INTERNATIONAL COUNCIL FOR HARMONISATION OF TECHNICAL REQUIREMENTS FOR PHARMACEUTICALS FOR HUMAN USE

ICH E2B(R3) Implementation Working Group

Appendix I (G) to the Implementation Guide for Electronic Transmission of Individual Case Safety Reports (ICSRs)

Technical Information

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Document History

Date of Finalisation	Title of Document	Version	Published for	WG
April 2013	Appendix I (G) to the Implementation Guide for Electronic Transmission of Individual Case Safety Reports (ICSRs) Technical Information	1.00	Step 4 document	E2B EWG
November 2014	Editorial corrections made– the accompanying history spreadsheet should be consulted for details of changes	1.01	Step 4 document	E2B IWG
November 2016	Change reference from M5 to ISO IDMP	1.02	Step 4 document	E2B IWG

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I. INTRODUCTION

This document provides necessary technical information to facilitate the preparation of a valid ICH ICSR message, or an ICSR Acknowledgment Message for electronic submission. All information in this document is consistent with the ICH ICSR Implementation Guide (IG), and details of technical points are summarised.

On requirements from changes in IT environments or identified errors contents in this document may be updated and maintained by ICH E2B(R3) IWG.

II. TECHNICAL INFORMATION

1. ICH Data Types, HL7 Data Types and XPath of E2B(R3) Data Elements

Data types in ICH and HL7are providedin the following table.

Several HL7 data types utilize codes defined by a specific system to represent concepts or data values. Three of the HL7 coded data types that are used by ICH are of a type know as a 'composite'. Composite data types allow components to express the concept and value in both a numerical code and in human readable text. The fourth code data type used by ICH, the CS data type, is not a composite but instead only conveys the coded value without any accompanying human readable text. For further details and a detailed description of each of these coded data types please refer to HL7 Data Type Specifications for.

The IG relies on HL7 data types, including the coded data types mentioned above. In the composite data types there is an optional *displayName* component that can be used to carry the human readable text to make the xml message easier to interpret for debugging or technical analysis. However this *displayName* is not mapped to any E2B(R3) data elements and therefore it is optional. The IG does not require or describe it, but since it is technically supported by the HL7 data type it can be included in the message to aid readability if desired. Please refer to regional guideline for guidance.

XPath is also provided in the following table to specify E2B(R3) data elements.Itincludes necessary schemaelements and attributes including codes and OIDs to create ICH ICSR and ACK messages. All messages transmitted between ICH regions should be consistent with the reference instance and the XPath to uniquely specify E2B(R3) data elements. It is noted that the XPath is developed based on the reference instances and thus both documents should have the same elements and attributes. If difference is found in the XPath, it is important to go back to the reference instance and the schemas to confirm original XML. The table below also provides

repeatable section (node) for the E2B(R3) data elements which allow repetition in the E2B(R3) data element structure. There are several possible nodes in XML message structure, but the defined node should be used for ICH ICSR or ACK messages. The ICH data type and its corresponding HL7 data type are listed in the table.

h: header e: entity	Element number	Element name	ICH Data Type	HL7 Data Type	HL7 Data Type (sub component)	Category	Xpath
h	N.1	ICH ICSR Transmission Identification (batch wrapper)					
e	N.1.1	Type of Messages in Batch	11A	Character String with Code (SC)	code=Coded With Equivalents (CE)	Value	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/name[@codeSystem='2.16.840.1.113883.3.989.2.1.1.1']/@code
		ICH Code List Version for Type of Messages in Batch					/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/name[@codeSystem='2.16.840.1.113883.3.989.2.1.1.1']/@codeSystemVersion
e	N.1.2	Batch Number	100AN	Instance Identifier (II)	extension=Character String (ST)	Value	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/id[@root='2.16.840.1.113883.3.989.2.1.3.22']/@extension
e	N.1.3	Batch Sender Identifier	60AN	Instance Identifier (II)	extension=Character String (ST)	Value	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/sender[@typeCode='SND']/device[@classCode='DEV'][@determinerCode='INSTANCE']/id[@root='2.16.840.1.113883.3.989.2.1.3.13'][1]/@extension
e	N.1.4	Batch Receiver Identifier	60AN	Instance Identifier (II)	extension=Character String (ST)	Value	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/receiver[@typeCode='RCV']/device[@classCode='DEV'][@determinerCode='INSTANCE']/id[@root='2.16.840.1.113883.3.989.2.1.3.14'][1]/@extension
e	N.1.5	Date of Batch Transmission	Date/Time	Point in Time (TS)		Value	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/creationTime/@value
h	N.2.r	ICH ICSR Message Header (message wrapper) (repeat as necessary)				Repeat Node	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV

e	N.2.r.1	Message Identifier	100AN	Instance Identifier (II)	extension=Character String (ST)	Value	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/id[@root='2.16.840.1.113883.3.989.2.1.3.1'][1]/@extension
e	N.2.r.2	Message Sender Identifier	60AN	Instance Identifier (II)	extension=Character String (ST)	Value	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/sender[@typeCode='SND']/device[@classCode='DEV'][@determinerCode='INSTANCE']/id[@root='2.16.840.1.113883.3.989.2.1.3.11'][1]/@extension
e	N.2.r.3	Message Receiver Identifier	60AN	Instance Identifier (II)	extension=Character String (ST)	Value	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/receiver[@typeCode='RCV']/device[@classCode='DEV'][@determinerCode='INSTANCE']/id[@root='2.16.840.1.113883.3.989.2.1.3.12'][1]/@extension
e	N.2.r.4	Date of Message Creation	Date/Time	Point in Time (TS)		Value	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/creationTime/@value
h	C.1	Identification of the Case Safety Report					

e	C.1.1	Sender's (case) Safety Report Unique Identifier	100AN	Instance Identifier (II)	extension=Character String (ST)	Value	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/id[@root='2.16.840.1.113883.3.989.2.1.3.1'][1]/@extension
e	C.1.2	Date of Creation	Date/Time	Point in Time (TS)		Value	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/effectiveTime/@value
e	C.1.3	Type of Report	1N	Coded With Equivalents (CE)	code=Character String (ST)	Value	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/subjectOf2[@typeCode='SUBJ'][investigationCharacteristic/code[@code='1'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.23']][1]/investigationCharacteristic[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='CE'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.2']/@code
		ICH Code List Version for Type of Report					/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/subjectOf2[@typeCode='SUBJ'][investigationCharacteristic/code[@code='1'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.23']][1]/investigationCharacteristic[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='CE'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.2']/@codeSystemVersion

e	C.1.4	Date Report Was First Received from Source	Date/Time	Interval of Point in Time (IVL<TS>)	low=Interval Boundary (IVXB)	Value	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/effectiveTime/low/@value
e	C.1.5	Date of Most Recent Information for This Report	Date/Time	Point in Time (TS)		Value	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/availabilityTime/@value
h	C.1.6	Additional Available Documents Held by Sender					
e	C.1.6.1	Are Additional Documents Available?	Boolean	Boolean (BL)		Value	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][observationEvent/code[@code='1'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']][1]/observationEvent[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='BL']/@value
h	C.1.6.1.r	Documents Held by Sender (repeat as necessary)				Repeat Node	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/reference[@typeCode='REFR'][document/code[@code='1'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.27']]

e	C.1.6.1.r.1	Documents Held by Sender	2000AN	Character String (ST)		Value	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/reference[@typeCode='REFR'][document/code[@code='1'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.27']][r]/document[@classCode='DOC'][@moodCode='EVN']/title/text()
e	C.1.6.1.r.2	Included Documents	N/A	Encapsulated Data (ED)		Value	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/reference[@typeCode='REFR'][document/code[@code='1'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.27']][r]/document[@classCode='DOC'][@moodCode='EVN']/text/text()
e	C.1.7	Does This Case Fulfil the Local Criteria for an Expedited Report?	Boolean	Boolean (BL)		Value	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][observationEvent/code[@code='23'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']][1]/observationEvent[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='BL']/@value
e						NullFlavor	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][observationEvent/code[@code='23'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']][1]/observationEvent[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='BL']/@nullFlavor

h	C.1.8	Worldwide Unique Case Identification				
e	C.1.8.1	Worldwide Unique Case Identification Number	100AN	Instance Identifier (II)	extension=Character String(ST)	Value	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/id[@root='2.16.840.1.113883.3.989.2.1.3.2'][1]/@extension
e	C.1.8.2	First Sender of This Case	1N	Coded With Equivalents (CE)	code=Character String (ST)	Value	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/outboundRelationship[@typeCode='SPRT'][relatedInvestigation/code[@code='1'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.22']][1]/relatedInvestigation[@classCode='INVSTG'][@moodCode='EVN']/subjectOf2[@typeCode='SUBJ'][1]/controlActEvent[@classCode='CACT'][@moodCode='EVN']/author[@typeCode='AUT']/assignedEntity[@classCode='ASSIGNED']/code[@codeSystem='2.16.840.1.113883.3.989.2.1.1.3']/@code
		ICH Code List Version for First Sender of This Case					/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/outboundRelationship[@typeCode='SPRT'][relatedInvestigation/code[@code='1'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.22']][1]/relatedInvestigation[@classCode='INVSTG'][@moodCode='EVN']/subjectOf2[@typeCode='SUBJ'][1]/controlActEvent[@classCode='CACT'][@moodCode='EVN']/author[@typeCode='AUT']/assignedEntity[@classCode='ASSIGNED']/code[@codeSystem='2.16.840.1.113883.3.989.2.1.1.3']/@codeSystemVersion
h	C.1.9	Other Case Identifiers				

e	C.1.9.1	Other Case Identifiers in Previous Transmissions	Boolean	Boolean (BL)		Value	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/subjectOf2[@typeCode='SUBJ'][investigationCharacteristic/code[@code='2'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.23']][1]/investigationCharacteristic[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='BL']/@value
e						NullFlavor	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/subjectOf2[@typeCode='SUBJ'][investigationCharacteristic/code[@code='2'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.23']][1]/investigationCharacteristic[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='BL']/@nullFlavor
h	C.1.9.1.r	Source(s) of the Case Identifier (repeat as necessary)				Repeat Node	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/subjectOf1[@typeCode='SUBJ'][controlActEvent/id]
e	C.1.9.1.r.1	Source(s) of the Case Identifier	100AN	Instance Identifier (II)	assigningAuthorityName=Character String (ST)	Value	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/subjectOf1[@typeCode='SUBJ'][controlActEvent/id][r]/controlActEvent/id[@root='2.16.840.1.113883.3.989.2.1.3.3'][1]/@assigningAuthorityName

e	C.1.9.1.r.2	Case Identifier(s)	100AN	Instance Identifier (II)	extension=Character String(ST)	Value	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/subjectOf1[@typeCode='SUBJ'][controlActEvent/id][r]/controlActEvent/id[@root='2.16.840.1.113883.3.989.2.1.3.3'][1]/@extension
e	C.1.10.r	Identification Number of the Report Which Is Linked to This Report (repeat as necessary)	100AN	Instance Identifier (II)	extension=Character String(ST)	Value	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/outboundRelationship[@typeCode='SPRT'][relatedInvestigation/code/@nullFlavor='NA'][r]/relatedInvestigation[@classCode='INVSTG'][@moodCode='EVN']/subjectOf2[@typeCode='SUBJ'][1]/controlActEvent[@classCode='CACT'][@moodCode='EVN']/id[@root='2.16.840.1.113883.3.989.2.1.3.2'][1]/@extension
h	C.1.11	Report Nullification / Amendment					
e	C.1.11.1	Report Nullification / Amendment	1N	Coded With Equivalents (CE)	code=Character String (ST)	Value	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/subjectOf2[@typeCode='SUBJ'][investigationCharacteristic/code[@code='3'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.23']][1]/investigationCharacteristic[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='CE'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.5']/@code

		ICH Code List Version for Report Nullification / Amendment					/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/subjectOf2[@typeCode='SUBJ'][investigationCharacteristic/code[@code='3'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.23']][1]/investigationCharacteristic[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='CE'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.5']/@codeSystemVersion
e	C.1.11.2	Reason for Nullification / Amendment	2000AN	Coded With Equivalents (CE)	originalText = Encapsulated Data (ED)	Value	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/subjectOf2[@typeCode='SUBJ'][investigationCharacteristic/code[@code='4'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.23']][1]/investigationCharacteristic[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='CE']/originalText/text()
h	C.2.r	Primary Source(s) of Information (repeat as necessary)				Repeat Node	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/outboundRelationship[@typeCode='SPRT'][relatedInvestigation/code[@code='2'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.22']]
h	C.2.r.1	Reporter's Name					

e	C.2.r.1.1	Reporter's Title	50AN	Person Name (PN)	prefix=Entity Name Part (ENXP)	Value	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/outboundRelationship[@typeCode='SPRT'][relatedInvestigation/code[@code='2'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.22']][r]/relatedInvestigation[@classCode='INVSTG'][@moodCode='EVN']/subjectOf2[@typeCode='SUBJ']/controlActEvent[@classCode='CACT'][@moodCode='EVN']/author[@typeCode='AUT']/assignedEntity[@classCode='ASSIGNED']/assignedPerson[@classCode='PSN'][@determinerCode='INSTANCE']/name/prefix[1]/text()
e						NullFlavor	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/outboundRelationship[@typeCode='SPRT'][relatedInvestigation/code[@code='2'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.22']][r]/relatedInvestigation[@classCode='INVSTG'][@moodCode='EVN']/subjectOf2[@typeCode='SUBJ']/controlActEvent[@classCode='CACT'][@moodCode='EVN']/author[@typeCode='AUT']/assignedEntity[@classCode='ASSIGNED']/assignedPerson[@classCode='PSN'][@determinerCode='INSTANCE']/name/prefix[1]/@nullFlavor
e	C.2.r.1.2	Reporter's Given Name	60AN	Person Name (PN)	given=Entity Name Part (ENXP)	Value	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/outboundRelationship[@typeCode='SPRT'][relatedInvestigation/code[@code='2'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.22']][r]/relatedInvestigation[@classCode='INVSTG'][@moodCode='EVN']/subjectOf2[@typeCode='SUBJ']/controlActEvent[@classCode='CACT'][@moodCode='EVN']/author[@typeCode='AUT']/assignedEntity[@classCode='ASSIGNED']/assignedPerson[@classCode='PSN'][@determinerCode='INSTANCE']/name/given[1]/text()

e						NullFlavor	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/outboundRelationship[@typeCode='SPRT'][relatedInvestigation/code[@code='2'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.22']][r]/relatedInvestigation[@classCode='INVSTG'][@moodCode='EVN']/subjectOf2[@typeCode='SUBJ']/controlActEvent[@classCode='CACT'][@moodCode='EVN']/author[@typeCode='AUT']/assignedEntity[@classCode='ASSIGNED']/assignedPerson[@classCode='PSN'][@determinerCode='INSTANCE']/name/given[1]/@nullFlavor
e	C.2.r.1.3	Reporter's Middle Name	60AN	Person Name (PN)	given=Entity Name Part (ENXP)	Value	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/outboundRelationship[@typeCode='SPRT'][relatedInvestigation/code[@code='2'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.22']][r]/relatedInvestigation[@classCode='INVSTG'][@moodCode='EVN']/subjectOf2[@typeCode='SUBJ']/controlActEvent[@classCode='CACT'][@moodCode='EVN']/author[@typeCode='AUT']/assignedEntity[@classCode='ASSIGNED']/assignedPerson[@classCode='PSN'][@determinerCode='INSTANCE']/name/given[2]/text()

e						NullFlavor	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/outboundRelationship[@typeCode='SPRT'][relatedInvestigation/code[@code='2'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.22']][r]/relatedInvestigation[@classCode='INVSTG'][@moodCode='EVN']/subjectOf2[@typeCode='SUBJ']/controlActEvent[@classCode='CACT'][@moodCode='EVN']/author[@typeCode='AUT']/assignedEntity[@classCode='ASSIGNED']/assignedPerson[@classCode='PSN'][@determinerCode='INSTANCE']/name/given[2]/@nullFlavor
e	C.2.r.1.4	Reporter's Family Name	60AN	Person Name (PN)	family=Entity Name Part (ENXP)	Value	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/outboundRelationship[@typeCode='SPRT'][relatedInvestigation/code[@code='2'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.22']][r]/relatedInvestigation[@classCode='INVSTG'][@moodCode='EVN']/subjectOf2[@typeCode='SUBJ']/controlActEvent[@classCode='CACT'][@moodCode='EVN']/author[@typeCode='AUT']/assignedEntity[@classCode='ASSIGNED']/assignedPerson[@classCode='PSN'][@determinerCode='INSTANCE']/name/family[1]/text()

e						NullFlavor	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/outboundRelationship[@typeCode='SPRT'][relatedInvestigation/code[@code='2'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.22']][r]/relatedInvestigation[@classCode='INVSTG'][@moodCode='EVN']/subjectOf2[@typeCode='SUBJ']/controlActEvent[@classCode='CACT'][@moodCode='EVN']/author[@typeCode='AUT']/assignedEntity[@classCode='ASSIGNED']/assignedPerson[@classCode='PSN'][@determinerCode='INSTANCE']/name/family[1]/@nullFlavor
h	C.2.r.2	Reporter's Address and Telephone					
e	C.2.r.2.1	Reporter's Organisation	60AN	Organization Name (ON)	name=Entity Name Part (ENXP)	Value	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/outboundRelationship[@typeCode='SPRT'][relatedInvestigation/code[@code='2'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.22']][r]/relatedInvestigation[@classCode='INVSTG'][@moodCode='EVN']/subjectOf2[@typeCode='SUBJ']/controlActEvent[@classCode='CACT'][@moodCode='EVN']/author[@typeCode='AUT']/assignedEntity[@classCode='ASSIGNED']/representedOrganization[@classCode='ORG'][@determinerCode='INSTANCE']/assignedEntity[@classCode='ASSIGNED']/representedOrganization[@classCode='ORG'][@determinerCode='INSTANCE']/name/text()

e						NullFlavor	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/outboundRelationship[@typeCode='SPRT'][relatedInvestigation/code[@code='2'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.22']][r]/relatedInvestigation[@classCode='INVSTG'][@moodCode='EVN']/subjectOf2[@typeCode='SUBJ']/controlActEvent[@classCode='CACT'][@moodCode='EVN']/author[@typeCode='AUT']/assignedEntity[@classCode='ASSIGNED']/representedOrganization[@classCode='ORG'][@determinerCode='INSTANCE']/assignedEntity[@classCode='ASSIGNED']/representedOrganization[@classCode='ORG'][@determinerCode='INSTANCE']/name/@nullFlavor
e	C.2.r.2.2	Reporter's Department	60AN	Organization Name (ON)	name=Entity Name Part (ENXP)	Value	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/outboundRelationship[@typeCode='SPRT'][relatedInvestigation/code[@code='2'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.22']][r]/relatedInvestigation[@classCode='INVSTG'][@moodCode='EVN']/subjectOf2[@typeCode='SUBJ']/controlActEvent[@classCode='CACT'][@moodCode='EVN']/author[@typeCode='AUT']/assignedEntity[@classCode='ASSIGNED']/representedOrganization[@classCode='ORG'][@determinerCode='INSTANCE']/name/text()

e						NullFlavor	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/outboundRelationship[@typeCode='SPRT'][relatedInvestigation/code[@code='2'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.22']][r]/relatedInvestigation[@classCode='INVSTG'][@moodCode='EVN']/subjectOf2[@typeCode='SUBJ']/controlActEvent[@classCode='CACT'][@moodCode='EVN']/author[@typeCode='AUT']/assignedEntity[@classCode='ASSIGNED']/representedOrganization[@classCode='ORG'][@determinerCode='INSTANCE']/name/@nullFlavor
e	C.2.r.2.3	Reporter's Street	100AN	Postal Address (AD)	streetAddressLine=Address Part (ADXP)	Value	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/outboundRelationship[@typeCode='SPRT'][relatedInvestigation/code[@code='2'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.22']][r]/relatedInvestigation[@classCode='INVSTG'][@moodCode='EVN']/subjectOf2[@typeCode='SUBJ']/controlActEvent[@classCode='CACT'][@moodCode='EVN']/author[@typeCode='AUT']/assignedEntity[@classCode='ASSIGNED']/addr[1]/streetAddressLine[1]/text()

e						NullFlavor	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/outboundRelationship[@typeCode='SPRT'][relatedInvestigation/code[@code='2'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.22']][r]/relatedInvestigation[@classCode='INVSTG'][@moodCode='EVN']/subjectOf2[@typeCode='SUBJ']/controlActEvent[@classCode='CACT'][@moodCode='EVN']/author[@typeCode='AUT']/assignedEntity[@classCode='ASSIGNED']/addr[1]/streetAddressLine[1]/@nullFlavor
e	C.2.r.2.4	Reporter's City	35AN	Postal Address (AD)	city=Address Part (ADXP)	Value	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/outboundRelationship[@typeCode='SPRT'][relatedInvestigation/code[@code='2'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.22']][r]/relatedInvestigation[@classCode='INVSTG'][@moodCode='EVN']/subjectOf2[@typeCode='SUBJ']/controlActEvent[@classCode='CACT'][@moodCode='EVN']/author[@typeCode='AUT']/assignedEntity[@classCode='ASSIGNED']/addr[1]/city[1]/text()
e						NullFlavor	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/outboundRelationship[@typeCode='SPRT'][relatedInvestigation/code[@code='2'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.22']][r]/relatedInvestigation[@classCode='INVSTG'][@moodCode='EVN']/subjectOf2[@typeCode='SUBJ']/controlActEvent[@classCode='CACT'][@moodCode='EVN']/author[@typeCode='AUT']/assignedEntity[@classCode='ASSIGNED']/addr[1]/city[1]/@nullFlavor

