo de=EVN]/component/@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment /@classCode=INVSIG][@moodCode=EVN]/subject[1]/typeCode=SBJ][1]/primaryRole/@classC ode=INVSBJ/player[1]/classCode=PSN][@determinerCode=INSTANCE]/role/@classCode=PR ST][1]/subjectOr[2]/@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/@typeC ode=COMP][observation/code/@codeSystem=2.16.840.1.113883.6.163][r/observation/@classCo de=OBS][@moodCode=EVN]/inboundRelationship/@typeCode=REFR][observation/code/@code =13][@codeSystem=2.16.840.1.113883.3.989.2.1.1.19][1]/observation/@classCode=OBS][@mo odCode=EVN]/value/@xsi:type=BL][1]/@value </pre> | <p>値</p> | <pre> /MCCJ_IN200100UV01/@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 /MCCJ_IN200100UV01.xsd]/P/RR_IN049016UV/]/controlActProcess/@classCode=CACT][@moo dCode=EVN]/subject/@typeCode=SUBJ][1]/investigationEvent/@classCode=INVSIG][@moodCo de=EVN]/component/@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment /@classCode=INVSIG][@moodCode=EVN]/subject[1]/typeCode=SBJ][1]/primaryRole/@classC ode=INVSBJ/player[1]/classCode=PSN][@determinerCode=INSTANCE]/role/@classCode=PR ST][1]/subjectOr[2]/@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/@typeC ode=COMP][observation/code/@codeSystem=2.16.840.1.113883.6.163][r/observation/@classCo de=OBS][@moodCode=EVN]/effectiveTime/@xsi:type=IVL_TS][high/@value </pre> | <p>値</p> | <pre> /MCCJ_IN200100UV01/@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 /MCCJ_IN200100UV01.xsd]/P/RR_IN049016UV/]/controlActProcess/@classCode=CACT][@moo dCode=EVN]/subject/@typeCode=SUBJ][1]/investigationEvent/@classCode=INVSIG][@moodCo de=EVN]/component/@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment /@classCode=INVSIG][@moodCode=EVN]/subject[1]/typeCode=SBJ][1]/primaryRole/@classC ode=INVSBJ/player[1]/classCode=PSN][@determinerCode=INSTANCE]/role/@classCode=PR ST][1]/subjectOr[2]/@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/@typeC ode=COMP][observation/code/@codeSystem=2.16.840.1.113883.6.163][r/observation/@classCo de=OBS][@moodCode=EVN]/effectiveTime/@xsi:type=IVL_TS][high/@value </pre> |
| <p>e</p> <p>D.10.7.1.r.4</p> <p>終了日</p> <p>日付/時間</p> <p>Interval of Point In Time (IVL&lt;TS&gt;)</p> <p>high=Interval Boundary (VXB)</p> <p>NullFlavor</p> | <pre> /MCCJ_IN200100UV01/@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 /MCCJ_IN200100UV01.xsd]/P/RR_IN049016UV/]/controlActProcess/@classCode=CACT][@moo dCode=EVN]/subject/@typeCode=SUBJ][1]/investigationEvent/@classCode=INVSIG][@moodCo de=EVN]/component/@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment /@classCode=INVSIG][@moodCode=EVN]/subject[1]/typeCode=SBJ][1]/primaryRole/@classC ode=INVSBJ/player[1]/classCode=PSN][@determinerCode=INSTANCE]/role/@classCode=PR ST][1]/subjectOr[2]/@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/@typeC ode=COMP][observation/code/@codeSystem=2.16.840.1.113883.6.163][r/observation/@classCo de=OBS][@moodCode=EVN]/effectiveTime/@xsi:type=IVL_TS][high/@value </pre>   | <p>値</p> | <pre> /MCCJ_IN200100UV01/@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 /MCCJ_IN200100UV01.xsd]/P/RR_IN049016UV/]/controlActProcess/@classCode=CACT][@moo dCode=EVN]/subject/@typeCode=SUBJ][1]/investigationEvent/@classCode=INVSIG][@moodCo de=EVN]/component/@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment /@classCode=INVSIG][@moodCode=EVN]/subject[1]/typeCode=SBJ][1]/primaryRole/@classC