IHE Quality, Research and Public Health (QRPH)
Technical Framework

Volume 3
QRPH TF-3
Content Modules

Revision 1.0 - Final Text
October 19, 2018

Please verify you have the most recent version of this document, which is published here.
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</tr>
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<td></td>
<td>75</td>
</tr>
</tbody>
</table>
1 Introduction

This document, Volume 3 of the IHE Quality, Research and Public Health (QRPH) Technical Framework, defines content modules used in the IHE Quality, Research and Public Health profiles.

1.1 Introduction to IHE

Integrating the Healthcare Enterprise (IHE) is an international initiative to promote the use of standards to achieve interoperability among health information technology (HIT) systems and effective use of electronic health records (EHRs). IHE provides a forum for care providers, HIT experts and other stakeholders in several clinical and operational domains to reach consensus on standards-based solutions to critical interoperability issues.

The primary output of IHE is system implementation guides, called IHE Profiles. IHE publishes each profile through a well-defined process of public review and trial implementation and gathers profiles that have reached final text status into an IHE Technical Framework, of which this volume is a part.

For more general information regarding IHE, refer to www.ihe.net. It is strongly recommended that, prior to reading this volume, the reader familiarizes themselves with the concepts defined in the IHE Technical Frameworks General Introduction.

1.2 Intended Audience

The intended audience of IHE Technical Frameworks Volume 3 is:

- IT departments of healthcare institutions
- Technical staff of vendors participating in the IHE initiative
- Experts involved in standards development

1.3 Overview of Technical Framework Volume 3

Volume 3 is comprised of several distinct sections:

- Section 1 provides background and reference material.
- Section 2 presents the conventions used in this volume to define the content modules.
- Section 3 provides an overview of Content Modules and the terminology used.
- Section 4 is reserved for domain unique Content Module specifications.
- Section 5 lists the namespaces and identifiers defined or referenced and the vocabularies defined or referenced herein.
Section 6 defines QRPH HL7\textsuperscript{1} V3 CDA\textsuperscript{2} Content Modules in detail.

Section 7 defines QRPH DICOM\textsuperscript{3} content modules.

Section 8 defines other types of content modules.

The appendices in Volume 3 provide clarification of technical details of the IHE data model and transactions. A glossary of terms and acronyms used in the IHE Technical Framework, including those from relevant standards, is provided in Appendix D to the IHE Technical Frameworks General Introduction. Due to the length of the document, some domains may divide Volume 3 into smaller volumes labeled 3a, 3b, etc. In this case, the Volume 3 appendices are gathered in Volume 3x. Code and message samples may also be stored on the IHE ftp server. In this case, explicit links to the ftp server will be provided in the transaction text.

1.4 Comment Process

IHE International welcomes comments on this document and the IHE initiative. They can be submitted by sending an email to the co-chairs and secretary of the Quality, Research and Public Health domain committees at qrph@ihe.net.

1.5 Copyright Licenses

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The licenses covered by this Copyright License are only to those copyrights owned or controlled by IHE International itself. If parts of the Technical Framework are included in products that also include materials owned or controlled by other parties, licenses to use those products are beyond the scope of this IHE document and would have to be obtained from that other party.

\textsuperscript{1} HL7 is the registered trademark of Health Level Seven International.

\textsuperscript{2} CDA is the registered trademark of Health Level Seven International.

\textsuperscript{3} DICOM is the registered trademark of the National Electrical Manufacturers Association for its standards publications relating to digital communications of medical information.


1.5.1 Copyright of Base Standards

IHE technical documents refer to and make use of a number of standards developed and published by several standards development organizations. All rights for their respective base standards are reserved by these organizations. This agreement does not supersede any copyright provisions applicable to such base standards.

Health Level Seven, Inc. has granted permission to IHE to reproduce from the HL7 standard. The HL7 tables in this document are copyrighted by Health Level Seven, Inc. All rights reserved. Material drawn from these documents is credited where used.