e	C.2.r.2.5	Reporter's State or Province	40AN	Postal Address (AD)	state=Address Part (ADXP)	Value	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/outboundRelationship[@typeCode='SPRT'][relatedInvestigation/code[@code='2'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.22']][r]/relatedInvestigation[@classCode='INVSTG'][@moodCode='EVN']/subjectOf2[@typeCode='SUBJ']/controlActEvent[@classCode='CACT'][@moodCode='EVN']/author[@typeCode='AUT']/assignedEntity[@classCode='ASSIGNED']/addr[1]/state[1]/text()
e						NullFlavor	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/outboundRelationship[@typeCode='SPRT'][relatedInvestigation/code[@code='2'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.22']][r]/relatedInvestigation[@classCode='INVSTG'][@moodCode='EVN']/subjectOf2[@typeCode='SUBJ']/controlActEvent[@classCode='CACT'][@moodCode='EVN']/author[@typeCode='AUT']/assignedEntity[@classCode='ASSIGNED']/addr[1]/state[1]/@nullFlavor
e	C.2.r.2.6	Reporter's Postcode	15AN	Postal Address (AD)	postalCode=Address Part (ADXP)	Value	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/outboundRelationship[@typeCode='SPRT'][relatedInvestigation/code[@code='2'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.22']][r]/relatedInvestigation[@classCode='INVSTG'][@moodCode='EVN']/subjectOf2[@typeCode='SUBJ']/controlActEvent[@classCode='CACT'][@moodCode='EVN']/author[@typeCode='AUT']/assignedEntity[@classCode='ASSIGNED']/addr[1]/postalCode[1]/text()

e						NullFlavor	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/outboundRelationship[@typeCode='SPRT'][relatedInvestigation/code[@code='2'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.22']][r]/relatedInvestigation[@classCode='INVSTG'][@moodCode='EVN']/subjectOf2[@typeCode='SUBJ']/controlActEvent[@classCode='CACT'][@moodCode='EVN']/author[@typeCode='AUT']/assignedEntity[@classCode='ASSIGNED']/addr[1]/postalCode[1]/@nullFlavor
e	C.2.r.2.7	Reporter's Telephone	33AN	Telecommunication Address (TEL)		Value	substring(/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/outboundRelationship[@typeCode='SPRT'][relatedInvestigation/code[@code='2'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.22']][r]/relatedInvestigation[@classCode='INVSTG'][@moodCode='EVN']/subjectOf2[@typeCode='SUBJ']/controlActEvent[@classCode='CACT'][@moodCode='EVN']/author[@typeCode='AUT']/assignedEntity[@classCode='ASSIGNED']/telecom[starts-with(@value,'tel:')][1]/@value, 5)
e						NullFlavor	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/outboundRelationship[@typeCode='SPRT'][relatedInvestigation/code[@code='2'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.22']][r]/relatedInvestigation[@classCode='INVSTG'][@moodCode='EVN']/subjectOf2[@typeCode='SUBJ']/controlActEvent[@classCode='CACT'][@moodCode='EVN']/author[@typeCode='AUT']/assignedEntity[@classCode='ASSIGNED']/telecom[starts-with(@value,'tel:')][1]/@nullFlavor

e	C.2.r.3	Reporter's Country Code	2A	Concept Descriptor (CD)	code=Character String (ST)	Value	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/outboundRelationship[@typeCode='SPRT'][relatedInvestigation/code[@code='2'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.22']][r]/relatedInvestigation[@classCode='INVSTG'][@moodCode='EVN']/subjectOf2[@typeCode='SUBJ']/controlActEvent[@classCode='CACT'][@moodCode='EVN']/author[@typeCode='AUT']/assignedEntity[@classCode='ASSIGNED']/assignedPerson[@classCode='PSN'][@determinerCode='INSTANCE']/asLocatedEntity[@classCode='LOCE'][1]/location[@classCode='COUNTRY'][@determinerCode='INSTANCE']/code[@codeSystem='1.0.3166.1.2.2']/@code
e						NullFlavor	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/outboundRelationship[@typeCode='SPRT'][relatedInvestigation/code[@code='2'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.22']][r]/relatedInvestigation[@classCode='INVSTG'][@moodCode='EVN']/subjectOf2[@typeCode='SUBJ']/controlActEvent[@classCode='CACT'][@moodCode='EVN']/author[@typeCode='AUT']/assignedEntity[@classCode='ASSIGNED']/assignedPerson[@classCode='PSN'][@determinerCode='INSTANCE']/asLocatedEntity[@classCode='LOCE'][1]/location[@classCode='COUNTRY'][@determinerCode='INSTANCE']/code[@codeSystem='1.0.3166.1.2.2']/@nullFlavor

| e | C.2.r.4 | Qualification | 1N | Coded With Equivalents (CE) | code=Character String (ST) | Value | /MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/outboundRelationship[@typeCode='SPRT'][relatedInvestigation/code[@code='2'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.22']][r]/relatedInvestigation[@classCode='INVSTG'][@moodCode='EVN']/subjectOf2[@typeCode='SUBJ']/controlActEvent[@classCode='CACT'][@moodCode='EVN']/author[@typeCode='AUT']/assignedEntity[@classCode='ASSIGNED']/assignedPerson[@classCode='PSN'][@determinerCode='INSTANCE']/asQualifiedEntity[@classCode='QUAL'][1]/code[@codeSystem='2.16.840.1.113883.3.989.2.1.1.6']/@code |
| | | ICH Code List Version for Qualification | | | | | /MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/outboundRelationship[@typeCode='SPRT'][relatedInvestigation/code[@code='2'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.22']][r]/relatedInvestigation[@classCode='INVSTG'][@moodCode='EVN']/subjectOf2[@typeCode='SUBJ']/controlActEvent[@classCode='CACT'][@moodCode='EVN']/author[@typeCode='AUT']/assignedEntity[@classCode='ASSIGNED']/assignedPerson[@classCode='PSN'][@determinerCode='INSTANCE']/asQualifiedEntity[@classCode='QUAL'][1]/code[@codeSystem='2.16.840.1.113883.3.989.2.1.1.6']/@codeSystemVersion |

e						NullFlavor	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/outboundRelationship[@typeCode='SPRT'][relatedInvestigation/code[@code='2'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.22']][r]/relatedInvestigation[@classCode='INVSTG'][@moodCode='EVN']/subjectOf2[@typeCode='SUBJ']/controlActEvent[@classCode='CACT'][@moodCode='EVN']/author[@typeCode='AUT']/assignedEntity[@classCode='ASSIGNED']/assignedPerson[@classCode='PSN'][@determinerCode='INSTANCE']/asQualifiedEntity[@classCode='QUAL'][1]/code[@codeSystem='2.16.840.1.113883.3.989.2.1.1.6']/@nullFlavor
e	C.2.r.5	Primary Source for Regulatory Purposes	1N	Real Number (REAL)		Value	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/outboundRelationship[@typeCode='SPRT'][relatedInvestigation/code[@code='2'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.22']][r]/priorityNumber/@value
h	C.3	Information on Sender of Case Safety Report					
e	C.3.1	Sender Type	1N	Coded With Equivalents (CE)	code=Character String (ST)	Value	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/subjectOf1[@typeCode='SUBJ'][controlActEvent/author/assignedEntity/code[@codeSystem='2.16.840.1.113883.3.989.2.1.1.7']][1]/controlActEvent[@classCode='CACT'][@moodCode='EVN']/author[@typeCode='AUT']/assignedEntity[@classCode='ASSIGNED']/code[@codeSystem='2.16.840.1.113883.3.989.2.1.1.7']/@code

		ICH Code List Version for Sender Type					/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/subjectOf1[@typeCode='SUBJ'][controlActEvent/author/assignedEntity/code[@codeSystem='2.16.840.1.113883.3.989.2.1.1.7']][1]/controlActEvent[@classCode='CACT'][@moodCode='EVN']/author[@typeCode='AUT']/assignedEntity[@classCode='ASSIGNED']/code[@codeSystem='2.16.840.1.113883.3.989.2.1.1.7']/@codeSystemVersion
e	C.3.2	Sender's Organisation	100AN	Organization Name (ON)	name=Entity Name Part (ENXP)	Value	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/subjectOf1[@typeCode='SUBJ'][controlActEvent/author/assignedEntity/code[@codeSystem='2.16.840.1.113883.3.989.2.1.1.7']][1]/controlActEvent[@classCode='CACT'][@moodCode='EVN']/author[@typeCode='AUT']/assignedEntity[@classCode='ASSIGNED']/representedOrganization[@classCode='ORG'][@determinerCode='INSTANCE']/assignedEntity[@classCode='ASSIGNED']/representedOrganization[@classCode='ORG'][@determinerCode='INSTANCE']/name/text()
h	C.3.3	Person Responsible for Sending the Report					
e	C.3.3.1	Sender's Department	60AN	Organization Name (ON)	name=Entity Name Part (ENXP)	Value	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/subjectOf1[@typeCode='SUBJ'][controlActEvent/author/assignedEntity/code[@codeSystem='2.16.840.1.113883.3.989.2.1.1.7']][1]/controlActEvent[@classCode='CACT'][@moodCode='EVN']/author[@typeCode='AUT']/assignedEntity[@classCode='ASSIGNED']/representedOrganization[@classCode='ORG'][@determinerCode='INSTANCE']/name/text()

e	C.3.3.2	Sender's Title	50AN	Person Name (PN)	prefix=Entity Name Part (ENXP)	Value	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/subjectOf1[@typeCode='SUBJ'][controlActEvent/author/assignedEntity/code[@codeSystem='2.16.840.1.113883.3.989.2.1.1.7']][1]/controlActEvent[@classCode='CACT'][@moodCode='EVN']/author[@typeCode='AUT']/assignedEntity[@classCode='ASSIGNED']/assignedPerson[@classCode='PSN'][@determinerCode='INSTANCE']/name/prefix[1]/text()
e	C.3.3.3	Sender's Given Name	60AN	Person Name (PN)	given=Entity Name Part (ENXP)	Value	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/subjectOf1[@typeCode='SUBJ'][controlActEvent/author/assignedEntity/code[@codeSystem='2.16.840.1.113883.3.989.2.1.1.7']][1]/controlActEvent[@classCode='CACT'][@moodCode='EVN']/author[@typeCode='AUT']/assignedEntity[@classCode='ASSIGNED']/assignedPerson[@classCode='PSN'][@determinerCode='INSTANCE']/name/given[1]/text()
e	C.3.3.4	Sender's Middle Name	60AN	Person Name (PN)	given=Entity Name Part (ENXP)	Value	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/subjectOf1[@typeCode='SUBJ'][controlActEvent/author/assignedEntity/code[@codeSystem='2.16.840.1.113883.3.989.2.1.1.7']][1]/controlActEvent[@classCode='CACT'][@moodCode='EVN']/author[@typeCode='AUT']/assignedEntity[@classCode='ASSIGNED']/assignedPerson[@classCode='PSN'][@determinerCode='INSTANCE']/name/given[2]/text()

e	C.3.3.5	Sender's Family Name	60AN	Person Name (PN)	family=Entity Name Part (ENXP)	Value	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/subjectOf1[@typeCode='SUBJ'][controlActEvent/author/assignedEntity/code[@codeSystem='2.16.840.1.113883.3.989.2.1.1.7']][1]/controlActEvent[@classCode='CACT'][@moodCode='EVN']/author[@typeCode='AUT']/assignedEntity[@classCode='ASSIGNED']/assignedPerson[@classCode='PSN'][@determinerCode='INSTANCE']/name/family[1]/text()
h	C.3.4	Sender's Address, Fax, Telephone and E-mail Address					
e	C.3.4.1	Sender's Street Address	100AN	Postal Address (AD)	streetAddressLine=Address Part (ADXP)	Value	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/subjectOf1[@typeCode='SUBJ'][controlActEvent/author/assignedEntity/code[@codeSystem='2.16.840.1.113883.3.989.2.1.1.7']][1]/controlActEvent[@classCode='CACT'][@moodCode='EVN']/author[@typeCode='AUT']/assignedEntity[@classCode='ASSIGNED']/addr[1]/streetAddressLine[1]/text()
e	C.3.4.2	Sender's City	35AN	Postal Address (AD)	city=Address Part (ADXP)	Value	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/subjectOf1[@typeCode='SUBJ'][controlActEvent/author/assignedEntity/code[@codeSystem='2.16.840.1.113883.3.989.2.1.1.7']][1]/controlActEvent[@classCode='CACT'][@moodCode='EVN']/author[@typeCode='AUT']/assignedEntity[@classCode='ASSIGNED']/addr[1]/city[1]/text()

e	C.3.4.3	Sender's State or Province	40AN	Postal Address (AD)	state=Address Part (ADXP)	Value	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/subjectOf1[@typeCode='SUBJ'][controlActEvent/author/assignedEntity/code[@codeSystem='2.16.840.1.113883.3.989.2.1.1.7']][1]/controlActEvent[@classCode='CACT'][@moodCode='EVN']/author[@typeCode='AUT']/assignedEntity[@classCode='ASSIGNED']/addr[1]/state[1]/text()
e	C.3.4.4	Sender's Postcode	15AN	Postal Address (AD)	postalCode=Address Part (ADXP)	Value	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/subjectOf1[@typeCode='SUBJ'][controlActEvent/author/assignedEntity/code[@codeSystem='2.16.840.1.113883.3.989.2.1.1.7']][1]/controlActEvent[@classCode='CACT'][@moodCode='EVN']/author[@typeCode='AUT']/assignedEntity[@classCode='ASSIGNED']/addr[1]/postalCode[1]/text()
e	C.3.4.5	Sender's Country Code	2A	Concept Descriptor (CD)	code=Character String (ST)	Value	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/subjectOf1[@typeCode='SUBJ'][controlActEvent/author/assignedEntity/code[@codeSystem='2.16.840.1.113883.3.989.2.1.1.7']][1]/controlActEvent[@classCode='CACT'][@moodCode='EVN']/author[@typeCode='AUT']/assignedEntity[@classCode='ASSIGNED']/assignedPerson[@classCode='PSN'][@determinerCode='INSTANCE']/asLocatedEntity[@classCode='LOCE'][1]/location[@classCode='COUNTRY'][@determinerCode='INSTANCE']/code[@codeSystem='1.0.3166.1.2.2']/@code

e	C.3.4.6	Sender's Telephone	33AN	Telecommunication Address (TEL)		Value	substring(/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/subjectOf1[@typeCode='SUBJ'][controlActEvent/author/assignedEntity/code[@codeSystem='2.16.840.1.113883.3.989.2.1.1.7']][1]/controlActEvent[@classCode='CACT'][@moodCode='EVN']/author[@typeCode='AUT']/assignedEntity[@classCode='ASSIGNED']/telecom[starts-with(@value, 'tel:')][1]/@value, 5)
e	C.3.4.7	Sender's Fax	33AN	Telecommunication Address (TEL)		Value	substring(/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/subjectOf1[@typeCode='SUBJ'][controlActEvent/author/assignedEntity/code[@codeSystem='2.16.840.1.113883.3.989.2.1.1.7']][1]/controlActEvent[@classCode='CACT'][@moodCode='EVN']/author[@typeCode='AUT']/assignedEntity[@classCode='ASSIGNED']/telecom[starts-with(@value, 'fax:')][1]/@value, 5)
e	C.3.4.8	Sender's E-mail Address	100AN	Telecommunication Address (TEL)		Value	substring(/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/subjectOf1[@typeCode='SUBJ'][controlActEvent/author/assignedEntity/code[@codeSystem='2.16.840.1.113883.3.989.2.1.1.7']][1]/controlActEvent[@classCode='CACT'][@moodCode='EVN']/author[@typeCode='AUT']/assignedEntity[@classCode='ASSIGNED']/telecom[starts-with(@value, 'mailto:')][1]/@value, 8)

h	C.4.r	Literature Reference(s) (repeat as necessary)				Repeat Node	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/reference[@typeCode='REFR'][document/code[@code='2'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.27']]
e	C.4.r.1	Literature Reference(s)	500AN	Encapsulated Data (ED)		Value	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/reference[@typeCode='REFR'][document/code[@code='2'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.27']][r]/document[@classCode='DOC'][@moodCode='EVN']/bibliographicDesignationText/text()
e						NullFlavor	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/reference[@typeCode='REFR'][document/code[@code='2'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.27']][r]/document[@classCode='DOC'][@moodCode='EVN']/bibliographicDesignationText/@nullFlavor
e	C.4.r.2	Included Documents	N/A	Encapsulated Data (ED)		Value	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/reference[@typeCode='REFR'][document/code[@code='2'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.27']][r]/document[@classCode='DOC'][@moodCode='EVN']/text/text()
h	C.5	Study Identification					

h	C.5.1.r	Study Registration (repeat as necessary)				Repeat Node	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf1[@typeCode='SBJ'][1]/researchStudy[@classCode='CLNTRL'][@moodCode='EVN']/authorization[@typeCode='AUTH']
e	C.5.1.r.1	Study Registration Number	50AN	Instance Identifier (II)	extension=Character String (ST)	Value	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf1[@typeCode='SBJ'][1]/researchStudy[@classCode='CLNTRL'][@moodCode='EVN']/authorization[@typeCode='AUTH'][r]/studyRegistration[@classCode='ACT'][@moodCode='EVN']/id[@root='2.16.840.1.113883.3.989.2.1.3.6']/@extension
e						NullFlavor	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf1[@typeCode='SBJ'][1]/researchStudy[@classCode='CLNTRL'][@moodCode='EVN']/authorization[@typeCode='AUTH'][r]/studyRegistration[@classCode='ACT'][@moodCode='EVN']/id[@root='2.16.840.1.113883.3.989.2.1.3.6']/@nullFlavor

e	C.5.1.r.2	Study Registration Country	2A	Concept Descriptor (CD)	code=Character String (ST)	Value	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf1[@typeCode='SBJ'][1]/researchStudy[@classCode='CLNTRL'][@moodCode='EVN']/authorization[@typeCode='AUTH'][r]/studyRegistration[@classCode='ACT'][@moodCode='EVN']/author[@typeCode='AUT']/territorialAuthority[@classCode='TERR']/governingPlace[@classCode='COUNTRY'][@determinerCode='INSTANCE']/code[@codeSystem='1.0.3166.1.2.2']/@code
e						NullFlavor	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf1[@typeCode='SBJ'][1]/researchStudy[@classCode='CLNTRL'][@moodCode='EVN']/authorization[@typeCode='AUTH'][r]/studyRegistration[@classCode='ACT'][@moodCode='EVN']/author[@typeCode='AUT']/territorialAuthority[@classCode='TERR']/governingPlace[@classCode='COUNTRY'][@determinerCode='INSTANCE']/code[@codeSystem='1.0.3166.1.2.2']/@nullFlavor

e	C.5.2	Study Name	2000AN	Character String (ST)		Value	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf1[@typeCode='SBJ'][1]/researchStudy[@classCode='CLNTRL'][@moodCode='EVN']/title/text()
e						NullFlavor	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf1[@typeCode='SBJ'][1]/researchStudy[@classCode='CLNTRL'][@moodCode='EVN']/title/@nullFlavor
e	C.5.3	Sponsor Study Number	50AN	Instance Identifier (II)	extension=Character String (ST)	Value	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf1[@typeCode='SBJ'][1]/researchStudy[@classCode='CLNTRL'][@moodCode='EVN']/id[@root='2.16.840.1.113883.3.989.2.1.3.5']/@extension

e						NullFlavor	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf1[@typeCode='SBJ'][1]/researchStudy[@classCode='CLNTRL'][@moodCode='EVN']/id[@root='2.16.840.1.113883.3.989.2.1.3.5']/@nullFlavor
e	C.5.4	Study Type Where Reaction(s) / Event(s) Were Observed	1N	Coded With Equivalents (CE)	code=Character String (ST)	Value	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf1[@typeCode='SBJ'][1]/researchStudy[@classCode='CLNTRL'][@moodCode='EVN']/code[@codeSystem='2.16.840.1.113883.3.989.2.1.1.8']/@code
		ICH Code List Version for Study Type Where Reaction(s) / Event(s) Were Observed					/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf1[@typeCode='SBJ'][1]/researchStudy[@classCode='CLNTRL'][@moodCode='EVN']/code[@codeSystem='2.16.840.1.113883.3.989.2.1.1.8']/@codeSytemVersion
h	D	Patient Characteristics					