ode=INVSBJ/player[1]/classCode=PSN][@determinerCode=INSTANCE]/role/@classCode=PR ST][1]/subjectOr[2]/@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/@typeC ode=COMP][observation/code/@codeSystem=2.16.840.1.113883.6.163][r/observation/@classCo de=OBS][@moodCode=EVN]/effectiveTime/@xsi:type=IVL_TS][high/@value </pre> | <p>値</p> | <pre> /MCCJ_IN200100UV01/@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 /MCCJ_IN200100UV01.xsd]/P/RR_IN049016UV/]/controlActProcess/@classCode=CACT][@moo dCode=EVN]/subject/@typeCode=SUBJ][1]/investigationEvent/@classCode=INVSIG][@moodCo de=EVN]/component/@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment /@classCode=INVSIG][@moodCode=EVN]/subject[1]/typeCode=SBJ][1]/primaryRole/@classC ode=INVSBJ/player[1]/classCode=PSN][@determinerCode=INSTANCE]/role/@classCode=PR ST][1]/subjectOr[2]/@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/@typeC ode=COMP][observation/code/@codeSystem=2.16.840.1.113883.6.163][r/observation/@classCo de=OBS][@moodCode=EVN]/effectiveTime/@xsi:type=IVL_TS][high/@value </pre> |
| <p>e</p> <p>D.10.7.1.r.5</p> <p>備考</p> <p>2000AN</p> <p>Encapsulated Data (ED)</p> <p>値</p>   | <pre> /MCCJ_IN200100UV01/@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 /MCCJ_IN200100UV01.xsd]/P/RR_IN049016UV/]/controlActProcess/@classCode=CACT][@moo dCode=EVN]/subject/@typeCode=SUBJ][1]/investigationEvent/@classCode=INVSIG][@moodCo de=EVN]/component/@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment /@classCode=INVSIG][@moodCode=EVN]/subject[1]/typeCode=SBJ][1]/primaryRole/@classC ode=INVSBJ/player[1]/classCode=PSN][@determinerCode=INSTANCE]/role/@classCode=PR ST][1]/subjectOr[2]/@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/@typeC ode=COMP][observation/code/@codeSystem=2.16.840.1.113883.6.163][r/observation/@classCo de=OBS][@moodCode=EVN]/effectiveTime/@xsi:type=IVL_TS][high/@value </pre>   | <p>値</p> | <pre> /MCCJ_IN200100UV01/@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 /MCCJ_IN200100UV01.xsd]/P/RR_IN049016UV/]/controlActProcess/@classCode=CACT][@moo dCode=EVN]/subject/@typeCode=SUBJ][1]/investigationEvent/@classCode=INVSIG][@moodCo de=EVN]/component/@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment /@classCode=INVSIG][@moodCode=EVN]/subject[1]/typeCode=SBJ][1]/primaryRole/@classC ode=INVSBJ/player[1]/classCode=PSN][@determinerCode=INSTANCE]/role/@classCode=PR ST][1]/subjectOr[2]/@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/@typeC ode=COMP][observation/code/@codeSystem=2.16.840.1.113883.6.163][r/observation/@classCo de=OBS][@moodCode=EVN]/effectiveTime/@xsi:type=IVL_TS][high/@value </pre> | <p>値</p> | <pre> /MCCJ_IN200100UV01/@ITSVersion=XML_1.0][@xsi:schemaLocation=urn:hl7-org:v3 /MCCJ_IN200100UV01.xsd]/P/RR_IN049016UV/]/controlActProcess/@classCode=CACT][@moo dCode=EVN]/subject/@typeCode=SUBJ][1]/investigationEvent/@classCode=INVSIG][@moodCo de=EVN]/component/@typeCode=COMP][adverseEventAssessment[1]/adverseEventAssessment /@classCode=INVSIG][@moodCode=EVN]/subject[1]/typeCode=SBJ][1]/primaryRole/@classC ode=INVSBJ/player[1]/classCode=PSN][@determinerCode=INSTANCE]/role/@classCode=PR ST][1]/subjectOr[2]/@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/@typeC ode=COMP][observation/code/@codeSystem=2.16.840.1.113883.6.163][r/observation/@classCo de=OBS][@moodCode=EVN]/effectiveTime/@xsi:type=IVL_TS][high/@value </pre> |