1.6 Trademark

IHE® and the IHE logo are trademarks of the Healthcare Information Management Systems Society in the United States and trademarks of IHE Europe in the European Community. They may only be used with the written consent of the IHE International Board Operations Committee, which may be given to a Member Organization in broad terms for any use that is consistent with the IHE mission and operating principles.

1.7 Disclaimer Regarding Patent Rights

Attention is called to the possibility that implementation of the specifications in this document may require use of subject matter covered by patent rights. By publication of this document, no position is taken with respect to the existence or validity of any patent rights in connection therewith. IHE International is not responsible for identifying Necessary Patent Claims for which a license may be required, for conducting inquiries into the legal validity or scope of Patents Claims or determining whether any licensing terms or conditions provided in connection with submission of a Letter of Assurance, if any, or in any licensing agreements are reasonable or non-discriminatory. Users of the specifications in this document are expressly advised that determination of the validity of any patent rights, and the risk of infringement of such rights, is entirely their own responsibility. Further information about the IHE International patent disclosure process including links to forms for making disclosures is available at http://www.ihe.net/Patent_Disclosure_Process. Please address questions about the patent disclosure process to the secretary of the IHE International Board: secretary@ihe.net.

1.8 History of Document Changes

This section provides a brief summary of changes and additions to this document.

<table>
<thead>
<tr>
<th>Date</th>
<th>Document Revision</th>
<th>Change Summary</th>
</tr>
</thead>
<tbody>
<tr>
<td>2011-09-02</td>
<td>0.1</td>
<td>Initial Trial Implementation Release (no Final Text profiles)</td>
</tr>
<tr>
<td>2018-10-19</td>
<td>1.0</td>
<td>Initial Final Text Release (includes CRD and DSC Final Text profiles). Volume 2 (of Rev. 0.1) split into Volume 2 and 3.</td>
</tr>
</tbody>
</table>
2 Conventions

This document has adopted the following conventions for representing the framework concepts and specifying how the standards upon which the IHE Technical Framework is based shall be applied.

2.1 Content Module Modeling and Profiling Conventions

In order to maintain consistent documentation, modeling methods for IHE content modules and profiling conventions, for frequently used standards, are maintained as Appendix E to the IHE Technical Frameworks General Introduction. Methods described include the standards conventions DICOM, HL7 v2.x, HL7 Clinical Document Architecture (CDA) Documents, etc. These conventions are critical to understanding this volume and should be reviewed prior to reading this text.

2.2 Additional Standards Profiling Conventions

This section defines profiling conventions for standards which are not described in the IHE Technical Frameworks General Introduction.

Not applicable
3 Content Modules Overview and Terminology

In the future, an appendix to the *IHE Technical Frameworks General Introduction* will provide and an overview of Content Modules. In the interim, information may be available on the IHE wiki at [http://wiki.ihe.net/index.php?title=Profiles](http://wiki.ihe.net/index.php?title=Profiles)
4 **Reserved**

Intentionally left blank.

5 **IHE Namespaces, Concept Domains, and Vocabularies**

This section references the namespaces, concept domains, and identifiers defined or referenced by the IHE QRPH Technical Framework, and the vocabularies defined or referenced herein.

5.1 **IHE Quality, Research and Public Health Namespaces**

For a listing of the QRPH Namespaces, see http://wiki.ihe.net/index.php/OID_Registration#IHE_Domain_Namespaces

5.2 **IHE Quality, Research and Public Health Concept Domains**

Concept Domains are named categories of things that are used when it isn’t possible to bind to a specific set of codes. There are a number of reasons you might not be able to define and bind to a specific set of codes, one of the most common being that the codes set needs to vary depending on locale or context.

For a listing of the QRPH Concept Domains see: NA

5.3 **IHE Quality, Research and Public Health Format Codes and Vocabularies**

The following vocabularies are referenced in the IHE QRPH Technical Framework. An extensive list of registered vocabularies can be found at http://hl7.amg-hq.net/oid/frames.cfm.