e	D.1	Patient (name or initials)	60AN	Entity Name (EN)	name=Entity Name Part (ENXP)	Value	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/player1[@classCode='PSN'][@determinerCode='INSTANCE']/name[1]/text()
e						NullFlavor	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/player1[@classCode='PSN'][@determinerCode='INSTANCE']/name[1]/@nullFlavor
h	D.1.1	Patient Medical Record Number(s) and Source(s) of the Record Number (if allowable)					
e	D.1.1.1	Patient Medical Record Number(s) and Source(s) of the Record Number (GP Medical Record Number)	20AN	Instance Identifier (II)	extension=Character String (ST)	Value	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/player1[@classCode='PSN'][@determinerCode='INSTANCE']/asIdentifiedEntity[@classCode='IDENT'][code[@code='1'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.4']][1]/id[@root='2.16.840.1.113883.3.989.2.1.3.7'][1]/@extension

e						NullFlavor	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/player1[@classCode='PSN'][@determinerCode='INSTANCE']/asIdentifiedEntity[@classCode='IDENT'][code[@code='1'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.4']][1]/id[@root='2.16.840.1.113883.3.989.2.1.3.7'][1]/@nullFlavor
e	D.1.1.2	Patient Medical Record Number(s) and Source(s) of the Record Number (Specialist Record Number)	20AN	Instance Identifier (II)	extension=Character String (ST)	Value	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/player1[@classCode='PSN'][@determinerCode='INSTANCE']/asIdentifiedEntity[@classCode='IDENT'][code[@code='2'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.4']][1]/id[@root='2.16.840.1.113883.3.989.2.1.3.8'][1]/@extension
e						NullFlavor	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/player1[@classCode='PSN'][@determinerCode='INSTANCE']/asIdentifiedEntity[@classCode='IDENT'][code[@code='2'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.4']][1]/id[@root='2.16.840.1.113883.3.989.2.1.3.8'][1]/@nullFlavor

e	D.1.1.3	Patient Medical Record Number(s) and Source(s) of the Record Number (Hospital Record Number)	20AN	Instance Identifier (II)	extension=Character String (ST)	Value	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/player1[@classCode='PSN'][@determinerCode='INSTANCE']/asIdentifiedEntity[@classCode='IDENT'][code[@code='3'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.4']][1]/id[@root='2.16.840.1.113883.3.989.2.1.3.9'][1]/@extension
e						NullFlavor	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/player1[@classCode='PSN'][@determinerCode='INSTANCE']/asIdentifiedEntity[@classCode='IDENT'][code[@code='3'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.4']][1]/id[@root='2.16.840.1.113883.3.989.2.1.3.9'][1]/@nullFlavor
e	D.1.1.4	Patient Medical Record Number(s) and Source(s) of the Record Number (Investigation Number)	20AN	Instance Identifier (II)	extension=Character String (ST)	Value	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/player1[@classCode='PSN'][@determinerCode='INSTANCE']/asIdentifiedEntity[@classCode='IDENT'][code[@code='4'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.4']][1]/id[@root='2.16.840.1.113883.3.989.2.1.3.10'][1]/@extension

e						NullFlavor	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/player1[@classCode='PSN'][@determinerCode='INSTANCE']/asIdentifiedEntity[@classCode='IDENT'][code[@code='4'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.4']][1]/id[@root='2.16.840.1.113883.3.989.2.1.3.10'][1]/@nullFlavor
h	D.2	Age Information					
e	D.2.1	Date of Birth	Date/Time	Point in Time (TS)		Value	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/player1[@classCode='PSN'][@determinerCode='INSTANCE']/birthTime/@value
e						NullFlavor	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/player1[@classCode='PSN'][@determinerCode='INSTANCE']/birthTime/@nullFlavor
h	D.2.2	Age at Time of Onset of Reaction / Event					

e	D.2.2a	Age at Time of Onset of Reaction / Event (number)	5N	Physical Quantity (PQ)	value=Real Number (REAL)	Value	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][observation/code[@code='3'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']][1]/observation[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='PQ'][1]/@value
e	D.2.2b	Age at Time of Onset of Reaction / Event (unit)	50AN	Physical Quantity (PQ)	unit=Coded Simple Value (CS)	Value	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][observation/code[@code='3'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']][1]/observation[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='PQ'][1]/@unit
e	D.2.2.1a	Gestation Period When Reaction / Event Was Observed in the Foetus (number)	3N	Physical Quantity (PQ)	value=Real Number (REAL)	Value	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][observation/code[@code='16'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']][1]/observation[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='PQ'][1]/@value

e	D.2.2.1b	Gestation Period When Reaction / Event Was Observed in the Foetus (unit)	50AN	Physical Quantity (PQ)	unit=Coded Simple Value (CS)	Value	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][observation/code[@code='16'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']][1]/observation[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='PQ'][1]/@unit
e	D.2.3	Patient Age Group (as per reporter)	1N	Coded With Equivalents (CE)	code=Character String (ST)	Value	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][observation/code[@code='4'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']][1]/observation[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='CE'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.9'][1]/@code
		ICH Code List Version for Patient Age Group (as per reporter)					/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][observation/code[@code='4'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']][1]/observation[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='CE'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.9'][1]/@codeSystemVersion

e	D.3	Body Weight (kg)	6N	Physical Quantity (PQ)	value=Real Number (REAL)	Value	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][observation/code[@code='7'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']][1]/observation[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='PQ'][@unit='kg'][1]/@value
e	D.4	Height (cm)	3N	Physical Quantity (PQ)	value=Real Number (REAL)	Value	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][observation/code[@code='17'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']][1]/observation[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='PQ'][@unit='cm'][1]/@value
e	D.5	Sex	1N	Coded With Equivalents (CE)	code=Character String (ST)	Value	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/player1[@classCode='PSN'][@determinerCode='INSTANCE']/administrativeGenderCode[@codeSystem='1.0.5218']/@code

e						NullFlavor	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/player1[@classCode='PSN'][@determinerCode='INSTANCE']/administrativeGenderCode[@codeSystem='1.0.5218']/@nullFlavor
e	D.6	Last Menstrual Period Date	Date/Time	Point in Time (TS)		Value	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][observation/code[@code='22'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']][1]/observation[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='TS'][1]/@value
e						NullFlavor	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][observation/code[@code='22'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']][1]/observation[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='TS'][1]/@nullFlavor

h	D.7	Relevant Medical History and Concurrent Conditions (not including reaction / event)				
h	D.7.1.r	Structured Information on Relevant Medical History (repeat as necessary)				Repeat Node	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][organizer/code[@code='1'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][observation/code[@codeSystem='2.16.840.1.113883.6.163']]
e	D.7.1.r.1a	MedDRA Version for Medical History	4AN	Concept Descriptor (CD)	codeSystemVersion= Character String (ST)	Value	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][organizer/code[@code='1'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][observation/code[@codeSystem='2.16.840.1.113883.6.163']][r]/observation[@classCode='OBS'][@moodCode='EVN']/code/@codeSystemVersion

| e | D.7.1.r.1b | Medical History (disease / surgical procedure / etc.) (MedDRA code) | 8N | Concept Descriptor (CD) | code=Character String (ST) | Value | /MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][organizer/code[@code='1'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][observation/code[@codeSystem='2.16.840.1.113883.6.163']][r]/observation[@classCode='OBS'][@moodCode='EVN']/code/@code |
| e | D.7.1.r.2 | Start Date | Date/Time | Interval of Point in Time (IVL<TS>) | low=Interval Boundary (IVXB) | Value | /MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][organizer/code[@code='1'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][observation/code[@codeSystem='2.16.840.1.113883.6.163']][r]/observation[@classCode='OBS'][@moodCode='EVN']/effectiveTime[@xsi:type='IVL_TS']/low/@value |

e						NullFlavor	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][organizer/code[@code='1'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][observation/code[@codeSystem='2.16.840.1.113883.6.163']][r]/observation[@classCode='OBS'][@moodCode='EVN']/effectiveTime[@xsi:type='IVL_TS']/low/@nullFlavor
e	D.7.1.r.3	Continuing	Boolean	Boolean (BL)		Value	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][organizer/code[@code='1'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][observation/code[@codeSystem='2.16.840.1.113883.6.163']][r]/observation[@classCode='OBS'][@moodCode='EVN']/inboundRelationship[@typeCode='REFR'][observation/code[@code='13'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']][1]/observation[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='BL'][1]/@value

e						NullFlavor	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][organizer/code[@code='1'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][observation/code[@codeSystem='2.16.840.1.113883.6.163']][r]/observation[@classCode='OBS'][@moodCode='EVN']/inboundRelationship[@typeCode='REFR'][observation/code[@code='13'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']][1]/observation[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='BL'][1]/@nullFlavor
e	D.7.1.r.4	End Date	Date/Time	Interval of Point in Time (IVL<TS>)	high=Interval Boundary (IVXB)	Value	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][organizer/code[@code='1'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][observation/code[@codeSystem='2.16.840.1.113883.6.163']][r]/observation[@classCode='OBS'][@moodCode='EVN']/effectiveTime[@xsi:type='IVL_TS']/high/@value

e							
e						NullFlavor	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][organizer/code[@code='1'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][observation/code[@codeSystem='2.16.840.1.113883.6.163']][r]/observation[@classCode='OBS'][@moodCode='EVN']/effectiveTime[@xsi:type='IVL_TS']/high/@nullFlavor
e	D.7.1.r.5	Comments	2000AN	Encapsulated Data (ED)		Value	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][organizer/code[@code='1'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][observation/code[@codeSystem='2.16.840.1.113883.6.163']][r]/observation[@classCode='OBS'][@moodCode='EVN']/outboundRelationship2[@typeCode='COMP'][observation/code[@code='10'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']][1]/observation[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='ED'][1]/text()

e	D.7.1.r.6	Family History	Boolean	Boolean (BL)		Value	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][organizer/code[@code='1'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][observation/code[@codeSystem='2.16.840.1.113883.6.163']][r]/observation[@classCode='OBS'][@moodCode='EVN']/outboundRelationship2[@typeCode='EXPL'][observation/code[@code='38'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']][1]/observation[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='BL'][1]/@value
e	D.7.2	Text for Relevant Medical History and Concurrent Conditions (not including reaction / event)	10000AN	Encapsulated Data (ED)		Value	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][organizer/code[@code='1'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][observation/code[@code='18'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']][1]/observation[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='ED'][1]/text()

| e | | | | | | NullFlavor | /MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][organizer/code[@code='1'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][observation/code[@code='18'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']][1]/observation[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='ED'][1]/@nullFlavor |
| e | D.7.3 | Concomitant Therapies | Boolean | Boolean (BL) | | Value | /MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][organizer/code[@code='1'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][observation/code[@code='11'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']][1]/observation[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='BL'][1]/@value |

h	D.8.r	Relevant Past Drug History (repeat as necessary)				Repeat Node	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][organizer/code[@code='2'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][substanceAdministration]
e	D.8.r.1	Name of Drug as Reported	250AN	Entity Name (EN)	name=Entity Name Part (ENXP)	Value	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][organizer/code[@code='2'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][substanceAdministration][r]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/consumable[@typeCode='CSM'][1]/instanceOfKind[@classCode='INST']/kindOfProduct[@classCode='MMAT'][@determinerCode='KIND']/name[1]/text()

e						NullFlavor	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][organizer/code[@code='2'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][substanceAdministration][r]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/consumable[@typeCode='CSM'][1]/instanceOfKind[@classCode='INST']/kindOfProduct[@classCode='MMAT'][@determinerCode='KIND']/name[1]/@nullFlavor
e	D.8.r.2a	MPID Version Date / Number	As per ISO IDMP	Coded With Equivalents (CE)	codeSystemVersion= Character String (ST)	Value	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][organizer/code[@code='2'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][substanceAdministration][r]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/consumable[@typeCode='CSM'][1]/instanceOfKind[@classCode='INST']/kindOfProduct[@classCode='MMAT'][@determinerCode='KIND']/code[@codeSystem='TBD-MPID']/@codeSystemVersion

e	D.8.r.2b	Medicinal Product Identifier (MPID)	As per ISO IDMP	Coded With Equivalents (CE)	code=Character String (ST)	Value	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][organizer/code[@code='2'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][substanceAdministration][r]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/consumable[@typeCode='CSM'][1]/instanceOfKind[@classCode='INST']/kindOfProduct[@classCode='MMAT'][@determinerCode='KIND']/code[@codeSystem='TBD-MPID']/@code
e	D.8.r.3a	PhPID Version Date / Number	As per ISO IDMP	Coded With Equivalents (CE)	codeSystemVersion= Character String (ST)	Value	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][organizer/code[@code='2'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][substanceAdministration][r]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/consumable[@typeCode='CSM'][1]/instanceOfKind[@classCode='INST']/kindOfProduct[@classCode='MMAT'][@determinerCode='KIND']/code[@codeSystem='TBD-PhPID']/@codeSystemVersion

e	D.8.r.3b	Pharmaceutical Product Identifier (PhPID)	As per ISO IDMP	Coded With Equivalents (CE)	code=Character String (ST)	Value	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][organizer/code[@code='2'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][substanceAdministration][r]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/consumable[@typeCode='CSM'][1]/instanceOfKind[@classCode='INST']/kindOfProduct[@classCode='MMAT'][@determinerCode='KIND']/code[@codeSystem='TBD-PhPID']/@code
e	D.8.r.4	Start Date	Date/Time	Interval of Point in Time (IVL<TS>)	low=Interval Boundary (IVXB)	Value	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][organizer/code[@code='2'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][substanceAdministration][r]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/effectiveTime[@xsi:type='IVL_TS']/low/@value

e						NullFlavor	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][organizer/code[@code='2'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][substanceAdministration][r]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/effectiveTime[@xsi:type='IVL_TS']/low/@nullFlavor
e	D.8.r.5	End Date	Date/Time	Interval of Point in Time (IVL<TS>)	high=Interval Boundary (IVXB)	Value	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][organizer/code[@code='2'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][substanceAdministration][r]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/effectiveTime[@xsi:type='IVL_TS']/high/@value

e						NullFlavor	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][organizer/code[@code='2'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][substanceAdministration][r]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/effectiveTime[@xsi:type='IVL_TS']/high/@nullFlavor
e	D.8.r.6a	MedDRA Version for Indication	4AN	Coded With Equivalents (CE)	codeSystemVersion= Character String (ST)	Value	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][organizer/code[@code='2'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][substanceAdministration][r]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/outboundRelationship2[@typeCode='RSON'][observation/code[@code='19'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']][1]/observation[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='CE'][@codeSystem='2.16.840.1.113883.6.163'][1]/@codeSystemVersion

e	D.8.r.6b	Indication (MedDRA code)	8N	Coded With Equivalents (CE)	code=Character String (ST)	Value	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][organizer/code[@code='2'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][substanceAdministration][r]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/outboundRelationship2[@typeCode='RSON'][observation/code[@code='19'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']][1]/observation[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='CE'][@codeSystem='2.16.840.1.113883.6.163'][1]/@code
e	D.8.r.7a	MedDRA Version for Reaction	4AN	Coded With Equivalents (CE)	codeSystemVersion= Character String (ST)	Value	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][organizer/code[@code='2'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][substanceAdministration][r]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/outboundRelationship2[@typeCode='CAUS'][observation/code[@code='29'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']][1]/observation[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='CE'][@codeSystem='2.16.840.1.113883.6.163'][1]/@codeSystemVersion

e	D.8.r.7b	Reaction (MedDRA code)	8N	Coded With Equivalents (CE)	code=Character String (ST)	Value	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][organizer/code[@code='2'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][substanceAdministration][r]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/outboundRelationship2[@typeCode='CAUS'][observation/code[@code='29'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']][1]/observation[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='CE'][@codeSystem='2.16.840.1.113883.6.163'][1]/@code
h	D.9	In Case of Death					
e	D.9.1	Date of Death	Date/Time	Point in Time (TS)		Value	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/player1[@classCode='PSN'][@determinerCode='INSTANCE']/deceasedTime/@value
e						NullFlavor	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/player1[@classCode='PSN'][@determinerCode='INSTANCE']/deceasedTime/@nullFlavor

h	D.9.2.r	Reported Cause(s) of Death (repeat as necessary)				Repeat Node	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][observation/code[@code='32'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']]
e	D.9.2.r.1a	MedDRA Version for Reported Cause(s) of Death	4AN	Coded With Equivalents (CE)	codeSystemVersion= Character String (ST)	Value	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][observation/code[@code='32'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']][r]/observation[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='CE'][@codeSystem='2.16.840.1.113883.6.163'][1]/@codeSystemVersion
e	D.9.2.r.1b	Reported Cause(s) of Death (MedDRA code)	8N	Coded With Equivalents (CE)	code=Character String (ST)	Value	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][observation/code[@code='32'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']][r]/observation[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='CE'][@codeSystem='2.16.840.1.113883.6.163'][1]/@code

e	D.9.2.r.2	Reported Cause(s) of Death (free text)	250AN	Coded With Equivalents (CE)	originalText = Encapsulated Data (ED)	Value	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][observation/code[@code='32'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']][r]/observation[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='CE'][@codeSystem='2.16.840.1.113883.6.163'][1]/originalText/text()
e	D.9.3	Was Autopsy Done?	Boolean	Boolean (BL)		Value	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][observation/code[@code='5'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']][1]/observation[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='BL'][1]/@value
e						NullFlavor	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][observation/code[@code='5'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']][1]/observation[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='BL'][1]/@nullFlavor

h	D.9.4.r	Autopsy-determined Cause(s) of Death (repeat as necessary)				Repeat Node	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][observation/code[@code='5'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']][1]/observation[@classCode='OBS'][@moodCode='EVN']/outboundRelationship2[@typeCode='DRIV'][observation/code[@code='8'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']]
e	D.9.4.r.1a	MedDRA Version for Autopsy-determined Cause(s) of Death	4AN	Coded With Equivalents (CE)	codeSystemVersion= Character String (ST)	Value	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][observation/code[@code='5'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']][1]/observation[@classCode='OBS'][@moodCode='EVN']/outboundRelationship2[@typeCode='DRIV'][observation/code[@code='8'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']][r]/observation[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='CE'][@codeSystem='2.16.840.1.113883.6.163'][1]/@codeSystemVersion

e	D.9.4.r.1b	Autopsy-determined Cause(s) of Death (MedDRA code)	8N	Coded With Equivalents (CE)	code=Character String (ST)	Value	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][observation/code[@code='5'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']][1]/observation[@classCode='OBS'][@moodCode='EVN']/outboundRelationship2[@typeCode='DRIV'][observation/code[@code='8'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']][r]/observation[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='CE'][@codeSystem='2.16.840.1.113883.6.163'][1]/@code
e	D.9.4.r.2	Autopsy-determined Cause(s) of Death (free text)	250AN	Coded With Equivalents (CE)	originalText = Encapsulated Data (ED)	Value	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][observation/code[@code='5'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']][1]/observation[@classCode='OBS'][@moodCode='EVN']/outboundRelationship2[@typeCode='DRIV'][observation/code[@code='8'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']][r]/observation[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='CE'][@codeSystem='2.16.840.1.113883.6.163'][1]/originalText/text()
h	D.10	For a Parent-child / Foetus Report, Information Concerning the Parent					

e	D.10.1	Parent Identification	60AN	Entity Name (EN)	name=Entity Name Part (ENXP)	Value	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/player1[@classCode='PSN'][@determinerCode='INSTANCE']/role[@classCode='PRS'][1]/associatedPerson[@classCode='PSN'][@determinerCode='INSTANCE']/name[1]/text()
e						NullFlavor	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/player1[@classCode='PSN'][@determinerCode='INSTANCE']/role[@classCode='PRS'][1]/associatedPerson[@classCode='PSN'][@determinerCode='INSTANCE']/name[1]/@nullFlavor
h	D.10.2	Parent Age Information					
e	D.10.2.1	Date of Birth of Parent	Date/Time	Point in Time (TS)		Value	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/player1[@classCode='PSN'][@determinerCode='INSTANCE']/role[@classCode='PRS'][1]/associatedPerson[@classCode='PSN'][@determinerCode='INSTANCE']/birthTime/@value

e						NullFlavor	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/player1[@classCode='PSN'][@determinerCode='INSTANCE']/role[@classCode='PRS'][1]/associatedPerson[@classCode='PSN'][@determinerCode='INSTANCE']/birthTime/@nullFlavor
e	D.10.2.2a	Age of Parent (number)	3N	Physical Quantity (PQ)	value=Real Number (REAL)	Value	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/player1[@classCode='PSN'][@determinerCode='INSTANCE']/role[@classCode='PRS'][1]/subjectOf2[@typeCode='SBJ'][observation/code[@code='3'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']][1]/observation[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='PQ'][1]/@value
e	D.10.2.2b	Age of Parent (unit)	50AN	Physical Quantity (PQ)	unit=Coded Simple Value (CS)	Value	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/player1[@classCode='PSN'][@determinerCode='INSTANCE']/role[@classCode='PRS'][1]/subjectOf2[@typeCode='SBJ'][observation/code[@code='3'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']][1]/observation[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='PQ'][1]/@unit

e	D.10.3	Last Menstrual Period Date of Parent	Date/Time	Point in Time (TS)		Value	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/player1[@classCode='PSN'][@determinerCode='INSTANCE']/role[@classCode='PRS'][1]/subjectOf2[@typeCode='SBJ'][observation/code[@code='22'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']][1]/observation[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='TS'][1]/@value
e						NullFlavor	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/player1[@classCode='PSN'][@determinerCode='INSTANCE']/role[@classCode='PRS'][1]/subjectOf2[@typeCode='SBJ'][observation/code[@code='22'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']][1]/observation[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='TS'][1]/@nullFlavor

e	D.10.4	Body Weight (kg) of Parent	6N	Physical Quantity (PQ)	value=Real Number (REAL)	Value	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/player1[@classCode='PSN'][@determinerCode='INSTANCE']/role[@classCode='PRS'][1]/subjectOf2[@typeCode='SBJ'][observation/code[@code='7'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']][1]/observation[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='PQ'][@unit='kg'][1]/@value
e	D.10.5	Height (cm) of Parent	3N	Physical Quantity (PQ)	value=Real Number (REAL)	Value	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/player1[@classCode='PSN'][@determinerCode='INSTANCE']/role[@classCode='PRS'][1]/subjectOf2[@typeCode='SBJ'][observation/code[@code='17'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']][1]/observation[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='PQ'][@unit='cm'][1]/@value

e	D.10.6	Sex of Parent	1N	Coded With Equivalents (CE)	code=Character String (ST)	Value	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/player1[@classCode='PSN'][@determinerCode='INSTANCE']/role[@classCode='PRS'][1]/associatedPerson[@classCode='PSN'][@determinerCode='INSTANCE']/administrativeGenderCode[@codeSystem='1.0.5218']/@code
e						NullFlavor	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/player1[@classCode='PSN'][@determinerCode='INSTANCE']/role[@classCode='PRS'][1]/associatedPerson[@classCode='PSN'][@determinerCode='INSTANCE']/administrativeGenderCode[@codeSystem='1.0.5218']/@nullFlavor
h	D.10.7	Relevant Medical History and Concurrent Conditions of Parent					

h	D.10.7.1.r	Structured Information of Parent (repeat as necessary)				Repeat Node	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/player1[@classCode='PSN'][@determinerCode='INSTANCE']/role[@classCode='PRS'][1]/subjectOf2[@typeCode='SBJ'][organizer/code[@code='1'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][observation/code[@codeSystem='2.16.840.1.113883.6.163']]
e	D.10.7.1.r.1a	MedDRA Version for Medical History	4AN	Concept Descriptor (CD)	codeSystemVersion= Character String (ST)	Value	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/player1[@classCode='PSN'][@determinerCode='INSTANCE']/role[@classCode='PRS'][1]/subjectOf2[@typeCode='SBJ'][organizer/code[@code='1'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][observation/code[@codeSystem='2.16.840.1.113883.6.163']][r]/observation[@classCode='OBS'][@moodCode='EVN']/code/@codeSystemVersion

e	D.10.7.1.r.1b	Medical History (disease / surgical procedure/ etc.) (MedDRA code)	8N	Concept Descriptor (CD)	code=Character String (ST)	Value	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/player1[@classCode='PSN'][@determinerCode='INSTANCE']/role[@classCode='PRS'][1]/subjectOf2[@typeCode='SBJ'][organizer/code[@code='1'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][observation/code[@codeSystem='2.16.840.1.113883.6.163']][r]/observation[@classCode='OBS'][@moodCode='EVN']/code/@code
e	D.10.7.1.r.2	Start Date	Date/Time	Interval of Point in Time (IVL<TS>)	low=Interval Boundary (IVXB)	Value	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/player1[@classCode='PSN'][@determinerCode='INSTANCE']/role[@classCode='PRS'][1]/subjectOf2[@typeCode='SBJ'][organizer/code[@code='1'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][observation/code[@codeSystem='2.16.840.1.113883.6.163']][r]/observation[@classCode='OBS'][@moodCode='EVN']/effectiveTime[@xsi:type='IVL_TS']/low/@value

e						NullFlavor	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/player1[@classCode='PSN'][@determinerCode='INSTANCE']/role[@classCode='PRS'][1]/subjectOf2[@typeCode='SBJ'][organizer/code[@code='1'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][observation/code[@codeSystem='2.16.840.1.113883.6.163']][r]/observation[@classCode='OBS'][@moodCode='EVN']/effectiveTime[@xsi:type='IVL_TS']/low/@nullFlavor
e	D.10.7.1.r.3	Continuing	Boolean	Boolean (BL)		Value	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/player1[@classCode='PSN'][@determinerCode='INSTANCE']/role[@classCode='PRS'][1]/subjectOf2[@typeCode='SBJ'][organizer/code[@code='1'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][observation/code[@codeSystem='2.16.840.1.113883.6.163']][r]/observation[@classCode='OBS'][@moodCode='EVN']/inboundRelationship[@typeCode='REFR'][observation/code[@code='13'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']][1]/observation[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='BL'][1]/@value

e	D.10.7.1.r.4	End Date	Date/Time	Interval of Point in Time (IVL<TS>)	high=Interval Boundary (IVXB)	Value	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/player1[@classCode='PSN'][@determinerCode='INSTANCE']/role[@classCode='PRS'][1]/subjectOf2[@typeCode='SBJ'][organizer/code[@code='1'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][observation/code[@codeSystem='2.16.840.1.113883.6.163']][r]/observation[@classCode='OBS'][@moodCode='EVN']/effectiveTime[@xsi:type='IVL_TS']/high/@value
e						NullFlavor	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/player1[@classCode='PSN'][@determinerCode='INSTANCE']/role[@classCode='PRS'][1]/subjectOf2[@typeCode='SBJ'][organizer/code[@code='1'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][observation/code[@codeSystem='2.16.840.1.113883.6.163']][r]/observation[@classCode='OBS'][@moodCode='EVN']/effectiveTime[@xsi:type='IVL_TS']/high/@nullFlavor

| e | D.10.7.1.r.5 | Comments | 2000AN | Encapsulated Data (ED) | | Value | /MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/player1[@classCode='PSN'][@determinerCode='INSTANCE']/role[@classCode='PRS'][1]/subjectOf2[@typeCode='SBJ'][organizer/code[@code='1'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][observation/code[@codeSystem='2.16.840.1.113883.6.163']][r]/observation[@classCode='OBS'][@moodCode='EVN']/outboundRelationship2[@typeCode='COMP'][observation/code[@code='10'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']][1]/observation[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='ED'][1]/text() |
| e | D.10.7.2 | Text for Relevant Medical History and Concurrent Conditions of Parent | 10000AN | Encapsulated Data (ED) | | Value | /MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/player1[@classCode='PSN'][@determinerCode='INSTANCE']/role[@classCode='PRS'][1]/subjectOf2[@typeCode='SBJ'][organizer/code[@code='1'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][observation/code[@code='18'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']][1]/observation[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='ED'][1]/text() |

h	D.10.8.r	Relevant Past Drug History of Parent (repeat as necessary)				Repeat Node	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/player1[@classCode='PSN'][@determinerCode='INSTANCE']/role[@classCode='PRS'][1]/subjectOf2[@typeCode='SBJ'][organizer/code[@code='2'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][substanceAdministration]
e	D.10.8.r.1	Name of Drug as Reported	250AN	Entity Name (EN)	name=Entity Name Part (ENXP)	Value	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/player1[@classCode='PSN'][@determinerCode='INSTANCE']/role[@classCode='PRS'][1]/subjectOf2[@typeCode='SBJ'][organizer/code[@code='2'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][substanceAdministration][r]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/consumable[@typeCode='CSM'][1]/instanceOfKind[@classCode='INST']/kindOfProduct[@classCode='MMAT'][@determinerCode='KIND']/name[1]/text()

| e | D.10.8.r.2a | MPID Version Date / Number | As per ISO IDMP | Coded With Equivalents (CE) | codeSystemVersion= Character String (ST) | Value | /MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/player1[@classCode='PSN'][@determinerCode='INSTANCE']/role[@classCode='PRS'][1]/subjectOf2[@typeCode='SBJ'][organizer/code[@code='2'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][substanceAdministration][r]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/consumable[@typeCode='CSM'][1]/instanceOfKind[@classCode='INST']/kindOfProduct[@classCode='MMAT'][@determinerCode='KIND']/code[@codeSystem='TBD-MPID']/@codeSystemVersion |
| e | D.10.8.r.2b | Medicinal Product Identifier (MPID) | As per ISO IDMP | Coded With Equivalents (CE) | code=Character String (ST) | Value | /MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/player1[@classCode='PSN'][@determinerCode='INSTANCE']/role[@classCode='PRS'][1]/subjectOf2[@typeCode='SBJ'][organizer/code[@code='2'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][substanceAdministration][r]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/consumable[@typeCode='CSM'][1]/instanceOfKind[@classCode='INST']/kindOfProduct[@classCode='MMAT'][@determinerCode='KIND']/code[@codeSystem='TBD-MPID']/@code |

e	D.10.8.r.3a	PhPID Version Date / Number	As per ISO IDMP	Coded With Equivalents (CE)	codeSystemVersion= Character String (ST)	Value	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/player1[@classCode='PSN'][@determinerCode='INSTANCE']/role[@classCode='PRS'][1]/subjectOf2[@typeCode='SBJ'][organizer/code[@code='2'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][substanceAdministration][r]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/consumable[@typeCode='CSM'][1]/instanceOfKind[@classCode='INST']/kindOfProduct[@classCode='MMAT'][@determinerCode='KIND']/code[@codeSystem='TBD-PhPID']/@codeSystemVersion
e	D.10.8.r.3b	Pharmaceutical Product Identifier (PhPID)	As per ISO IDMP	Coded With Equivalents (CE)	code=Character String (ST)	Value	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/player1[@classCode='PSN'][@determinerCode='INSTANCE']/role[@classCode='PRS'][1]/subjectOf2[@typeCode='SBJ'][organizer/code[@code='2'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][substanceAdministration][r]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/consumable[@typeCode='CSM'][1]/instanceOfKind[@classCode='INST']/kindOfProduct[@classCode='MMAT'][@determinerCode='KIND']/code[@codeSystem='TBD-PhPID']/@code

| e | D.10.8.r.4 | Start Date | Date/Time | Interval of Point in Time (IVL<TS>) | low=Interval Boundary (IVXB) | Value | /MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/player1[@classCode='PSN'][@determinerCode='INSTANCE']/role[@classCode='PRS'][1]/subjectOf2[@typeCode='SBJ'][organizer/code[@code='2'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][substanceAdministration][r]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/effectiveTime[@xsi:type='IVL_TS']/low/@value |
| e | | | | | | NullFlavor | /MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/player1[@classCode='PSN'][@determinerCode='INSTANCE']/role[@classCode='PRS'][1]/subjectOf2[@typeCode='SBJ'][organizer/code[@code='2'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][substanceAdministration][r]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/effectiveTime[@xsi:type='IVL_TS']/low/@nullFlavor |

e	D.10.8.r.5	End Date	Date/Time	Interval of Point in Time (IVL<TS>)	high=Interval Boundary (IVXB)	Value	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/player1[@classCode='PSN'][@determinerCode='INSTANCE']/role[@classCode='PRS'][1]/subjectOf2[@typeCode='SBJ'][organizer/code[@code='2'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][substanceAdministration][r]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/effectiveTime[@xsi:type='IVL_TS']/high/@value
e						NullFlavor	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/player1[@classCode='PSN'][@determinerCode='INSTANCE']/role[@classCode='PRS'][1]/subjectOf2[@typeCode='SBJ'][organizer/code[@code='2'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][substanceAdministration][r]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/effectiveTime[@xsi:type='IVL_TS']/high/@nullFlavor

e	D.10.8.r.6a	MedDRA Version for Indication	4AN	Coded With Equivalents (CE)	codeSystemVersion= Character String (ST)	Value	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/player1[@classCode='PSN'][@determinerCode='INSTANCE']/role[@classCode='PRS'][1]/subjectOf2[@typeCode='SBJ'][organizer/code[@code='2'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][substanceAdministration][r]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/outboundRelationship2[@typeCode='RSON'][observation/code[@code='19'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']][1]/observation[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='CE'][@codeSystem='2.16.840.1.113883.6.163'][1]/@codeSystemVersion
e	D.10.8.r.6b	Indication (MedDRA code)	8N	Coded With Equivalents (CE)	code=Character String (ST)	Value	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/player1[@classCode='PSN'][@determinerCode='INSTANCE']/role[@classCode='PRS'][1]/subjectOf2[@typeCode='SBJ'][organizer/code[@code='2'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][substanceAdministration][r]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/outboundRelationship2[@typeCode='RSON'][observation/code[@code='19'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']][1]/observation[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='CE'][@codeSystem='2.16.840.1.113883.6.163'][1]/@code

e	D.10.8.r.7a	MedDRA Version for Reaction	4AN	Coded With Equivalents (CE)	codeSystemVersion= Character String (ST)	Value	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/player1[@classCode='PSN'][@determinerCode='INSTANCE']/role[@classCode='PRS'][1]/subjectOf2[@typeCode='SBJ'][organizer/code[@code='2'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][substanceAdministration][r]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/outboundRelationship2[@typeCode='CAUS'][observation/code[@code='29'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']][1]/observation[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='CE'][@codeSystem='2.16.840.1.113883.6.163'][1]/@codeSystemVersion
e	D.10.8.r.7b	Reactions (MedDRA code)	8N	Coded With Equivalents (CE)	code=Character String (ST)	Value	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/player1[@classCode='PSN'][@determinerCode='INSTANCE']/role[@classCode='PRS'][1]/subjectOf2[@typeCode='SBJ'][organizer/code[@code='2'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][substanceAdministration][r]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/outboundRelationship2[@typeCode='CAUS'][observation/code[@code='29'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']][1]/observation[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='CE'][@codeSystem='2.16.840.1.113883.6.163'][1]/@code

h	E.i	Reaction(s) / Event(s) (repeat as necessary)				Repeat Node	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][observation[id][code[@code='29'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']]]]
h	E.i.1	Reaction / Event as Reported by the Primary Source					
e	E.i.1.1a	Reaction / Event as Reported by the Primary Source in Native Language	250AN	Coded With Equivalents (CE)	originalText = Encapsulated Data (ED)	Value	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][observation[id][code[@code='29'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']]][i]/observation[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='CE'][@codeSystem='2.16.840.1.113883.6.163'][1]/originalText/text()

e	E.i.1.1b	Reaction / Event as Reported by the Primary Source Language	3A	Coded With Equivalents (CE)	originalText/language =Coded Simple Value (CS)	Value	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][observation[id][code[@code='29'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']]][i]/observation[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='CE'][@codeSystem='2.16.840.1.113883.6.163'][1]/originalText/@language
e	E.i.1.2	Reaction / Event as Reported by the Primary Source for Translation	250AN	Encapsulated Data (ED)		Value	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][observation[id][code[@code='29'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']]][i]/observation[@classCode='OBS'][@moodCode='EVN']/outboundRelationship2[@typeCode='PERT'][observation/code[@code='30'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']][1]/observation[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='ED'][1]/text()

| e | E.i.2.1a | MedDRA Version for Reaction / Event | 4AN | Coded With Equivalents (CE) | codeSystemVersion= Character String (ST) | Value | /MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][observation[id][code[@code='29'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']]][i]/observation[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='CE'][@codeSystem='2.16.840.1.113883.6.163'][1]/@codeSystemVersion |
| e | E.i.2.1b | Reaction / Event (MedDRA code) | 8N | Coded With Equivalents (CE) | code=Character String (ST) | Value | /MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][observation[id][code[@code='29'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']]][i]/observation[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='CE'][@codeSystem='2.16.840.1.113883.6.163'][1]/@code |

e	E.i.3.1	Term Highlighted by the Reporter	1N	Coded With Equivalents (CE)	code=Character String (ST)	Value	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][observation[id][code[@code='29'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']]][i]/observation[@classCode='OBS'][@moodCode='EVN']/outboundRelationship2[@typeCode='PERT'][observation/code[@code='37'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']][1]/observation[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='CE'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.10'][1]/@code
		ICH Code List Version for Term Highlighted by the Reporter					/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][observation[id][code[@code='29'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']]][i]/observation[@classCode='OBS'][@moodCode='EVN']/outboundRelationship2[@typeCode='PERT'][observation/code[@code='37'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']][1]/observation[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='CE'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.10'][1]/@codeSystemVersion
h	E.i.3.2	Seriousness Criteria at Event Level					

| e | E.i.3.2a | Results in Death | Boolean | Boolean (BL) | | Value | /MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][observation[id][code[@code='29'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']]][i]/observation[@classCode='OBS'][@moodCode='EVN']/outboundRelationship2[@typeCode='PERT'][observation/code[@code='34'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']][1]/observation[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='BL'][1]/@value |
| e | | | | | | NullFlavor | /MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][observation[id][code[@code='29'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']]][i]/observation[@classCode='OBS'][@moodCode='EVN']/outboundRelationship2[@typeCode='PERT'][observation/code[@code='34'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']][1]/observation[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='BL'][1]/@nullFlavor |

e	E.i.3.2b	Life Threatening	Boolean	Boolean (BL)		Value	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][observation[id][code[@code='29'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']]][i]/observation[@classCode='OBS'][@moodCode='EVN']/outboundRelationship2[@typeCode='PERT'][observation/code[@code='21'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']][1]/observation[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='BL'][1]/@value
e						NullFlavor	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][observation[id][code[@code='29'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']]][i]/observation[@classCode='OBS'][@moodCode='EVN']/outboundRelationship2[@typeCode='PERT'][observation/code[@code='21'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']][1]/observation[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='BL'][1]/@nullFlavor

| e | E.i.3.2c | Caused / Prolonged Hospitalisation | Boolean | Boolean (BL) | | Value | /MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][observation[id][code[@code='29'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']]][i]/observation[@classCode='OBS'][@moodCode='EVN']/outboundRelationship2[@typeCode='PERT'][observation/code[@code='33'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']][1]/observation[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='BL'][1]/@value |
| e | | | | | | NullFlavor | /MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][observation[id][code[@code='29'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']]][i]/observation[@classCode='OBS'][@moodCode='EVN']/outboundRelationship2[@typeCode='PERT'][observation/code[@code='33'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']][1]/observation[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='BL'][1]/@nullFlavor |

| e | E.i.3.2d | Disabling / Incapacitating | Boolean | Boolean (BL) | | Value | /MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][observation[id][code[@code='29'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']]][i]/observation[@classCode='OBS'][@moodCode='EVN']/outboundRelationship2[@typeCode='PERT'][observation/code[@code='35'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']][1]/observation[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='BL'][1]/@value |
| e | | | | | | NullFlavor | /MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][observation[id][code[@code='29'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']]][i]/observation[@classCode='OBS'][@moodCode='EVN']/outboundRelationship2[@typeCode='PERT'][observation/code[@code='35'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']][1]/observation[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='BL'][1]/@nullFlavor |

e	E.i.3.2e	Congenital Anomaly / Birth Defect	Boolean	Boolean (BL)		Value	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][observation[id][code[@code='29'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']]][i]/observation[@classCode='OBS'][@moodCode='EVN']/outboundRelationship2[@typeCode='PERT'][observation/code[@code='12'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']][1]/observation[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='BL'][1]/@value
e						NullFlavor	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][observation[id][code[@code='29'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']]][i]/observation[@classCode='OBS'][@moodCode='EVN']/outboundRelationship2[@typeCode='PERT'][observation/code[@code='12'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']][1]/observation[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='BL'][1]/@nullFlavor

e	E.i.3.2f	Other Medically Important Condition	Boolean	Boolean (BL)		Value	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][observation[id][code[@code='29'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']]][i]/observation[@classCode='OBS'][@moodCode='EVN']/outboundRelationship2[@typeCode='PERT'][observation/code[@code='26'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']][1]/observation[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='BL'][1]/@value
e						NullFlavor	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][observation[id][code[@code='29'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']]][i]/observation[@classCode='OBS'][@moodCode='EVN']/outboundRelationship2[@typeCode='PERT'][observation/code[@code='26'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']][1]/observation[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='BL'][1]/@nullFlavor

| e | E.i.4 | Date of Start of Reaction / Event | Date/Time | 1. When all the elements E.i.4, E.i.5, and E.i.6 do not appear