<table>
<thead>
<tr>
<th>codeSystem</th>
<th>codeSystemName</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.3.6.1.4.1.19376.1.5.3.1</td>
<td>IHE PCC Template Identifiers</td>
<td>This is the root OID for all IHE PCC Templates.</td>
</tr>
<tr>
<td>1.3.6.1.4.1.19376.1.5.3.2</td>
<td>IHEActCode</td>
<td>See IHEActCode Vocabulary below</td>
</tr>
<tr>
<td>1.3.6.1.4.1.19376.1.5.3.3</td>
<td>IHE PCC RoleCode</td>
<td>See IHERoleCode Vocabulary below</td>
</tr>
<tr>
<td>1.3.6.1.4.1.19376.1.5.3.4</td>
<td>IHE PCC RoleCode</td>
<td>Namespace OID used for IHE Extensions to CDA Release 2.0</td>
</tr>
<tr>
<td>2.16.840.1.113883.10.20.1</td>
<td>CCD®⁴ Root OID</td>
<td>Root OID used for by ASTM/HL7 Continuity of Care Document</td>
</tr>
<tr>
<td>2.16.840.1.113883.5.112</td>
<td>RouteOfAdministration</td>
<td>See the HL7 RouteOfAdministration Vocabulary</td>
</tr>
<tr>
<td>2.16.840.1.113883.5.1063</td>
<td>SeverityObservation</td>
<td>See the HL7 SeverityObservation Vocabulary</td>
</tr>
</tbody>
</table>

⁴ CCD is the registered trademark of Health Level Seven International.

<table>
<thead>
<tr>
<th>codeSystem</th>
<th>codeSystemName</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.16.840.1.113883.6.1</td>
<td>LOINC</td>
<td>Logical Observation Identifier Names and Codes</td>
</tr>
<tr>
<td>2.16.840.1.113883.6.96</td>
<td>SNOMED-CT</td>
<td>SNOMED Controlled Terminology</td>
</tr>
<tr>
<td>2.16.840.1.113883.6.103</td>
<td>ICD-9CM (diagnosis codes)</td>
<td>International Classification of Diseases, Clinical Modifiers, Version 9</td>
</tr>
<tr>
<td>2.16.840.1.113883.6.104</td>
<td>ICD-9CM (procedure codes)</td>
<td>International Classification of Diseases, Clinical Modifiers, Version 9</td>
</tr>
<tr>
<td>2.16.840.1.113883.6.26</td>
<td>MEDCIN</td>
<td>A classification system from MEDICOMP Systems.</td>
</tr>
<tr>
<td>2.16.840.1.113883.6.88</td>
<td>RxNorm</td>
<td>RxNorm</td>
</tr>
<tr>
<td>2.16.840.1.113883.6.63</td>
<td>FDDC</td>
<td>First DataBank Drug Codes</td>
</tr>
<tr>
<td>2.16.840.1.113883.6.257</td>
<td>Minimum Data Set for Long Term Care</td>
<td>The root OID for Minimum Data Set Answer Lists</td>
</tr>
</tbody>
</table>

5.3.1 IHE Format Codes

For IHE Format Codes please see the IHE Format Codes wiki page at http://wiki.ihe.net/index.php/IHE_Format_Codes.

5.3.2 IHEActCode Vocabulary

- CCD ASTM/HL7 Continuity of Care Document
- CCR ASTM CCR Implementation Guide

The IHEActCode vocabulary is a small vocabulary of clinical acts that are not presently supported by the HL7 ActCode vocabulary. The root namespace (OID) for this vocabulary is 1.3.5.1.4.1.19376.1.5.3.2. These vocabulary terms are based on the vocabulary and concepts used in the CCR and CCD standards listed above.


5.3.3 IHERoleCode Vocabulary

The IHERoleCode vocabulary is a small vocabulary of role codes that are not presently supported by the HL7 Role Code vocabulary. The root namespace (OID) for this vocabulary is 1.3.5.1.4.1.19376.1.5.3.3.

6 QRPH HL7 V3 CDA Content Modules

6.1 Conventions
HL7 V3 CDA Conventions are defined in Appendix E to the IHE Technical Frameworks General Introduction.

6.2 Folder Modules
Intentionally left blank.

6.3 Content Modules
This section defines each IHE Quality, Research and Public Health Content Modules in detail, specifying the standards used and the information defined.