HL7 Data Type: Interval of Point in Time (IVL\<TS>) | 1. When all the elements E.i.4, E.i.5, and E.i.6 do not appear

low=Interval Boundary (IVXB) | Value | /MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][observation[id][code[@code='29'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']]][i]/observation[@classCode='OBS'][@moodCode='EVN']/effectiveTime[@xsi:type='IVL_TS']/low/@value |
| e | | | | | | NullFlavor | /MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][observation[id][code[@code='29'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']]][i]/observation[@classCode='OBS'][@moodCode='EVN']/effectiveTime[@xsi:type='IVL_TS']/low/@nullFlavor |

e				2. When all the elements E.i.4, E.i.5, and E.i.6 appear The first comp element with data type SXPR HL7 Data Type: Parenthetic Set Expression of Point in Time (SXPR<TS>)	2. When all the elements E.i.4, E.i.5, and E.i.6 appear The first comp element with data type SXPR comp/low=Interval Boundary (IVXB)	Value	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][observation[id][code[@code='29'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']]][i]/observation[@classCode='OBS'][@moodCode='EVN']/effectiveTime[@xsi:type='SXPR_TS']/comp[@xsi:type='IVL_TS']/low/@value
e						NullFlavor	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][observation[id][code[@code='29'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']]][i]/observation[@classCode='OBS'][@moodCode='EVN']/effectiveTime[@xsi:type='SXPR_TS']/comp[@xsi:type='IVL_TS']/low/@nullFlavor

| | | | | 3. When all the elements E.i.4, E.i.5, and E.i.6 appear

The second comp element with data type SXPR

HL7 Data Type: Parenthetic Set Expression of Point in Time (SXPR<TS>) | 3. When all the elements E.i.4, E.i.5, and E.i.6 appear

The second comp element with data type SXPR

comp/low=Interval Boundary (IVXB) | Value | /MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][observation[id][code[@code='29'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']]][i]/observation[@classCode='OBS'][@moodCode='EVN']/effectiveTime[@xsi:type='SXPR_TS']/comp[@xsi:type='IVL_TS'][@operator='A']/low/@value |
| | | | | | | NullFlavor | /MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][observation[id][code[@code='29'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']]][i]/observation[@classCode='OBS'][@moodCode='EVN']/effectiveTime[@xsi:type='SXPR_TS']/comp[@xsi:type='IVL_TS'][@operator='A']/low/@nullFlavor |

e	E.i.5	Date of End of Reaction / Event	Date/Time	1. When all the elements E.i.4, E.i.5, and E.i.6 do not appear HL7 Data Type: Interval of Point in Time (IVL<TS>)	1. When all the elements E.i.4, E.i.5, and E.i.6 do not appear high=Interval Boundary (IVXB)	Value	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][observation[id][code[@code='29'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']]][i]/observation[@classCode='OBS'][@moodCode='EVN']/effectiveTime[@xsi:type='IVL_TS']/high/@value
e						NullFlavor	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][observation[id][code[@code='29'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']]][i]/observation[@classCode='OBS'][@moodCode='EVN']/effectiveTime[@xsi:type='IVL_TS']/high/@nullFlavor

e					2. When all the elements E.i.4, E.i.5, and E.i.6 appear The first comp element with data type SXPR HL7 Data Type: Parenthetic Set Expression of Point in Time (SXPR<TS>)	2. When all the elements E.i.4, E.i.5, and E.i.6 appear The first comp element with data type SXPR comp/high=Interval Boundary (IVXB)	Value	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][observation[id][code[@code='29'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']]][i]/observation[@classCode='OBS'][@moodCode='EVN']/effectiveTime[@xsi:type='SXPR_TS']/comp[@xsi:type='IVL_TS']/high/@value
e							NullFlavor	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][observation[id][code[@code='29'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']]][i]/observation[@classCode='OBS'][@moodCode='EVN']/effectiveTime[@xsi:type='SXPR_TS']/comp[@xsi:type='IVL_TS']/high/@nullFlavor

				3. When all the elements E.i.4, E.i.5, and E.i.6 appear The second comp element with data type SXPR HL7 Data Type: Parenthetic Set Expression of Point in Time (SXPR<TS>)	3. When all the elements E.i.4, E.i.5, and E.i.6 appear The second comp element with data type SXPR comp/high=Interval Boundary (IVXB)	Value	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][observation[id][code[@code='29'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']]][i]/observation[@classCode='OBS'][@moodCode='EVN']/effectiveTime[@xsi:type='SXPR_TS']/comp[@xsi:type='IVL_TS'][@operator='A']/high/@value
						NullFlavor	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][observation[id][code[@code='29'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']]][i]/observation[@classCode='OBS'][@moodCode='EVN']/effectiveTime[@xsi:type='SXPR_TS']/comp[@xsi:type='IVL_TS'][@operator='A']/high/@nullFlavor

| e | E.i.6a | Duration of Reaction / Event (number) | 5N | 1. When all the elements E.i.4, E.i.5, and E.i.6 do not appear

HL7 Data Type: Interval of Point in Time (IVL<TS>) | 1. When all the elements E.i.4, E.i.5, and E.i.6 do not appear

width/value=Real Number (REAL) | Value | /MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][observation[id][code[@code='29'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']]][i]/observation[@classCode='OBS'][@moodCode='EVN']/effectiveTime[@xsi:type='IVL_TS']/width/@value |
| e | | | | 2. When all the elements E.i.4, E.i.5, and E.i.6 appear

The first comp element with data type SXPR

HL7 Data Type: Parenthetic Set Expression of Point in Time (SXPR<TS>) | 2. When all the elements E.i.4, E.i.5, and E.i.6 appear

The first comp element with data type SXPR

comp/width/value= Real Number (REAL) | Value | /MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][observation[id][code[@code='29'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']]][i]/observation[@classCode='OBS'][@moodCode='EVN']/effectiveTime[@xsi:type='SXPR_TS']/comp[@xsi:type='IVL_TS']/width/@value |

				3. When all the elements E.i.4, E.i.5, and E.i.6 appear The second comp element with data type SXPR HL7 Data Type: Parenthetic Set Expression of Point in Time (SXPR<TS>)	3. When all the elements E.i.4, E.i.5, and E.i.6 appear The second comp element with data type SXPR comp/width/value= Real Number (REAL)	Value	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][observation[id][code[@code='29'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']]][i]/observation[@classCode='OBS'][@moodCode='EVN']/effectiveTime[@xsi:type='SXPR_TS']/comp[@xsi:type='IVL_TS'][@operator='A']/width/@value
e	E.i.6b	Duration of Reaction / Event (unit)	50AN	1. When all the elements E.i.4, E.i.5, and E.i.6 do not appear HL7 Data Type: Interval of Point in Time (IVL<TS>)	1. When all the elements E.i.4, E.i.5, and E.i.6 do not appear width/unit=Coded Simple Value (CS)	Value	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][observation[id][code[@code='29'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']]][i]/observation[@classCode='OBS'][@moodCode='EVN']/effectiveTime[@xsi:type='IVL_TS']/width/@unit

| e | | | | 2. When all the elements E.i.4, E.i.5, and E.i.6 appearThe first comp element with data type SXPRHL7 Data Type: Parenthetic Set Expression of Point in Time (SXPR<TS>) | 2. When all the elements E.i.4, E.i.5, and E.i.6 appearThe first comp element with data type SXPRcomp/width/unit =Coded Simple Value (CS) | Value | /MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][observation[id][code[@code='29'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']]][i]/observation[@classCode='OBS'][@moodCode='EVN']/effectiveTime[@xsi:type='SXPR_TS']/comp[@xsi:type='IVL_TS']/width/@unit |
| e | | | | 3. When all the elements E.i.4, E.i.5, and E.i.6 appear

The second comp element with data type SXPR

HL7 Data Type: Parenthetic Set Expression of Point in Time (SXPR<TS>) | 3. When all the elements E.i.4, E.i.5, and E.i.6 appear

The second comp element with data type SXPR

comp/width/unit=Coded Simple Value (CS) | Value | /MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][observation[id][code[@code='29'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']]][i]/observation[@classCode='OBS'][@moodCode='EVN']/effectiveTime[@xsi:type='SXPR_TS']/comp[@xsi:type='IVL_TS'][@operator='A']/width/@unit |

e	E.i.7	Outcome of Reaction / Event at the Time of Last Observation	1N	Coded With Equivalents (CE)	code=Character String (ST)	Value	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][observation[id][code[@code='29'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']]][i]/observation[@classCode='OBS'][@moodCode='EVN']/outboundRelationship2[@typeCode='PERT'][observation/code[@code='27'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']][1]/observation[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='CE'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.11'][1]/@code
		ICH Code List Version for Outcome of Reaction / Event at the Time of Last Observation					/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][observation[id][code[@code='29'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']]][i]/observation[@classCode='OBS'][@moodCode='EVN']/outboundRelationship2[@typeCode='PERT'][observation/code[@code='27'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']][1]/observation[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='CE'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.11'][1]/@codeSystemVersion

e	E.i.8	Medical Confirmation by Healthcare Professional	Boolean	Boolean (BL)		Value	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][observation[id][code[@code='29'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']]][i]/observation[@classCode='OBS'][@moodCode='EVN']/outboundRelationship2[@typeCode='PERT'][observation/code[@code='24'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']][1]/observation[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='BL']/@value
e	E.i.9	Identification of the Country Where the Reaction / Event Occurred	2A	Concept Descriptor (CD)	code=Character String (ST)	Value	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][observation[id][code[@code='29'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']]][i]/observation[@classCode='OBS'][@moodCode='EVN']/location[@typeCode='LOC'][1]/locatedEntity[@classCode='LOCE']/locatedPlace[@classCode='COUNTRY'][@determinerCode='INSTANCE']/code[@codeSystem='1.0.3166.1.2.2']/@code

h	F.r	Results of Tests and Procedures Relevant to the Investigation of the Patient (repeat as necessary)				Repeat Node	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][organizer/code[@code='3'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][observation/code[@codeSystem='2.16.840.1.113883.6.163']]
e	F.r.1	Test Date	Date/Time	Point in Time (TS)		Value	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][organizer/code[@code='3'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][observation/code[@codeSystem='2.16.840.1.113883.6.163']][r]/observation[@classCode='OBS'][@moodCode='EVN']/effectiveTime/@value

e						NullFlavor	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][organizer/code[@code='3'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][observation/code[@codeSystem='2.16.840.1.113883.6.163']][r]/observation[@classCode='OBS'][@moodCode='EVN']/effectiveTime/@nullFlavor
h	F.r.2	Test Name					
e	F.r.2.1	Test Name (free text)	250AN	Concept Descriptor (CD)	originalText=Encapsulated Data (ED)	Value	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][organizer/code[@code='3'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][observation/code[@codeSystem='2.16.840.1.113883.6.163']][r]/observation[@classCode='OBS'][@moodCode='EVN']/code/originalText/text()

e	F.r.2.2a	MedDRA Version for Test Name	4AN	Concept Descriptor (CD)	codeSystemVersion= Character String (ST)	Value	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][organizer/code[@code='3'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][observation/code[@codeSystem='2.16.840.1.113883.6.163']][r]/observation[@classCode='OBS'][@moodCode='EVN']/code/@codeSystemVersion
e	F.r.2.2b	Test Name (MedDRA code)	8N	Concept Descriptor (CD)	code=Character String (ST)	Value	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][organizer/code[@code='3'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][observation/code[@codeSystem='2.16.840.1.113883.6.163']][r]/observation[@classCode='OBS'][@moodCode='EVN']/code/@code
h	F.r.3	Test Result					

| e | F.r.3.1 | Test Result (code) | 1N | Coded With Equivalents (CE) | code=Character String (ST) | Value | /MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][organizer/code[@code='3'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][observation/code[@codeSystem='2.16.840.1.113883.6.163']][r]/observation[@classCode='OBS'][@moodCode='EVN']/interpretationCode[@codeSystem='2.16.840.1.113883.3.989.2.1.1.12'][1]/@code |
| | | ICH Code List Version for Test Result (code) | | | | | /MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][organizer/code[@code='3'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][observation/code[@codeSystem='2.16.840.1.113883.6.163']][r]/observation[@classCode='OBS'][@moodCode='EVN']/interpretationCode[@codeSystem='2.16.840.1.113883.3.989.2.1.1.12'][1]/@codeSystemVersion |

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

| e | | | | | | 3. GE
low=Interval
Boundary (IVXB) | Value | /MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][organizer/code[@code='3'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][observation/code[@codeSystem='2.16.840.1.113883.6.163']][r]/observation[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='IVL_PQ'][high/@nullFlavor='PINF'][1]/low[@inclusive='true']/@value |
| e | | | | | | 4. LT
high=Interval
Boundary (IVXB) | Value | /MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][organizer/code[@code='3'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][observation/code[@codeSystem='2.16.840.1.113883.6.163']][r]/observation[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='IVL_PQ'][low/@nullFlavor='NINF'][1]/high[@inclusive='false']/@value |

e					5. LEhigh=Interval Boundary (IVXB)	Value	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][organizer/code[@code='3'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][observation/code[@codeSystem='2.16.840.1.113883.6.163']][r]/observation[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='IVL_PQ'][low/@nullFlavor='NINF'][1]/high[@inclusive='true']/@value
e	F.r.3.3	Test Result (unit)	50AN	Interval of Physical Quantity (IVL<PQ>)	1. EQ center/value/unit=Physical Quantity (PQ)	Value	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][organizer/code[@code='3'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][observation/code[@codeSystem='2.16.840.1.113883.6.163']][r]/observation[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='IVL_PQ'][1]/center/@unit

| e | | | | | | 2. GT
low/value/unit=Coded
Simple Value (CS) | Value | /MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][organizer/code[@code='3'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][observation/code[@codeSystem='2.16.840.1.113883.6.163']][r]/observation[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='IVL_PQ'][high/@nullFlavor='PINF'][1]/low[@inclusive='false']/@unit |
| e | | | | | | 3. GE
low/value/unit=Coded
Simple Value (CS) | Value | /MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][organizer/code[@code='3'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][observation/code[@codeSystem='2.16.840.1.113883.6.163']][r]/observation[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='IVL_PQ'][high/@nullFlavor='PINF'][1]/low[@inclusive='true']/@unit |

					4. LT high/value/unit=Code d Simple Value (CS)	Value	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][organizer/code[@code='3'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][observation/code[@codeSystem='2.16.840.1.113883.6.163']][r]/observation[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='IVL_PQ'][low/@nullFlavor='NINF'][1]/high[@inclusive='false']/@unit
e							
e					5. LE high/value/unit=Code d Simple Value (CS)	Value	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][organizer/code[@code='3'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][observation/code[@codeSystem='2.16.840.1.113883.6.163']][r]/observation[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='IVL_PQ'][low/@nullFlavor='NINF'][1]/high[@inclusive='true']/@unit

e	F.r.3.4	Result Unstructured Data (free text)	2000AN	Encapsulated Data (ED)		Value	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][organizer/code[@code='3'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][observation/code[@codeSystem='2.16.840.1.113883.6.163']][r]/observation[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='ED'][1]/text()
e	F.r.4	Normal Low Value	50AN	Physical Quantity (PQ)	value=Real Number (REAL)	Value	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][organizer/code[@code='3'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][observation/code[@codeSystem='2.16.840.1.113883.6.163']][r]/observation[@classCode='OBS'][@moodCode='EVN']/referenceRange[@typeCode='REFV'][observationRange/interpretationCode[@code='L'][@codeSystem='2.16.840.1.113883.5.83']][1]/observationRange[@classCode='OBS'][@moodCode='EVN.CRT']/value[@xsi:type='PQ']/@value

e	F.r.5	Normal High Value	50AN	Physical Quantity (PQ)	value=Real Number (REAL)	Value	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][organizer/code[@code='3'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][observation/code[@codeSystem='2.16.840.1.113883.6.163']][r]/observation[@classCode='OBS'][@moodCode='EVN']/referenceRange[@typeCode='REFV'][observationRange/interpretationCode[@code='H'][@codeSystem='2.16.840.1.113883.5.83']][1]/observationRange[@classCode='OBS'][@moodCode='EVN.CRT']/value[@xsi:type='PQ']/@value
e	F.r.6	Comments (free text)	2000AN	Encapsulated Data (ED)		Value	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][organizer/code[@code='3'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][observation/code[@codeSystem='2.16.840.1.113883.6.163']][r]/observation[@classCode='OBS'][@moodCode='EVN']/outboundRelationship2[@typeCode='PERT'][observation/code[@code='10'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']]/observation[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='ED'][1]/text()

e	F.r.7	More Information Available	Boolean	Boolean (BL)		Value	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][organizer/code[@code='3'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][observation/code[@codeSystem='2.16.840.1.113883.6.163']][r]/observation[@classCode='OBS'][@moodCode='EVN']/outboundRelationship2[@typeCode='REFR'][observation/code[@code='25'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']]/observation[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='BL'][1]/@value
h	G.k	Drug(s) Information (repeat as necessary)				Repeat Node	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][organizer/code[@code='4'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][substanceAdministration/id]

e	G.k.1	Characterisation of Drug Role	1N	Coded With Equivalents (CE)	code=Character String (ST)	Value	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][causalityAssessment/code[@code='20'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']]/causalityAssessment[@classCode='OBS'][@moodCode='EVN'][subject2[@typeCode='SUBJ']/productUseReference[@classCode='SBADM'][@moodCode='EVN']/id[@root='UUID of k-th drug']]/value[@xsi:type='CE'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.13']/@code
		ICH Code List Version for Characterisation of Drug Role					/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][causalityAssessment/code[@code='20'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']]/causalityAssessment[@classCode='OBS'][@moodCode='EVN'][subject2[@typeCode='SUBJ']/productUseReference[@classCode='SBADM'][@moodCode='EVN']/id[@root='UUID of k-th drug']]/value[@xsi:type='CE'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.13']/@codeSystemVersion
h	G.k.2	Drug Identification					
h	G.k.2.1	Medical Product Unique Identifier / Pharmaceutical Product Identifier					

| e | G.k.2.1.1a | MPID Version Date / Number | As per ISO IDMP | Coded With Equivalents (CE) | codeSystemVersion= Character String (ST) | Value | /MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][organizer/code[@code='4'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][substanceAdministration/id][k]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/consumable[@typeCode='CSM'][1]/instanceOfKind[@classCode='INST']/kindOfProduct[@classCode='MMAT'][@determinerCode='KIND']/code[@codeSystem='TBD-MPID']/@codeSystemVersion |
| e | G.k.2.1.1b | Medicinal Product Identifier (MPID) | As per ISO IDMP | Coded With Equivalents (CE) | code=Character String (ST) | Value | /MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][organizer/code[@code='4'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][substanceAdministration/id][k]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/consumable[@typeCode='CSM'][1]/instanceOfKind[@classCode='INST']/kindOfProduct[@classCode='MMAT'][@determinerCode='KIND']/code[@codeSystem='TBD-MPID']/@code |

e	G.k.2.1.2a	PhPID Version Date / Number	As per ISO IDMP	Coded With Equivalents (CE)	codeSystemVersion= Character String (ST)	Value	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][organizer/code[@code='4'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][substanceAdministration/id][k]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/consumable[@typeCode='CSM'][1]/instanceOfKind[@classCode='INST']/kindOfProduct[@classCode='MMAT'][@determinerCode='KIND']/code[@codeSystem='TBD-PhPID']/@codeSystemVersion
e	G.k.2.1.2b	Pharmaceutical Product Identifier (PhPID)	As per ISO IDMP	Coded With Equivalents (CE)	code=Character String (ST)	Value	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][organizer/code[@code='4'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][substanceAdministration/id][k]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/consumable[@typeCode='CSM'][1]/instanceOfKind[@classCode='INST']/kindOfProduct[@classCode='MMAT'][@determinerCode='KIND']/code[@codeSystem='TBD-PhPID']/@code

e	G.k.2.2	Medicinal Product Name as Reported by the Primary Source	250AN	Entity Name (EN)	name=Entity Name Part (ENXP)	Value	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][organizer/code[@code='4'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][substanceAdministration/id][k]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/consumable[@typeCode='CSM'][1]/instanceOfKind[@classCode='INST']/kindOfProduct[@classCode='MMAT'][@determinerCode='KIND']/name[1]/text()
h	G.k.2.3.r	Substance / Specified Substance Identifier and Strength (repeat as necessary)				Repeat Node	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][organizer/code[@code='4'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][substanceAdministration/id][k]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/consumable[@typeCode='CSM'][1]/instanceOfKind[@classCode='INST']/kindOfProduct[@classCode='MMAT'][@determinerCode='KIND']/ingredient[@classCode='ACTI']

e	G.k.2.3.r.1	Substance / Specified Substance Name	250AN	Trivial Name (TN)	name=Entity Name Part (ENXP)	Value	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][organizer/code[@code='4'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][substanceAdministration/id][k]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/consumable[@typeCode='CSM'][1]/instanceOfKind[@classCode='INST']/kindOfProduct[@classCode='MMAT'][@determinerCode='KIND']/ingredient[@classCode='ACTI'][r]/ingredientSubstance[@classCode='MMAT'][@determinerCode='KIND']/name[1]/text()
e	G.k.2.3.r.2a	Substance / Specified Substance TermID Version Date / Number	As per ISO IDMP	Coded With Equivalents (CE)	codeSystemVersion= Character String (ST)	Value	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][organizer/code[@code='4'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][substanceAdministration/id][k]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/consumable[@typeCode='CSM'][1]/instanceOfKind[@classCode='INST']/kindOfProduct[@classCode='MMAT'][@determinerCode='KIND']/ingredient[@classCode='ACTI'][r]/ingredientSubstance[@classCode='MMAT'][@determinerCode='KIND']/code[@codeSystem='TBD-Substance']/@codeSystemVersion

e	G.k.2.3.r.2b	Substance / Specified Substance TermID	As per ISO IDMP	Coded With Equivalents (CE)	code=Character String (ST)	Value	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][organizer/code[@code='4'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][substanceAdministration/id][k]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/consumable[@typeCode='CSM'][1]/instanceOfKind[@classCode='INST']/kindOfProduct[@classCode='MMAT'][@determinerCode='KIND']/ingredient[@classCode='ACTI'][r]/ingredientSubstance[@classCode='MMAT'][@determinerCode='KIND']/code[@codeSystem='TBD-Substance']/@code
e	G.k.2.3.r.3a	Strength (number)	10N	Physical Quantity (PQ)	value=Real Number (REAL)	Value	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][organizer/code[@code='4'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][substanceAdministration/id][k]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/consumable[@typeCode='CSM'][1]/instanceOfKind[@classCode='INST']/kindOfProduct[@classCode='MMAT'][@determinerCode='KIND']/ingredient[@classCode='ACTI'][r]/quantity[denominator/@value='1']/numerator/@value

e	G.k.2.3.r.3b	Strength (unit)	50AN	Physical Quantity (PQ)	unit=Coded Simple Value (CS)	Value	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][organizer/code[@code='4'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][substanceAdministration/id][k]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/consumable[@typeCode='CSM'][1]/instanceOfKind[@classCode='INST']/kindOfProduct[@classCode='MMAT'][@determinerCode='KIND']/ingredient[@classCode='ACTI'][r]/quantity[denominator/@value='1']/numerator/@unit
e	G.k.2.4	Identification of the Country Where the Drug Was Obtained	2A	Postal Address (AD)	country=Address Part (ADXP)	Value	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][organizer/code[@code='4'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][substanceAdministration/id][k]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/consumable[@typeCode='CSM'][1]/instanceOfKind[@classCode='INST']/subjectOf[@typeCode='SBJ'][1]/productEvent[@classCode='ACT'][@moodCode='EVN'][code[@code='1'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.18']]/performer[@typeCode='PRF']/assignedEntity[@classCode='ASSIGNED']/representedOrganization[@classCode='ORG'][@determinerCode='INSTANCE']/addr/country[1]/text()

e	G.k.2.5	Investigational Product Blinded	Boolean	Boolean (BL)		Value	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][organizer/code[@code='4'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][substanceAdministration/id][k]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/outboundRelationship2[@typeCode='PERT'][observation/code[@code='6'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']][1]/observation[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='BL'][1]/@value
h	G.k.3	Holder and Authorisation / Application Number of Drug					
e	G.k.3.1	Authorisation / Application Number	35AN	Instance Identifier (II)	extension=Character String (ST)	Value	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][organizer/code[@code='4'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][substanceAdministration/id][k]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/consumable[@typeCode='CSM'][1]/instanceOfKind[@classCode='INST']/kindOfProduct[@classCode='MMAT'][@determinerCode='KIND']/asManufacturedProduct[@classCode='MANU']/subjectOf[@typeCode='SBJ'][1]/approval[@classCode='CNTRCT'][@moodCode='EVN']/id[@root='2.16.840.1.113883.3.989.2.1.3.4']/@extension

e	G.k.3.2	Country of Authorisation / Application	2A	Coded With Equivalents (CE)	code=Character String (ST)	Value	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][organizer/code[@code='4'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][substanceAdministration/id][k]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/consumable[@typeCode='CSM'][1]/instanceOfKind[@classCode='INST']/kindOfProduct[@classCode='MMAT'][@determinerCode='KIND']/asManufacturedProduct[@classCode='MANU']/subjectOf[@typeCode='SBJ'][1]/approval[@classCode='CNTRCT'][@moodCode='EVN']/author[@typeCode='AUT']/territorialAuthority[@classCode='TERR']/territory[@classCode='NAT'][@determinerCode='INSTANCE']/code[@codeSystem='1.0.3166.1.2.2']/@code

e	G.k.3.3	Name of Holder / Applicant	60AN	Organization Name (ON)	name=Entity Name Part (ENXP)	Value	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][organizer/code[@code='4'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][substanceAdministration/id][k]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/consumable[@typeCode='CSM'][1]/instanceOfKind[@classCode='INST']/kindOfProduct[@classCode='MMAT'][@determinerCode='KIND']/asManufacturedProduct[@classCode='MANU']/subjectOf[@typeCode='SBJ'][1]/approval[@classCode='CNTRCT'][@moodCode='EVN']/holder[@typeCode='HLD'][1]/role[@classCode='HLD']/playingOrganization[@classCode='ORG'][@determinerCode='INSTANCE']/name/text()
h	G.k.4.r	Dosage and Relevant Information (repeat as necessary)				Repeat Node	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][organizer/code[@code='4'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][substanceAdministration/id][k]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/outboundRelationship2[@typeCode='COMP'][substanceAdministration]

e	G.k.4.r.1a	Dose (number)	8N	Physical Quantity (PQ)	value=Real Number (REAL)	Value	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][organizer/code[@code='4'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][substanceAdministration/id][k]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/outboundRelationship2[@typeCode='COMP'][substanceAdministration][r]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/doseQuantity/@value
e	G.k.4.r.1a	Dose (number)	8N	When unit in G.k.4.r.3 is Total: Physical Quantity (PQ)	value=Real Number (REAL)	Value	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][organizer/code[@code='4'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][substanceAdministration/id][k]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/outboundRelationship2[@typeCode='COMP'][substanceAdministration][r]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/doseCheckQuantity[denominator[@xsi:type='PQ'][@nullFlavor='UNK']]/numerator[@xsi:type='PQ']/@value

e	G.k.4.r.1b	Dose (unit)	50AN	Physical Quantity (PQ)	unit=Coded Simple Value (CS)	Value	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][organizer/code[@code='4'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][substanceAdministration/id][k]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/outboundRelationship2[@typeCode='COMP'][substanceAdministration][r]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/doseQuantity/@unit
e	G.k.4.r.1b	Dose (unit)	50AN	When unit in G.k.4.r.3 is Total: Physical Quantity (PQ)	unit=Coded Simple Value (CS)	Value	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][organizer/code[@code='4'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][substanceAdministration/id][k]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/outboundRelationship2[@typeCode='COMP'][substanceAdministration][r]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/doseCheckQuantity[denominator[@xsi:type='PQ'][@nullFlavor='UNK']]/numerator[@xsi:type='PQ']/@unit

e	G.k.4.r.2	Number of Units in the Interval	4N	1. When more than two values in the following data elements appear 1) G.k.4.r.2、G.k.4.r.3 2) G.k.4.r.4 3) G.k.4.r.5 4) G.k.4.r.6a、G.k.4.r.6bThe first comp element with data type SXPRParenthetic Set Expression of Time (SXPR_TS) [Periodic Interval of Time (PIVL_TS)]	period/value=Real Number (REAL)	Value	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][organizer/code[@code='4'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][substanceAdministration/id][k]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/outboundRelationship2[@typeCode='COMP'][substanceAdministration][r]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/effectiveTime[@xsi:type='SXPR_TS']/comp[@xsi:type='PIVL_TS']/period/@value

				2. When more than two values in the following data elements appear
				
				  1) G.k.4.r.2、G.k.4.r.3
				  2) G.k.4.r.4
				  3) G.k.4.r.5
				  4) G.k.4.r.6a、G.k.4.r.6b
				
				The second comp element with data type SXPR
				
				Parenthetic Set Expression of Time (SXPR_TS) [Periodic Interval of Time (PIVL_TS)]
						Value	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][organizer/code[@code='4'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][substanceAdministration/id][k]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/outboundRelationship2[@typeCode='COMP'][substanceAdministration][r]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/effectiveTime[@xsi:type='SXPR_TS']/comp[@xsi:type='PIVL_TS'][@operator='A']/period/@value

| e | | | | | 3. When only one value in the following data elements appears

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

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

| e | G.k.4.r.3 | Definition of the Time Interval Unit | 50AN | 1. When two values in the following data elements appear

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

The first comp element with data type SXPR

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

| | | | | 2. When more than two values in the following data elements appear 1) G.k.4.r.2、 G.k.4.r.3   2) G.k.4.r.4   3) G.k.4.r.5   4) G.k.4.r.6a、 G.k.4.r.6bThe second comp element with data type SXPRParenthetic Set Expression of Time (SXPR_TS) [Periodic Interval of Time (PIVL_TS)] | | Value | /MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][organizer/code[@code='4'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][substanceAdministration/id][k]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/outboundRelationship2[@typeCode='COMP'][substanceAdministration][r]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/effectiveTime[@xsi:type='SXPR_TS']/comp[@xsi:type='PIVL_TS'][@operator='A']/period/@unit |

e				3. When only one value in the following data elements appears 1) G.k.4.r.2、G.k.4.r.3 2) G.k.4.r.4 3) G.k.4.r.5 4) G.k.4.r.6a、G.k.4.r.6b Periodic Interval of Time (PIVL_TS)	period/unit=Coded Simple Value (CS)	Value	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][organizer/code[@code='4'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][substanceAdministration/id][k]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/outboundRelationship2[@typeCode='COMP'][substanceAdministration][r]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/effectiveTime[@xsi:type='PIVL_TS']/period/@unit

| e | G.k.4.r.4 | Date and Time of Start of Drug | Date/Time | 1. When more than two values in the following data elements appear

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

The first comp element with data type SXPR

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

e						NullFlavor	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][organizer/code[@code='4'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][substanceAdministration/id][k]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/outboundRelationship2[@typeCode='COMP'][substanceAdministration][r]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/effectiveTime[@xsi:type='SXPR_TS']/comp[@xsi:type='IVL_TS']/low/@nullFlavor

				2. When more than two values in the following data elements appear
				
				  1) G.k.4.r.2、G.k.4.r.3
				  2) G.k.4.r.4
				  3) G.k.4.r.5
				  4) G.k.4.r.6a、G.k.4.r.6b
				
				The second comp element with data type SXPR
				
				Parenthetic Set Expression of Time (SXPR_TS) [Intervale of Point in Time (IVL_TS)]
						Value	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][organizer/code[@code='4'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][substanceAdministration/id][k]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/outboundRelationship2[@typeCode='COMP'][substanceAdministration][r]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/effectiveTime[@xsi:type='SXPR_TS']/comp[@xsi:type='IVL_TS'][@operator='A']/low/@value

						NullFlavor	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][organizer/code[@code='4'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][substanceAdministration/id][k]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/outboundRelationship2[@typeCode='COMP'][substanceAdministration][r]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/effectiveTime[@xsi:type='SXPR_TS']/comp[@xsi:type='IVL_TS'][@operator='A']/low/@nullFlavor
e					3. When only one value in the following data elements appears 1) G.k.4.r.2、G.k.4.r.3 2) G.k.4.r.4 3) G.k.4.r.5 4) G.k.4.r.6a、G.k.4.r.6bInterval of Point in Time (IVL_TS)	low=Interval Boundary (IVXB)	Value	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][organizer/code[@code='4'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][substanceAdministration/id][k]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/outboundRelationship2[@typeCode='COMP'][substanceAdministration][r]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/effectiveTime[@xsi:type='IVL_TS']/low/@value

| e | | | | | | NullFlavor | /MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][organizer/code[@code='4'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][substanceAdministration/id][k]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/outboundRelationship2[@typeCode='COMP'][substanceAdministration][r]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/effectiveTime[@xsi:type='IVL_TS']/low/@nullFlavor |

e	G.k.4.r.5	Date and Time of Last Administration	Date/Time	1. When more than two values in the following data elements appear
				
				    1) G.k.4.r.2、G.k.4.r.3
				    2) G.k.4.r.4
				    3) G.k.4.r.5
				    4) G.k.4.r.6a、G.k.4.r.6b
				
				The first comp element with data type SXPR
				
				Parenthetic Set Expression of Time (SXPR_TS) [Intervale of Point in Time (IVL_TS)]
					high=Interval Boundary (IVXB)	Value	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][organizer/code[@code='4'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][substanceAdministration/id][k]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/outboundRelationship2[@typeCode='COMP'][substanceAdministration][r]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/effectiveTime[@xsi:type='SXPR_TS']/comp[@xsi:type='IVL_TS']/high/@value

e						NullFlavor	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][organizer/code[@code='4'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][substanceAdministration/id][k]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/outboundRelationship2[@typeCode='COMP'][substanceAdministration][r]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/effectiveTime[@xsi:type='SXPR_TS']/comp[@xsi:type='IVL_TS']/high/@nullFlavor

				2. When more than two values in the following data elements appear
				
				  1) G.k.4.r.2、G.k.4.r.3
				  2) G.k.4.r.4
				  3) G.k.4.r.5
				  4) G.k.4.r.6a、G.k.4.r.6b
				
				The second comp element with data type SXPR
				
				Parenthetic Set Expression of Time (SXPR_TS) [Intervale of Point in Time (IVL_TS)]
						Value	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][organizer/code[@code='4'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][substanceAdministration/id][k]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/outboundRelationship2[@typeCode='COMP'][substanceAdministration][r]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/effectiveTime[@xsi:type='SXPR_TS']/comp[@xsi:type='IVL_TS'][@operator='A']/high/@value

						NullFlavor	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][organizer/code[@code='4'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][substanceAdministration/id][k]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/outboundRelationship2[@typeCode='COMP'][substanceAdministration][r]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/effectiveTime[@xsi:type='SXPR_TS']/comp[@xsi:type='IVL_TS'][@operator='A']/high/@nullFlavor
e				3. When only one value in the following data elements appears 1) G.k.4.r.2、G.k.4.r.3 2) G.k.4.r.4 3) G.k.4.r.5 4) G.k.4.r.6a、G.k.4.r.6b Interval of Point in Time (IVL_TS)	high=Interval Boundary (IVXB)	Value	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][organizer/code[@code='4'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][substanceAdministration/id][k]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/outboundRelationship2[@typeCode='COMP'][substanceAdministration][r]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/effectiveTime[@xsi:type='IVL_TS']/high/@value

e						NullFlavor	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][organizer/code[@code='4'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][substanceAdministration/id][k]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/outboundRelationship2[@typeCode='COMP'][substanceAdministration][r]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/effectiveTime[@xsi:type='IVL_TS']/high/@nullFlavor

e	G.k.4.r.6a	Duration of Drug Administration (number)	5N	1. When more than two values in the following data elements appear 1) G.k.4.r.2、G.k.4.r.3 2) G.k.4.r.4 3) G.k.4.r.5 4) G.k.4.r.6a、G.k.4.r.6b The first comp element with data type SXPR Parenthetic Set Expression of Time (SXPR_TS) [Intervale of Point in Time (IVL_TS)]	width/value=Real Number (REAL)	Value	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][organizer/code[@code='4'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][substanceAdministration/id][k]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/outboundRelationship2[@typeCode='COMP'][substanceAdministration][r]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/effectiveTime[@xsi:type='SXPR_TS']/comp[@xsi:type='IVL_TS']/width/@value

| | | | | 2. When more than two values in the following data elements appear

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

The second comp element with data type SXPR

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

| e | | | | | 3. When only one value in the following data elements appears

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

Interval of Point in Time (IVL_TS) | width/value=Real Number (REAL) | Value | /MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][organizer/code[@code='4'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][substanceAdministration/id][k]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/outboundRelationship2[@typeCode='COMP'][substanceAdministration][r]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/effectiveTime[@xsi:type='IVL_TS']/width/@value |

e	G.k.4.r.6b	Duration of Drug Administration (unit)	50AN	1. When more than two values in the following data elements appear 1) G.k.4.r.2、G.k.4.r.3 2) G.k.4.r.4 3) G.k.4.r.5 4) G.k.4.r.6a、G.k.4.r.6b The first comp element with data type SXPR Parenthetic Set Expression of Time (SXPR_TS) [Intervale of Point in Time (IVL_TS)]	width/unit=Coded Simple Value (CS)	Value	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][organizer/code[@code='4'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][substanceAdministration/id][k]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/outboundRelationship2[@typeCode='COMP'][substanceAdministration][r]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/effectiveTime[@xsi:type='SXPR_TS']/comp[@xsi:type='IVL_TS']/width/@unit

| | | | | 2. When more than two values in the following data elements appear 1) G.k.4.r.2、G.k.4.r.3 2) G.k.4.r.4 3) G.k.4.r.5 4) G.k.4.r.6a、G.k.4.r.6bThe second comp element with data type SXPRParenthetic Set Expression of Time (SXPR_TS) [Intervale of Point in Time (IVL_TS)] | | Value | /MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][organizer/code[@code='4'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][substanceAdministration/id][k]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/outboundRelationship2[@typeCode='COMP'][substanceAdministration][r]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/effectiveTime[@xsi:type='SXPR_TS']/comp[@xsi:type='IVL_TS'][@operator='A']/width/@unit |

| e | | | | 3. When only one value in the following data elements appears

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

Interval of Point in Time (IVL_TS) | width/unit=Coded Simple Value (CS) | Value | /MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][organizer/code[@code='4'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][substanceAdministration/id][k]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/outboundRelationship2[@typeCode='COMP'][substanceAdministration][r]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/effectiveTime[@xsi:type='IVL_TS']/width/@unit |

e	G.k.4.r.7	Batch / Lot Number	35AN	Character String (ST)		Value	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][organizer/code[@code='4'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][substanceAdministration/id][k]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/outboundRelationship2[@typeCode='COMP'][substanceAdministration][r]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/consumable[@typeCode='CSM'][1]/instanceOfKind[@classCode='INST']/productInstanceInstance[@classCode='MMAT'][@determinerCode='INSTANCE']/lotNumberText/text()
e	G.k.4.r.8	Dosage Text	2000AN	Encapsulated Data (ED)		Value	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][organizer/code[@code='4'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][substanceAdministration/id][k]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/outboundRelationship2[@typeCode='COMP'][substanceAdministration][r]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/text/text()
h	G.k.4.r.9	Pharmaceutical Dose Form					

| e | G.k.4.r.9.1 | Pharmaceutical Dose Form (free text) | 60AN | Coded With Equivalents (CE) | originalText=Encapsulated Data (ED) | Value | /MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][organizer/code[@code='4'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][substanceAdministration/id][k]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/outboundRelationship2[@typeCode='COMP'][substanceAdministration][r]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/consumable[@typeCode='CSM'][1]/instanceOfKind[@classCode='INST']/kindOfProduct[@classCode='MMAT'][@determinerCode='KIND']/formCode[@codeSystem='TBD-DoseForm']/originalText/text() |
| e | | | | | | NullFlavor | /MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][organizer/code[@code='4'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][substanceAdministration/id][k]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/outboundRelationship2[@typeCode='COMP'][substanceAdministration][r]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/consumable[@typeCode='CSM'][1]/instanceOfKind[@classCode='INST']/kindOfProduct[@classCode='MMAT'][@determinerCode='KIND']/formCode[@codeSystem='TBD-DoseForm']/originalText/@nullFlavor |

e	G.k.4.r.9.2a	Pharmaceutical Dose Form TermID Version Date / Number	As per ISO IDMP	Coded With Equivalents (CE)	codeSystemVersion= Character String (ST)	Value	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][organizer/code[@code='4'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][substanceAdministration/id][k]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/outboundRelationship2[@typeCode='COMP'][substanceAdministration][r]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/consumable[@typeCode='CSM'][1]/instanceOfKind[@classCode='INST']/kindOfProduct[@classCode='MMAT'][@determinerCode='KIND']/formCode[@codeSystem='TBD-DoseForm']/@codeSystemVersion
e	G.k.4.r.9.2b	Pharmaceutical Dose Form TermID	As per ISO IDMP	Coded With Equivalents (CE)	code=Character String (ST)	Value	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][organizer/code[@code='4'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][substanceAdministration/id][k]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/outboundRelationship2[@typeCode='COMP'][substanceAdministration][r]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/consumable[@typeCode='CSM'][1]/instanceOfKind[@classCode='INST']/kindOfProduct[@classCode='MMAT'][@determinerCode='KIND']/formCode[@codeSystem='TBD-DoseForm']/@code
h	G.k.4.r.10	Route of Administration					

e	G.k.4.r.10.1	Route of Administration (free text)	60AN	Coded With Equivalents (CE)	originalText=Encapsulated Data (ED)	Value	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][organizer/code[@code='4'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][substanceAdministration/id][k]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/outboundRelationship2[@typeCode='COMP'][substanceAdministration][r]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/routeCode[@codeSystem='2.16.840.1.113883.3.989.2.1.1.14']/originalText/text()
e						NullFlavor	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][organizer/code[@code='4'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][substanceAdministration/id][k]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/outboundRelationship2[@typeCode='COMP'][substanceAdministration][r]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/routeCode[@codeSystem='2.16.840.1.113883.3.989.2.1.1.14']/originalText/@nullFlavor

| e | G.k.4.r.10.2a | Route of Administration TermID Version Date / Number | As per ISO IDMP | Coded With Equivalents (CE) | codeSystemVersion= Character String (ST) | Value | /MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][organizer/code[@code='4'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][substanceAdministration/id][k]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/outboundRelationship2[@typeCode='COMP'][substanceAdministration][r]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/routeCode[@codeSystem='2.16.840.1.113883.3.989.2.1.1.14']/@codeSystemVersion |
| e | G.k.4.r.10.2b | Route of Administration TermID | As per ISO IDMP (3N) | Coded With Equivalents (CE) | code=Character String (ST) | Value | /MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][organizer/code[@code='4'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][substanceAdministration/id][k]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/outboundRelationship2[@typeCode='COMP'][substanceAdministration][r]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/routeCode[@codeSystem='2.16.840.1.113883.3.989.2.1.1.14']/@code |