6.3.1 CDA Document Content Modules
The prepopData and workflowData data elements are included in the Retrieve Form [ITI-34] Request message sent by the Form Filler to the Form Manager during the Retrieve Form transaction. As indicated in Table 6.3.1-1 which further constrain them, those data elements also constitute the archiveContent data element which is archived by the Form Filler to the Form Archiver during the Archive Source Documents transaction when the option “Archive Source Documents” is selected.

<table>
<thead>
<tr>
<th>Parameter Name</th>
<th>REQ</th>
<th>Description</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>prepopData</td>
<td>R</td>
<td>The xml for pre-population</td>
<td>As defined in ITI TF-2b: 3.34</td>
</tr>
<tr>
<td>workflowData</td>
<td>R</td>
<td>The xml representation of workflow specific values.</td>
<td>This value is a well-formed xml document.as defined below.</td>
</tr>
<tr>
<td>formID</td>
<td>R</td>
<td>The identifier of a form.</td>
<td>A string identifying the form</td>
</tr>
<tr>
<td>encodedResponse</td>
<td>R</td>
<td>Tells the Form Archiver whether or not to return an encoded response</td>
<td>{true,false}</td>
</tr>
<tr>
<td>archiveURL</td>
<td>R</td>
<td>Tells the Form Archiver whether or not the Form Filler is exercising the Archive Option</td>
<td>the URL of any Form Filler identified Form Archiver or the null string</td>
</tr>
<tr>
<td>context</td>
<td>R</td>
<td>The xml specifics of workflow context</td>
<td>As defined in Section 6.3.1.2</td>
</tr>
<tr>
<td>instanceID</td>
<td>R</td>
<td>An id value of a previously submitted instance of data.</td>
<td>A string identifying an instance of previously submitted data; may be nil.</td>
</tr>
</tbody>
</table>

Many tables will be introduced further in this section. They contain a column titled “Optionality” which uses some code. Table 6.3.1-2 provides more information on this code.
**Table 6.3.1-2: Optionality Key**

<table>
<thead>
<tr>
<th>Code</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>R</td>
<td>Required Section</td>
</tr>
<tr>
<td>R2</td>
<td>Required Section if data present</td>
</tr>
<tr>
<td>O</td>
<td>Optional section</td>
</tr>
</tbody>
</table>

### 6.3.1.1 CRD prepopData Document Content Module

Table 6.3.1.1-1 below lists the data elements which SHALL be provided as part of the prepop data and the constraints (expressed in terms of optionality and templates) they SHALL obey in order to claim conformance to the CRD Profile. The last but one column of the table indicates the places where exhaustive information on these data elements (including their CCD parents’ template IDs and names) can be found.

**Table 6.3.1.1-1: Clinical Research Document Prepop Data Content**

<table>
<thead>
<tr>
<th>Template ID</th>
<th>Parent Template</th>
<th>General Description</th>
<th>Document Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.3.6.1.4.1.19376.1.7.3.1.1.10</td>
<td>CCD document: 2.16.840.1.113883.10.20.1</td>
<td>The CRD document content module template specifies the content structure for an XML document containing Prepop data and provided by the Form Filler to the Form Manager during the Retrieve Form [ITI-34] transaction.</td>
<td>LOINC Code: 34133-9 “Summary of Episode Note”</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Opt</th>
<th>Data Element or Section Name</th>
<th>Template ID</th>
<th>Specification Document</th>
<th>Constraint</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>R</td>
<td>Date of Birth</td>
<td>patientRole/patient/birthTime</td>
<td>1.3.6.1.4.1.19376.1.5.3.1.3.6</td>
<td></td>
</tr>
<tr>
<td>R</td>
<td>Gender</td>
<td>patientRole/patient/administrativeGenderCode</td>
<td>1.3.6.1.4.1.19376.1.5.3.1.3.6</td>
<td></td>
</tr>
<tr>
<td>O</td>
<td>Ethnicity</td>
<td>patientRole/patient/ethnicGroupCode</td>
<td>1.3.6.1.4.1.19376.1.5.3.1.3.6</td>
<td></td>
</tr>
<tr>
<td>R2</td>
<td>Race</td>
<td>patientRole/patient/raceCode</td>
<td>1.3.6.1.4.1.19376.1.5.3.1.3.6</td>
<td></td>
</tr>
</tbody>
</table>