		Parent Route of Administration (in case of a parent child / foetus report)					
h	G.k.4.r.11	Parent Route of Administration (in case of a parent child / foetus report)					
e	G.k.4.r.11.1	Parent Route of Administration (free text)	60AN	Coded With Equivalents (CE)	originalText=Encapsulated Data (ED)	Value	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][organizer/code[@code='4'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][substanceAdministration/id][k]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/outboundRelationship2[@typeCode='COMP'][substanceAdministration][r]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/inboundRelationship[@typeCode='REFR'][observation/code[@code='28'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']][1]/observation[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='CE'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.14'][1]/originalText/text()

| | | | | | | | NullFlavor | /MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][organizer/code[@code='4'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][substanceAdministration/id][k]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/outboundRelationship2[@typeCode='COMP'][substanceAdministration][r]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/inboundRelationship[@typeCode='REFR'][observation/code[@code='28'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']][1]/observation[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='CE'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.14'][1]/originalText/@nullFlavor |
| e | | | | | | | | |

e	G.k.4.r.11.2a	Parent Route of Administration TermID Version Date / Number	As per ISO IDMP	Coded With Equivalents (CE)	codeSystemVersion= Character String (ST)	Value	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][organizer/code[@code='4'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][substanceAdministration/id][k]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/outboundRelationship2[@typeCode='COMP'][substanceAdministration][r]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/inboundRelationship[@typeCode='REFR'][observation/code[@code='28'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']][1]/observation[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='CE'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.14'][1]/@codeSystemVersion

| e | G.k.4.r.11.2b | Parent Route of Administration TermID | As per ISO IDMP (3N) | Coded With Equivalents (CE) | code=Character String (ST) | Value | /MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][organizer/code[@code='4'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][substanceAdministration/id][k]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/outboundRelationship2[@typeCode='COMP'][substanceAdministration][r]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/inboundRelationship[@typeCode='REFR'][observation/code[@code='28'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']][1]/observation[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='CE'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.14'][1]/@code |
| e | G.k.5a | Cumulative Dose to First Reaction (number) | 10N | Physical Quantity (PQ) | value=Real Number (REAL) | Value | /MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][organizer/code[@code='4'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][substanceAdministration/id][k]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/outboundRelationship2[@typeCode='SUMM'][observation/code[@code='14'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']][1]/observation[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='PQ'][1]/@value |

e	G.k.5b	Cumulative Dose to First Reaction (unit)	50AN	Physical Quantity (PQ)	unit=Coded Simple Value (CS)	Value	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][organizer/code[@code='4'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][substanceAdministration/id][k]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/outboundRelationship2[@typeCode='SUMM'][observation/code[@code='14'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']][1]/observation[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='PQ'][1]/@unit
e	G.k.6a	Gestation Period at Time of Exposure (number)	3N	Physical Quantity (PQ)	value=Real Number (REAL)	Value	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][organizer/code[@code='4'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][substanceAdministration/id][k]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/outboundRelationship2[@typeCode='PERT'][observation/code[@code='16'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']][1]/observation[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='PQ'][1]/@value

e	G.k.6b	Gestation Period at Time of Exposure (unit)	50AN	Physical Quantity (PQ)	unit=Coded Simple Value (CS)	Value	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][organizer/code[@code='4'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][substanceAdministration/id][k]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/outboundRelationship2[@typeCode='PERT'][observation/code[@code='16'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']][1]/observation[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='PQ'][1]/@unit
h	G.k.7.r	Indication for Use in Case (repeat as necessary)				Repeat Node	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][organizer/code[@code='4'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][substanceAdministration/id][k]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/inboundRelationship[@typeCode='RSON'][observation/code[@code='19'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']]

| e | G.k.7.r.1 | Indication as Reported by the Primary Source | 250AN | Coded With Equivalents (CE) | originalText=Encapsulated Data (ED) | Value | /MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][organizer/code[@code='4'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][substanceAdministration/id][k]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/inboundRelationship[@typeCode='RSON'][observation/code[@code='19'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']][r]/observation[@classCode='OBS'][@moodCode='EVN'][performer[@typeCode='PRF']/assignedEntity[@classCode='ASSIGNED']/code[@code='3'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.21']][1]/value[@xsi:type='CE'][@codeSystem='2.16.840.1.113883.6.163'][1]/originalText/text() |

| e | | | | | | NullFlavor | /MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][organizer/code[@code='4'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][substanceAdministration/id][k]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/inboundRelationship[@typeCode='RSON'][observation/code[@code='19'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']][r]/observation[@classCode='OBS'][@moodCode='EVN'][performer[@typeCode='PRF']/assignedEntity[@classCode='ASSIGNED']/code[@code='3'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.21']][1]/value[@xsi:type='CE'][@codeSystem='2.16.840.1.113883.6.163'][1]/originalText/@nullFlavor |

| e | G.k.7.r.2a | MedDRA Version for Indication | 4AN | Coded With Equivalents (CE) | codeSystemVersion= Character String (ST) | Value | /MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][organizer/code[@code='4'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][substanceAdministration/id][k]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/inboundRelationship[@typeCode='RSON'][observation/code[@code='19'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']][r]/observation[@classCode='OBS'][@moodCode='EVN'][performer[@typeCode='PRF']/assignedEntity[@classCode='ASSIGNED']/code[@code='3'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.21']][1]/value[@xsi:type='CE'][@codeSystem='2.16.840.1.113883.6.163'][1]/@codeSystemVersion |

e	G.k.7.r.2b	Indication (MedDRA code)	8N	Coded With Equivalents (CE)	code=Character String (ST)	Value	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][organizer/code[@code='4'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][substanceAdministration/id][k]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/inboundRelationship[@typeCode='RSON'][observation/code[@code='19'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']][r]/observation[@classCode='OBS'][@moodCode='EVN'][performer[@typeCode='PRF']/assignedEntity[@classCode='ASSIGNED']/code[@code='3'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.21']][1]/value[@xsi:type='CE'][@codeSystem='2.16.840.1.113883.6.163'][1]/@code
e	G.k.8	Action(s) Taken with Drug	1N	Concept Descriptor (CD)	code=Character String (ST)	Value	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][organizer/code[@code='4'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][substanceAdministration/id][k]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/inboundRelationship[@typeCode='CAUS'][act/code[@codeSystem='2.16.840.1.113883.3.989.2.1.1.15']][1]/act[@classCode='ACT'][@moodCode='EVN']/code[@codeSystem='2.16.840.1.113883.3.989.2.1.1.15']/@code

		ICH Code List Version for Action(s) Taken with Drug					/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][organizer/code[@code='4'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][substanceAdministration/id][k]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/inboundRelationship[@typeCode='CAUS'][act/code[@codeSystem='2.16.840.1.113883.3.989.2.1.1.15']][1]/act[@classCode='ACT'][@moodCode='EVN']/code[@codeSystem='2.16.840.1.113883.3.989.2.1.1.15']/@codeSystemVersion
h	G.k.9.i	Drug-reaction(s) / Event(s) Matrix (repeat as necessary)					
e	G.k.9.i.1	Reaction(s) / Event(s) Assessed	N/A			Value	
h	G.k.9.i.2.r	Assessment of Relatedness of Drug to Reaction(s) / Event(s) (repeat as necessary)				Repeat Node	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][causalityAssessment[code[@code='39'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']]][subject1[@typeCode='SUBJ']/adverseEffectReference[@classCode='OBS'][@moodCode='EVN']/id[@root='UUID of i-th reaction']][subject2[@typeCode='SUBJ']/productUseReference[@classCode='SBADM'][@moodCode='EVN']/id[@root='UUID of k-th drug']]]

e	G.k.9.i.2.r.1	Source of Assessment	60AN	Coded With Equivalents (CE)	originalText=Encapsulated Data (ED)	Value	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][causalityAssessment/code[@code='39'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']]][r]/causalityAssessment[@classCode='OBS'][@moodCode='EVN'][subject1[@typeCode='SUBJ']/adverseEffectReference[@classCode='OBS'][@moodCode='EVN']/id[@root='UUID of i-th reaction]][subject2[@typeCode='SUBJ']/productUseReference[@classCode='SBADM'][@moodCode='EVN']/id[@root='UUID of k-th drug']]/author[@typeCode='AUT'][1]/assignedEntity[@classCode='ASSIGNED']/code/originalText/text()
e	G.k.9.i.2.r.2	Method of Assessment	60AN	Coded With Equivalents (CE)	originalText=Encapsulated Data (ED)	Value	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][causalityAssessment/code[@code='39'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']]][r]/causalityAssessment[@classCode='OBS'][@moodCode='EVN'][subject1[@typeCode='SUBJ']/adverseEffectReference[@classCode='OBS'][@moodCode='EVN']/id[@root='UUID of i-th reaction']][subject2[@typeCode='SUBJ']/productUseReference[@classCode='SBADM'][@moodCode='EVN']/id[@root='UUID of k-th drug']]/methodCode[1]/originalText/text()

e	G.k.9.i.2.r.3	Result of Assessment	60AN	Character String (ST)		Value	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][causalityAssessment/code[@code='39'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']]][r]/causalityAssessment[@classCode='OBS'][@moodCode='EVN'][subject1[@typeCode='SUBJ']/adverseEffectReference[@classCode='OBS'][@moodCode='EVN']/id[@root='UUID of i-th reaction']][subject2[@typeCode='SUBJ']/productUseReference[@classCode='SBADM'][@moodCode='EVN']/id[@root='UUID of k-th drug']]/value[@xsi:type='ST']/text()
e	G.k.9.i.3.1a	Time Interval between Beginning of Drug Administration and Start of Reaction / Event (number)	5N	Physical Quantity (PQ)	value=Real Number (REAL)	Value	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ']/organizer[@classCode='CATEGORY'][@moodCode='EVN'][code[@code='4'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/component[@typeCode='COMP'][substanceAdministration/id][k]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/outboundRelationship1[@typeCode='SAS'][actReference[@classCode='OBS'][@moodCode='EVN']/id[@root='UUID of i-th reaction']]/pauseQuantity/@value

| e | G.k.9.i.3.1b | Time Interval between Beginning of Drug Administration and Start of Reaction / Event (unit) | 50AN | Physical Quantity (PQ) | unit=Coded Simple Value (CS) | Value | /MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ']/organizer[@classCode='CATEGORY'][@moodCode='EVN'][code[@code='4'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/component[@typeCode='COMP'][substanceAdministration/id][k]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/outboundRelationship1[@typeCode='SAS'][actReference[@classCode='OBS'][@moodCode='EVN']/id[@root='UUID of i-th reaction']]/pauseQuantity/@unit |
| e | G.k.9.i.3.2a | Time Interval between Last Dose of Drug and Start of Reaction / Event (number) | 5N | Physical Quantity (PQ) | value=Real Number (REAL) | Value | /MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ']/organizer[@classCode='CATEGORY'][@moodCode='EVN'][code[@code='4'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/component[@typeCode='COMP'][substanceAdministration/id][k]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/outboundRelationship1[@typeCode='SAE'][actReference[@classCode='OBS'][@moodCode='EVN']/id[@root='UUID of i-th reaction']]/pauseQuantity/@value |

e	G.k.9.i.3.2b	Time Interval between Last Dose of Drug and Start of Reaction / Event (unit)	50AN	Physical Quantity (PQ)	unit=Coded Simple Value (CS)	Value	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ']/organizer[@classCode='CATEGORY'][@moodCode='EVN'][code[@code='4'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/component[@typeCode='COMP'][substanceAdministration/id][k]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/outboundRelationship1[@typeCode='SAE'][actReference[@classCode='OBS'][@moodCode='EVN']/id[@root='UUID of i-th reaction']]/pauseQuantity/@unit
e	G.k.9.i.4	Did Reaction Recur on Re-administration?	1N	Coded With Equivalents (CE)	code=Character String (ST)	Value	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ']/organizer[@classCode='CATEGORY'][@moodCode='EVN'][code[@code='4'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/component[@typeCode='COMP'][substanceAdministration/id][k]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/outboundRelationship2[@typeCode='PERT'][observation/code[@code='31'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']]/observation[@classCode='OBS'][@moodCode='EVN'][outboundRelationship1[@typeCode='REFR']/actReference[@classCode='OBS'][@moodCode='EVN']/id[@root='UUID of i-th reaction']]/value[@xsi:type='CE'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.16'][1]/@code

							/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ']/organizer[@classCode='CATEGORY'][@moodCode='EVN'][code[@code='4'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/component[@typeCode='COMP'][substanceAdministration/id][k]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/outboundRelationship2[@typeCode='PERT'][observation/code[@code='31'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']]/observation[@classCode='OBS'][@moodCode='EVN'][outboundRelationship1[@typeCode='REFR']/actReference[@classCode='OBS'][@moodCode='EVN']/id[@root='UUID of i-th reaction']]/value[@xsi:type='CE'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.16'][1]/@codeSystemVerison
		ICH Code List Version for Did Reaction Recur on Re-administration?					
e	G.k.10.r	Additional Information on Drug (coded) (repeat as necessary)	2N	Coded With Equivalents (CE)	code=Character String (ST)	Value	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][organizer/code[@code='4'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][substanceAdministration/id][k]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/outboundRelationship2[@typeCode='REFR'][observation/code[@code='9'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']][r]/observation[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='CE'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.17'][1]/@code

		ICH Code List Version for Additional Information on Drug (coded) (repeat as necessary)					/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][organizer/code[@code='4'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][substanceAdministration/id][k]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/outboundRelationship2[@typeCode='REFR'][observation/code[@code='9'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']][r]/observation[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='CE'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.17'][1]/@codeSystemVersion
e						Repeat Node	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][organizer/code[@code='4'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][substanceAdministration/id][k]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/outboundRelationship2[@typeCode='REFR'][observation/code[@code='9'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']]

e	G.k.11	Additional Information on Drug (free text)	2000AN	Character String (ST)		Value	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][organizer/code[@code='4'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][substanceAdministration/id][k]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/outboundRelationship2[@typeCode='REFR'][observation/code[@code='2'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']][1]/observation[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='ST'][1]/text()
h	H	Narrative Case Summary and Further Information					
e	H.1	Case Narrative Including Clinical Course, Therapeutic Measures, Outcome and Additional Relevant Information	100000AN	Encapsulated Data (ED)		Value	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/text/text()

e	H.2	Reporter's Comments	20000AN	Encapsulated Data (ED)		Value	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/component1[@typeCode='COMP'][observationEvent[code[@code='10'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']]][author[@typeCode='AUT']/assignedEntity[@classCode='ASSIGNED']/code[@code='3'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.21']]][1]/observationEvent[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='ED']/text()
h	H.3.r	Sender's Diagnosis (repeat as necessary)				Repeat Node	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/component1[@typeCode='COMP'][observationEvent[code[@code='15'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']][author[@typeCode='AUT']/assignedEntity[@classCode='ASSIGNED']/code[@code='1'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.21']]]

e	H.3.r.1a	MedDRA Version for Sender's Diagnosis / Syndrome and / or Reclassification of Reaction / Event	4AN	Coded with Equivalents (CE)	codeSystemVersion= Character String (ST)	Value	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/component1[@typeCode='COMP'][observationEvent[code[@code='15'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']]][author[@typeCode='AUT']/assignedEntity[@classCode='ASSIGNED']/code[@code='1'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.21']]][r]/observationEvent[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='CE'][@codeSystem='2.16.840.1.113883.6.163']/@codeSystemVersion
e	H.3.r.1b	Sender's Diagnosis / Syndrome and / or Reclassification of Reaction / Event (MedDRA code)	8N	Coded with Equivalents (CE)	code=Character String (ST)	Value	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/component1[@typeCode='COMP'][observationEvent[code[@code='15'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']]][author[@typeCode='AUT']/assignedEntity[@classCode='ASSIGNED']/code[@code='1'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.21']]][r]/observationEvent[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='CE'][@codeSystem='2.16.840.1.113883.6.163']/@code

e	H.4	Sender's Comments	20000AN	Encapsulated Data (ED)		Value	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/component1[@typeCode='COMP'][observationEvent[code[@code='10'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']]][author[@typeCode='AUT']/assignedEntity[@classCode='ASSIGNED']/code[@code='1'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.21']]][1]/observationEvent[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='ED']/text()
h	H.5.r	Case Summary and Reporter's Comments in Native Language (repeat as necessary)				Repeat Node	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][observationEvent[code[@code='36'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']][author[@typeCode='AUT']/assignedEntity[@classCode='ASSIGNED']/code[@code='2'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.21']]]
e	H.5.r.1a	Case Summary and Reporter's Comments Text	100000AN	Encapsulated Data (ED)		Value	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][observationEvent[code[@code='36'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']][author[@typeCode='AUT']/assignedEntity[@classCode='ASSIGNED']/code[@code='2'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.21']]][r]/observationEvent[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='ED']/text()

e	H.5.r.1b	Case Summary and Reporter's Comments Language	3A	Encapsulated Data (ED)	language=Coded Simple Value (CS)	Value	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][observationEvent[code[@code='36'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.19']]][author[@typeCode='AUT']/assignedEntity[@classCode='ASSIGNED']/code[@code='2'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.21']]]][r]/observationEvent[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='ED']/@language

h: header e: entity	Field number	Field name	Field number in ICSR message	ICH Data Type	HL7 Data Type	HL7 Data Type (sub component)	Category	Xpath
h	ACK.M/A	ICH ICSR Batch Acknowledgement Header						
e	ACK.M.1	Acknowledgement Batch Number		100AN	Instance Identifier (II)	extension=Character String (ST)	Value	/MCCI_IN200101UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200101UV01.xsd']/id[@root='2.16.840.1.113883.3.989.2.1.3.20']/@extension
e	ACK.M.2	Acknowledgement Batch Sender Identifier	N.1.4	60AN	Instance Identifier (II)	extension=Character String (ST)	Value	/MCCI_IN200101UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200101UV01.xsd']/sender[@typeCode='SND']/device[@classCode='DEV'][@determiner Code='INSTANCE']/id[@root='2.16.840.1.113883.3.989.2.1.3.17'][1]/@extension
e	ACK.M.3	Acknowledgement Batch Receiver Identifier	N.1.3	60AN	Instance Identifier (II)	extension=Character String (ST)	Value	/MCCI_IN200101UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200101UV01.xsd']/receiver[@typeCode='RCV']/device[@classCode='DEV'][@determine rCode='INSTANCE']/id[@root='2.16.840.1.113883.3.989.2.1.3.18'][1]/@extension
e	ACK.M.4	Acknowledgement Date of Batch Transmission		Date/Time	Point in Time (TS)		Value	/MCCI_IN200101UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200101UV01.xsd']/creationTime/@value
e	ACK.A.1	ICSR Batch Number	N.1.2	100AN	Instance Identifier (II)	extension=Character String (ST)	Value	/MCCI_IN200101UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200101UV01.xsd']/acknowledgement[@typeCode]/targetBatch/id[@root='2.16.840.1.113 883.3.989.2.1.3.22']/@extension
e	ACK.A.2	AcknowledgementLocal Message Number		100AN	Instance Identifier (II)	extension=Character String (ST)	Value	/MCCI_IN200101UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200101UV01.xsd']/attentionLine[keyWordText[@code='2'][@codeSystem='2.16.840.1.11 3883.3.989.2.1.1.24']][1]/value[@xsi:type='II'][@root='2.16.840.1.113883.3.989.2.1.3.21']/@extens ion

e	ACK.A.3	Date of ICSR Batch Transmission	N.1.5	Date/Time	Point in Time (TS)		Value	/MCCI_IN200101UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200101UV01.xsd']/attentionLine[keyWordText[@code='3'][@codeSystem='2.16.840.1.11 3883.3.989.2.1.1.24']][1]/value[@xsi:type='TS']/@value
e	ACK.A.4	Transmission Acknowledgement Code		2A	Coded Simple Value (CS)		Value	/MCCI_IN200101UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200101UV01.xsd']/acknowledgement/@typeCode
e	ACK.A.5	Batch Validation Error		250AN	Encapsulated Data (ED)		Value	/MCCI_IN200101UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200101UV01.xsd']/acknowledgement[@typeCode]/acknowledgementDetail[1]/text/text()
h	ACK.B	ICH ICSR Message Acknowledgement Header					Repeat Node	/MCCI_IN200101UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200101UV01.xsd']/MCCI_IN000002UV01
e	ACK.B.r.1	ICSR Message Number	N.2.r.1, C.1.1	100AN	Instance Identifier (II)	extension=Character String (ST)	Value	/MCCI_IN200101UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200101UV01.xsd']/MCCI_IN000002UV01[r]/acknowledgement[@typeCode][1]/targetMes sage/id[@root='2.16.840.1.113883.3.989.2.1.3.1']/@extension
e	ACK.B.r.2	Local Report Number		100AN	Instance Identifier (II)	extension=Character String (ST)	Value	/MCCI_IN200101UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200101UV01.xsd']/MCCI_IN000002UV01[r]/id[@root='2.16.840.1.113883.3.989.2.1.3.19']/@extension
e	ACK.B.r.3	ICSR Message ACK Receiver	N.2.r.2	60AN	Instance Identifier (II)	extension=Character String (ST)	Value	/MCCI_IN200101UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200101UV01.xsd']/MCCI_IN000002UV01[r]/receiver[@typeCode='RCV']/device[@class Code='DEV'][@determinerCode='INSTANCE']/id[@root='2.16.840.1.113883.3.989.2.1.3.16']/@ext ension
e	ACK.B.r.4	ICSR Message ACK Sender	N.2.r.3	60AN	Instance Identifier (II)	extension=Character String (ST)	Value	/MCCI_IN200101UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200101UV01.xsd']/MCCI_IN000002UV01[r]/sender[@typeCode='SND']/device[@classC ode='DEV'][@determinerCode='INSTANCE']/id[@root='2.16.840.1.113883.3.989.2.1.3.15']/@exte nsion

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e	ACK.B.r.5	Date of ICSR Message Creation	N.2.r.4, C.1.2	Date/Time	Point in Time (TS)		Value	/MCCI_IN200101UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200101UV01.xsd']/MCCI_IN000002UV01[r]/attentionLine[keyWordText[@code='1'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.24']][1]/value[@xsi:type='TS']/@value
e	ACK.B.r.6	Acknowledgment Code for a ICSR Message		2A	Coded Simple Value (CS)		Value	/MCCI_IN200101UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200101UV01.xsd']/MCCI_IN000002UV01[r]/acknowledgement[1]/@typeCode
e	ACK.B.r.7	Error / Warning Message or Comment		250AN	Encapsulated Data (ED)		Value	/MCCI_IN200101UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200101UV01.xsd']/MCCI_IN000002UV01[r]/acknowledgement[@typeCode][1]/acknowledgementDetail[1]/text/text()

2. XML snippets for multiple XML expression

In ICSR messages, the schema defines a single way of describing XML in most of theE2B(R3) data elements, however, it provides multiple way of description in some data elements. To support the values or combination of E2B(R3) data elementsin theISO/HL7 ICSR model, there are multiple ways of coding the XML to allow this variability. The most appropriate data types and attributes in the schema should be used. For example, time interval unit (G.k.4.r.3) in dosing section has values as UCUM and non-UCUM codes for cyclical, as necessary and total. XML for dose (G.k.4.r.1a) and dose unit (G.k.4.r.1b) varies when the value in G.k.4.r.3 is 'total' or another value. Another example about combination of data elements is start date (E.i.4), end date (E.i.5) and duration (E.i.6). The schema defines differentHL7data types and attributes whenall three data elements appear or when only start date and duration are used. XML snippets for these cases are provided in this section.

2.1 Start date, End date, and Duration

Two of three elements should be populated as indicated in business rules in section 3.4 in the IG.

2.1.1. E.i.4 Start Date and E.i.5 End date are populated, but E.i.5 Duration is not populated

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

2.1.2. E.i.4 Start Date (or E.i.5 End Date) and E.i.5 Duration are populated

```
<observation classCode="OBS" moodCode="EVN">
    <id root="154eb889-958b-45f2-a02f-42d4d6f4657f"/>
        <code code="29" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" displayName="reaction"/>
        <effectiveTime xsi:type="IVL_TS">
```

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

2.1.3. E.i.4 Start date, E.i.5 End date, and E.i.5 Duration are populated

```xml
<observation classCode="OBS" moodCode="EVN">
<id root="154eb889-958b-45f2-a02f-42d4d6f4657f"/>
<code code="29" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" displayName="reaction"/>
<effectiveTime xsi:type="SXPR_TS">
<comp xsi:type="IVL_TS">
<low value="20090101"/>
<!-- E.i.4 Date of Start of Reaction / Event -->
<high value="20090102"/>
<!-- E.i.5: Date of End of Reaction / Event -->
</comp>
<comp xsi:type="IVL_TS" operator="A">
<width value="24" unit="h"/>
<!-- E.i.6a: Duration of Reaction / Event -->
<!-- E.i.6b: Duration of Reaction / Event (Duration Unit) -->
</comp>
</effectiveTime>
<value xsi:type="CE" code="E.i.2.1b" codeSystem="2.16.840.1.113883.6.163"
codeSystemVersion="E.i.2.1a">
<!-- E.i.2.1a: MedDRA Version for Reaction / Event -->
<!-- E.i.2.1b: Reaction / Event in MedDRA Terminology-->
<originalText language="E.i.1.1b">E.i.1.1a</originalText>
<!-- E.i.1.1a: Reaction / Event as Reported by the Primary Source in Native Language -->
```

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

2.1.4. G.k.4.r.4 Start Date and G.k.4.r.5 End Date are populated, but G.k.4.6 is not populated

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

2.1.5. G.k.4.r.4 Start Date (or G.k.4.r.5 End Date) and G.k.4.6 are populated

```
    <substanceAdministration classCode="SBADM" moodCode="EVN">
        <text>G.k.4.r.8</text>
        <!-- G.k.4.r.8: Dosage Text -->
        <effectiveTime xsi:type="SXPR_TS">
            <comp xsi:type="PIVL_TS">
                <period value="10" unit="G.k.4.r.3"/>
                <!-- G.k.4.r.2: Number of Units in the Interval -->
                <!-- G.k.4.r.3: Definition of the Time Interval Unit -->
            </comp>
            <comp xsi:type="IVL_TS" operator="A">
                <low value="20090101"/>
                <!-- G.k.4.r.4: Date and Time of Start of Drug -->
                <width value ="4" unit ="G.k.4.6b"/>
                <!-- G.k.4.6a: Duration of Drug Administration (number) -->
                <!-- G.k.4.6b: Duration of Drug Administration (unit) -->
            </comp>
```

```
        </effectiveTime>
```

2.1.6. G.k.4.r.2 and G.k.4.r.3 are NOT populated, but one of the element from G.k.4.r.5, G.k.4.7, or G.k.4.r.6 is populated

In this case, data type should be IVL_TS or PIVL_TS to avoid schema error. SXPR_TS is not permitted.

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

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

2.1.7. G.k.4.r.4 Start date,   G.k.4.r.5 End date, and G.k.4.8 Duration are populated
```
    <substanceAdministration classCode="SBADM" moodCode="EVN">
        <text>G.k.4.r.8</text>
            <!-- G.k.4.r.8: Dosage Text -->
            <effectiveTime xsi:type="SXPR_TS">
                <comp xsi:type="PIVL_TS">
                    <period value="10" unit="G.k.4.r.3"/>
                    <!-- G.k.4.r.2: Number of Units in the Interval -->
                    <!-- G.k.4.r.3: Definition of the Time Interval Unit -->
                </comp>
```

```
            <comp xsi:type="IVL_TS" operator="A">
                <low value="20090101"/>
                <!-- G.k.4.r.4: Date and Time of Start of Drug-->
                <high value="20090101"/>
                <!-- G.k.4.r.5: Date and Time of Last Administration -->
            </comp>
            <comp xsi:type="IVL_TS" operator="A">
                <width value="24" unit="h"/>
                <!-- G.k.4.r.6a: Duration of Drug Administration (number) -->
                <!-- G.k.4.r.6b: Duration of Drug Administration (unit) -->
            </comp>
        </effectiveTime>
```

2.2. F Test Result

2.2.1. F.r.3.2 Value and Qualifier

2.2.1.1. A value (e.g., "10 mg/dl")

In such case, the HL7 "value" element is composed of a single "center" element:

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

2.2.1.2. Greater than a value (e.g. " > 10 mg/dl")

In such case, the HL7 "value" element is composed of a range with "low" and "high" values. The "greater than" qualifier is represented with a positive infinite high value (i.e., using the "PINF" null flavour). The attribute "inclusive" is set to "false" to state that the qualifier is strict (i.e., with the equality):

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

2.2.1.3. Less than a value (e.g. " < 10 mg/dl")

In such case, the HL7 "value" element is composed of a range with "low" and "high" values. The "less than" qualifier is represented with a negative infinite low value (i.e., using the "NINF" null flavour). The attribute "inclusive" is set to "false" to state that the qualifier is strict (i.e., with the equality):

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

2.2.1.4. Greater than or equal to a value (e.g. " >= 10 mg/dl")

In such case, the HL7 "value" element is composed of a range with "low" and "high" values. The "greater than or equal to" qualifier is represented with a positive infinite high value (i.e., using the "PINF" null flavour). The attribute "inclusive" is set to "true" to represent the equality:

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

2.2.1.5. Less than or equal to a value (e.g. " <= 10 mg/dl")

In such case, the HL7 "value" element is composed of a range with "low" and "high" values. The "less than" qualifier is represented with a negative infinite low value (i.e., using the "NINF" null flavour). The attribute "inclusive" is set to "true" to represent the equality:

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

2.2.2 F.r.3.2 and F.r.3.3

```
<observation moodCode="EVN" classCode="OBS">
    <code code="F.r.2.2b" codeSystem="2.16.840.1.113883.6.163" codeSystemVersion="F.r.2.2a">
    <!-- F.r.2.2a: Test Name (MedDRA version) -->
    <!-- F.r.2.1b: Test Name (MedDRA code) -->
        <originalText>F.r.2.1</originalText>
        <!-- F.r.2.1: Test Name (free text) -->
    </code>
    <effectiveTime value="20090101"/>
    <!-- F.r.1: Test Date -->
    <value xsi:type="IVL_PQ">
    <center value="10" unit="mg/dl"/>
```

```
<!-- F.r.3.2: Test Result (Value) -->
<!-- F.r.3.3: Unit -->
    </value>
```

2.2.3. F.r.3.1

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

2.2.4. F.r.3.4

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

2.3. G.k.4 Dosing Examples

2.3.1. 1 per day

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

2.3.2. 1 tablet per day

```xml
<outboundRelationship2 typeCode="COMP">

    <substanceAdministration classCode="SBADM" moodCode="EVN">

        <text>1 tablet per day </text>

        <effectiveTime xsi:type="SXPR_TS">

            <comp xsi:type="PIVL_TS">

                <period value="1" unit="d"/>

            </comp>

        </effectiveTime>

        <doseQuantity value="1" unit="{DF}"/>

        <consumable typeCode="CSM">

            <instanceOfKind classCode="INST">

                <kindOfProduct classCode="MMAT" determinerCode="KIND">

                    <formCode>

                        <originalText>Tablet</originalText>

                    </formCode>

                </kindOfProduct>

            </instanceOfKind>

        </consumable>

    </substanceAdministration>

</outboundRelationship2>
```

2.3.3. One time daily, 1/4 tablet

```xml
<outboundRelationship2 typeCode="COMP">

    <substanceAdministration classCode="SBADM" moodCode="EVN">

        <effectiveTime xsi:type="SXPR_TS">

            <comp xsi:type="PIVL_TS">
```

```
                <period value="1" unit="d"/>

            </comp>

        </effectiveTime>

        <doseQuantity value="0.25" unit="{DF}"/>

        <consumable typeCode="CSM">

            <instanceOfKind classCode="INST">

                <kindOfProduct classCode="MMAT" determinerCode="KIND">

                    <formCode>

                        <originalText>Tablet</originalText>

                    </formCode>

                </kindOfProduct>

            </instanceOfKind>

        </consumable>

    </substanceAdministration>

</outboundRelationship2>
```

2.3.4. Once per week, 6 tablets

```
<outboundRelationship2 typeCode="COMP">

    <substanceAdministration classCode="SBADM" moodCode="EVN">

        <effectiveTime xsi:type="SXPR_TS">

            <comp xsi:type="PIVL_TS">

                <period value="1" unit="w"/>

            </comp>

        </effectiveTime>

        <doseQuantity value="6" unit="{DF}"/>

        <consumable typeCode="CSM">
```

```
            <instanceOfKind classCode="INST">

                <kindOfProduct classCode="MMAT" determinerCode="KIND">

                    <formCode>

                        <originalText>Tablet</originalText>

                    </formCode>

                </kindOfProduct>

            </instanceOfKind>

        </consumable>

    </substanceAdministration>

</outboundRelationship2>
```

2.3.5. Two times a day, 1 tablet

Sample1

```
<outboundRelationship2 typeCode="COMP">

    <substanceAdministration classCode="SBADM" moodCode="EVN">

        <effectiveTime xsi:type="SXPR_TS">

            <comp xsi:type="PIVL_TS">

                <period value="12" unit="h"/>

            </comp>

        </effectiveTime>

        <doseQuantity value="1" unit="{DF}"/>

        <consumable typeCode="CSM">

            <instanceOfKind classCode="INST">

                <kindOfProduct classCode="MMAT" determinerCode="KIND">

                    <formCode>

                        <originalText>Tablet</originalText>

                    </formCode>
```

```
                        </kindOfProduct>

                    </instanceOfKind>

                </consumable>

            </substanceAdministration>

        </outboundRelationship2>



Sample2

    <outboundRelationship2 typeCode="COMP">

        <substanceAdministration classCode="SBADM" moodCode="EVN">

            <effectiveTime xsi:type="SXPR_TS">

                <comp xsi:type="PIVL_TS">

                    <period value="1" unit="d"/>

                </comp>

            </effectiveTime>

            <doseQuantity value="2" unit="{DF}"/>

            <consumable typeCode="CSM">

                <instanceOfKind classCode="INST">

                    <kindOfProduct classCode="MMAT" determinerCode="KIND">

                        <formCode>

                            <originalText>Tablet</originalText>

                        </formCode>

                    </kindOfProduct>

                </instanceOfKind>

            </consumable>

        </substanceAdministration>

    </outboundRelationship2>
```

2.3.6. Four times a day, 7.5 milligrams

Sample1

```
    <outboundRelationship2 typeCode="COMP">

        <substanceAdministration classCode="SBADM" moodCode="EVN">

            <effectiveTime xsi:type="SXPR_TS">

                <comp xsi:type="PIVL_TS">

                    <period value="6" unit="h"/>
```

```
                </comp>

            </effectiveTime>

            <doseQuantity value="7.5" unit="mg"/>

        </substanceAdministration>

    </outboundRelationship2>
```

Sample2
```
    <outboundRelationship2 typeCode="COMP">

        <substanceAdministration classCode="SBADM" moodCode="EVN">

            <effectiveTime xsi:type="SXPR_TS">

                <comp xsi:type="PIVL_TS">

                    <period value="1" unit="d"/>

                </comp>

            </effectiveTime>

            <doseQuantity value="30" unit="mg"/>

        </substanceAdministration>

    </outboundRelationship2>
```

2.3.7. One time daily 15 ml
```
    <outboundRelationship2 typeCode="COMP">

        <substanceAdministration classCode="SBADM" moodCode="EVN">

            <effectiveTime xsi:type="SXPR_TS">

                <comp xsi:type="PIVL_TS">

                    <period value="1" unit="d"/>

                </comp>

            </effectiveTime>

            <doseQuantity value="15" unit="mL"/>

        </substanceAdministration>

    </outboundRelationship2>
```

2.3.8.1 tablet every other day
```
    <outboundRelationship2 typeCode="COMP">

        <substanceAdministration classCode="SBADM" moodCode="EVN">

            <effectiveTime xsi:type="SXPR_TS">

                <comp xsi:type="PIVL_TS">

                    <period value="2" unit="d"/>
```

```
            </comp>

        </effectiveTime>

        <doseQuantity value="1" unit="{DF}"/>

        <consumable typeCode="CSM">

            <instanceOfKind classCode="INST">

                <kindOfProduct classCode="MMAT" determinerCode="KIND">

                    <formCode>

                        <originalText>Tablet</originalText>

                    </formCode>

                </kindOfProduct>

            </instanceOfKind>

        </consumable>

    </substanceAdministration>

</outboundRelationship2>
```

2.3.9. As Necessary, 1 tablet, Start date, end date

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

2.3.10. As Necessary, 20mg

```
<outboundRelationship2 typeCode="COMP">
    <substanceAdministration classCode="SBADM" moodCode="EVN">
    <effectiveTime xsi:type="PIVL_TS">
```

```
            <periodunit="{as necessary}"/>

        </effectiveTime>

        <doseQuantity value="20" unit="mg"/>
```

2.3.11. Cyclical, 500mg, start date, end date

```
<outboundRelationship2 typeCode="COMP">

    <substanceAdministration classCode="SBADM" moodCode="EVN">

        <effectiveTime xsi:type="SXPR_TS">

            <comp xsi:type="PIVL_TS">

                <periodunit="{cyclical}"/>

            </comp>

            <comp xsi:type="IVL_TS" operator="A">

                <low value="200906"/>

                <high value="200908/>

            </comp>

        </effectiveTime>

        <doseQuantity value="500" unit="mg"/>
```

2.3.12. Cyclical, 500mg

```
<outboundRelationship2 typeCode="COMP">

    <substanceAdministration classCode="SBADM" moodCode="EVN">

        <effectiveTime xsi:type="PIVL_TS">

            <periodunit="{cyclical}"/>

        </effectiveTime>

        <doseQuantity value="500" unit="mg"/>
```

2.3.13. Total in 20,000mg, start date, end date

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

    <effectiveTimexsi:type="SXPR_TS">

        <comp xsi:type="PIVL_TS">

            <periodunit="{total}"/>

        </comp>

        <comp xsi:type="IVL_TS" operator="A">

            <low value="200906"/>

            <high value="201005/>

        </comp>

    </effectiveTime>

    <doseCheckQuantity>
```

```
            <numerator xsi:type="PQ" value="20000" unit="mg"/>

            <denominator xsi:type="PQ" nullFlavor="UNK"/>

    </doseCheckQuantity>
```

2.4. Tel, fax, and e-mail C.3.4.6, C.3.4.7, and C.3.4.8

Syntax for HL7 telecom data type –

```
            <telecom value="tel:C.3.4.6"/>

            <!-- C.3.4.6: Sender's Telephone -->

            <telecom value="fax:C.3.4.7"/>

            <!-- C.3.4.7: Sender's Fax -->

            <telecom value="mailto:C.3.4.8"/>

            <!-- C.3.4.8 : Sender's E-mail Address -->
```

2.5. Express "Provacy" for Reporter's Telephone C.2.r.2.7

To express "Privacy", ICH E2B recommends sender use null favor=MSK after the telecom scheme.
For example –

```
        <telecom value="tel:" nullFlavor="MSK"/>

        <!--C.2.r.2.7: Reporter's Telephone is Masked for Privacy -->
```

Please note that this is not a standard HL7 null flavor.

2.6. D.2.2.1b (gestation Period) using {trimester}

```
    <subjectOf2 typeCode="SBJ">

        <observation moodCode="EVN" classCode="OBS">

            <code code="16" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" displayName="gestationPeriod"/>

            <value xsi:type="PQ" value="1" unit="{trimester}"/>

        </observation>

    </subjectOf2>
```

2.7. Example for G.k.2.3.r.1 (substance) when value is not available, null flavor is required by the schema.

```
    <ingredient classCode="ACTI">

        <quantity>

            <numerator value="10" unit="mg"/>

            <denominator value="1"/>
```

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```
            </quantity>
            <ingredientSubstance classCode="MMAT" determinerCode="KIND">
                  <name nullFlavor="UNK"/>
            </ingredientSubstance>
      </ingredient>
```

2.8. Example for associating causality information for each reaction

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

III NOTES ON THE REFERENCE INSTANCE

- The element number for each data element in the E2B(R3) IG is given in thereference instances instead of actual values to show how each data element is captured in XML. The title of each data element is provided as comments.

- When a code is numeric, text (label) of the code is provided in *display name* to make human readable.

- The XPath associated with the reference instance is cross referenced in Appendix I (D).

- When the data type for element is 'PQ', then the unit of the value is not indicated in the reference instance due to the rule for the HL7 PQ data type. For valid ICH units please refer to the ICH E2B code lists 25 and 26 in Appendix I (F).

- The associations between patient and parent route of administrations (G.k.4.r.11)are captured using a series of recursive and nested relationship references (inbound and outbound relationships) within the Drug Information organizer section. The parent route of administration is captured as a nested 'inboundRelationship' and expressed using an observation code and value pair that supports both coded and free text information.

Example:

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

IV REFERENCE

E2B(R3) Data Element Structure in ICSR messages

The spreadsheet explains how E2B(R3) data elements are organised in ICSR message. XML tags in the reference instance are grouped by E2B(R3) data elements, which enables a user to see a repeating block and hierarchy of the data elements. Please note that this document may not be updated after the first publication since the purpose of this document is toease interpretation of the reference instance for those who are not familiar with HL7 based XML messages.