**Header Elements**

<table>
<thead>
<tr>
<th>Opt</th>
<th>Data Element or Section Name</th>
<th>Template ID</th>
<th>Specification Document</th>
<th>Constraint</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>R</td>
<td>Date of Birth</td>
<td>patientRole/patient/birthTime</td>
<td>1.3.6.1.4.1.19376.1.5.3.1.3.6</td>
<td></td>
</tr>
<tr>
<td>R</td>
<td>Gender</td>
<td>patientRole/patient/administrativeGenderCode</td>
<td>1.3.6.1.4.1.19376.1.5.3.1.3.6</td>
<td></td>
</tr>
<tr>
<td>O</td>
<td>Ethnicity</td>
<td>patientRole/patient/ethnicGroupCode</td>
<td>1.3.6.1.4.1.19376.1.5.3.1.3.6</td>
<td></td>
</tr>
<tr>
<td>R2</td>
<td>Race</td>
<td>patientRole/patient/raceCode</td>
<td>1.3.6.1.4.1.19376.1.5.3.1.3.6</td>
<td></td>
</tr>
</tbody>
</table>

**Sections**

<table>
<thead>
<tr>
<th>Opt</th>
<th>Data Element or Section Name</th>
<th>Template ID</th>
<th>Specification Document</th>
<th>Constraint</th>
</tr>
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<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>R</td>
<td>Active Problems</td>
<td>1.3.6.1.4.1.19376.1.5.3.1.3.6</td>
<td>PCC TF-2: 6.3.3.2.3</td>
<td></td>
</tr>
<tr>
<td>R2</td>
<td>History of Past Illness</td>
<td>1.3.6.1.4.1.19376.1.5.3.1.3.8</td>
<td>PCC TF-2: 6.3.3.2.5</td>
<td></td>
</tr>
<tr>
<td>R2</td>
<td>Procedures</td>
<td>2.16.840.1.113883.10.20.1.12</td>
<td>CCD specification: 3.14</td>
<td></td>
</tr>
</tbody>
</table>
6.3.1.2 CRD Workflow Data Content Module

Workflow data is a well-formed XML content sent via the Retrieve Form [ITI-34] transaction or the Archive Source Documents [QRPH-36] transaction. Full detail on the data elements which constitute this content can be found in the ITI TF-2b: 3.34.1.

In particular, the Workflow data has a “Context” data element which contains some information on the context of the transaction taking place. This data element is the only one modified in this profile, and this is what this section is about.

Table 6.3.1.2-1 below lists the data elements which SHALL be provided as sub elements of that “Context” data element and the constraints (expressed in terms of optionality) they SHALL obey in order to claim conformance to the CRD Profile.

Most of these sub elements are defined using CDASH Common Identifier Variables. Table 6.3.1.2-2 provides a definition of these variables as well as a mapping to the CRD Workflow Data elements to which they are linked and the specification document where they are defined.

The sub element “PrePopArchiveID” (Table 6.3.1.2-1) contains the “documentId” of the prepopulation and workflow data submitted to the Form Archiver through the transaction Archive Source Documents transaction. Recall that this archiving of the prepopulation and workflow data (when the required option is selected) takes place before the Retrieve Form [ITI-34] transaction.

<table>
<thead>
<tr>
<th>Optionality</th>
<th>Data element</th>
<th>Data Location</th>
</tr>
</thead>
<tbody>
<tr>
<td>R</td>
<td>context</td>
<td>workflowData/context</td>
</tr>
<tr>
<td>R</td>
<td>StudyID</td>
<td>workflowData/context/StudyID</td>
</tr>
<tr>
<td>R</td>
<td>SiteID</td>
<td>workflowData/context/SiteID</td>
</tr>
<tr>
<td>R</td>
<td>SubjID</td>
<td>workflowData/context/SubjID</td>
</tr>
<tr>
<td>O</td>
<td>USubjID</td>
<td>workflowData/context/USubjID</td>
</tr>
<tr>
<td>Optionality</td>
<td>Data element</td>
<td>Data Location</td>
</tr>
<tr>
<td>-------------</td>
<td>--------------</td>
<td>-----------------------------</td>
</tr>
<tr>
<td>O</td>
<td>InvID</td>
<td>workflowData/context/ InvID</td>
</tr>
<tr>
<td>O</td>
<td>SpID</td>
<td>workflowData/context/ SpID</td>
</tr>
<tr>
<td>O</td>
<td>Visit</td>
<td>workflowData/context/ Visit</td>
</tr>
<tr>
<td>O</td>
<td>VisitNum</td>
<td>workflowData/context/ VisitNum</td>
</tr>
<tr>
<td>R</td>
<td>VisDatTim</td>
<td>workflowData/context/ VisDatTim</td>
</tr>
<tr>
<td>R2</td>
<td>PrePopArchiveID</td>
<td>workflowData/context/ PrePopArchiveID</td>
</tr>
</tbody>
</table>

Table 6.3.1.2-2: Data elements CDASH reference

<table>
<thead>
<tr>
<th>CDASH Data Collection Field</th>
<th>Definition</th>
<th>Specification document</th>
</tr>
</thead>
<tbody>
<tr>
<td>Protocol/Study Identifier</td>
<td>Unique Identifier for a study within a submission</td>
<td>CDASH Standard, version 1.1: section 5.1.2</td>
</tr>
<tr>
<td>Site Identifier Within a Study</td>
<td>Unique identifier for the study site</td>
<td>CDASH Standard, version 1.1: section 5.1.3</td>
</tr>
<tr>
<td>Subject Identifier</td>
<td>Subject identifier for the study</td>
<td>CDASH Standard, version 1.1: section 5.1.4</td>
</tr>
<tr>
<td>Unique Subject Identifier</td>
<td>Unique subject identifier within a submission</td>
<td>CDASH Standard, version 1.1: section 5.1.5</td>
</tr>
<tr>
<td>Investigator Identifier</td>
<td>Investigator identifier</td>
<td>CDASH Standard, version 1.1: section 5.1.6</td>
</tr>
<tr>
<td>Sponsor-Defined Identifier</td>
<td>Sponsor-defined reference number</td>
<td>CDASH Standard, version 1.1: section 5.1.1</td>
</tr>
<tr>
<td>Visit</td>
<td>Visit Name / Visit Number</td>
<td>CDASH Standard, version 1.1: section 5.2.1/5.2.2</td>
</tr>
<tr>
<td>Date of Visit</td>
<td>Date the visit took place</td>
<td>CDASH Standard, version 1.1: section 5.2.3/5.2.4</td>
</tr>
<tr>
<td>Time of Visit</td>
<td>Time the visit took place</td>
<td>CDASH Standard, version 1.1: section 5.2.5/5.2.6</td>
</tr>
</tbody>
</table>

6.3.1.2.1 Workflow Data Sample

The content of workflowData parameter SHALL minimally be:

```
<workflowData>
  <formID>a String identifying the form</formID>
  <encodedResponse> false</encodedResponse>
  <archiveURL />
  <instanceID/>
  <context>
    <StudyID> a String identifying the Protocol/Study Identifier </StudyID>
    <SiteID> a String identifying the Site Identifier </SiteID>
  </context>
</workflowData>
```
<SubjID> a String identifying the Subject Identifier </SubjID>
<VisDatTim>
  <effectiveTime xsi:type='TS'>
    <low value=' '/>
    <high value=' '/>
  </effectiveTime>
  </VisDatTim>
</PrePopArchiveID>

The content of workflowData parameter SHALL optimally be:
<workflowData>
  <formID>a String identifying the form</formID>
  <encodedResponse>false</encodedResponse>
  <archiveURL/>
  <instanceID/>
  <context>
    <StudyID> a String identifying the Protocol/Study Identifier </StudyID>
    <SiteID> a String identifying the Site Identifier </SiteID>
    <SubjID> a String identifying the Subject Identifier </SubjID>
    <USubjID> a String identifying the Unique Subject Identifier </USubjID>
    <InvID> a String identifying the Investigator Identifier </InvID>
    <SpID> a String identifying the Sponsor-Defined Identifier </SpID>
    <Visit> a String identifying the Visit Name </Visit>
    <VisitNum> a String identifying the Visit Number </VisitNum>
    <VisDatTim>
      <effectiveTime xsi:type="TS">
        <low value=" "/>
        <high value=" "/>
      </effectiveTime>
    </VisDatTim>
    <PrePopArchiveID>a String identifying the Prepopulation Archive XDSDocumentEntry.uniqueId</PrePopArchiveID>
  </context>
</workflowData>

Note: The visit start date/time SHALL be recorded in the <low> element of the <effectiveTime> element when known. The visit end date/time SHALL be recorded in the <high> element of the <effectiveTime> element when known. The nullFlavor attribute SHALL be set to 'UNK' if the date is not known.

Submit Form [ITI-35] transaction constraint
This profile further constrains the Submit Form [ITI-35] transaction as defined in ITI TF-2a: 3.35. In order to claim support of the CRD Profile, BOTH the form instance data and the information contained in the workflowData data element SHALL be transmitted during the Submit Form transaction to the Form Receiver. The submission of the workflowData data element along with the instance form is not profiled and is under the responsibility of the Form Manager.

Archive Form [ITI-36] transaction constraint
This profile further constrains the Archive Form [ITI-36] transaction as defined in ITI TF-2a: 3.36. In order to claim support of the CRD Profile, BOTH the form instance data and the information contained in the workflowData data element SHALL be transmitted during the Archive Form transaction to the Form Archiver. The submission of the workflowData data element along with the instance form is not profiled and is under the responsibility of the Form Manager.

6.3.1.3 DSC prepToPopData Document Content Module

6.3.1.3.1 Standards

CDAR2: Clinical Document Architecture, Release 2, 2005 HL7


CCD: ASTM/HL7 Continuity of Care Document (Draft)

6.3.1.3.2 Data Element Index

A relevant data set for drug safety content reporting includes those elements identified within the US efforts under the Healthcare Information Technology Standards Panel (HITSP). The Drug Safety Content CCD described below overlays these data elements. This Data Element Index is an attempt to describe which sections are intended to cover which domains. The list includes data elements not currently represented in standards, most of which are optional. Where such standards do not exist, the Form Manager will enhance with non-standard fields.
6.3.1.3.3 Form Data Element Mapping Specification

Table 6.3.1.3.3-1: Form Data Element Mapping Specification

<table>
<thead>
<tr>
<th>Data Element</th>
<th>Definition</th>
<th>CCD Description</th>
<th>Template ID</th>
<th>CCD XPATH</th>
<th>Mapping Constraints (CodeSystem and /or value sets)</th>
<th>CCD Code</th>
<th>Optionality</th>
</tr>
</thead>
<tbody>
<tr>
<td>Facility/Importer Name</td>
<td>The name of the facility that the health care provider diagnosed the subject of the Case Report.</td>
<td>Facility</td>
<td></td>
<td>ClinicalDocument.author.assignedAuth or.representedOrganization.Name</td>
<td></td>
<td>R</td>
<td></td>
</tr>
<tr>
<td>Facility Identifier</td>
<td>Unique facility identifier.</td>
<td>Facility</td>
<td></td>
<td>ClinicalDocument.author.assignedAuth or.representedOrganization.Id</td>
<td></td>
<td>O</td>
<td></td>
</tr>
<tr>
<td>Address</td>
<td>The address (Street, City, State, Zip Code) of the person or facility that diagnosed the subject of the Case Report</td>
<td>Facility</td>
<td></td>
<td>ClinicalDocument.author.assignedAuth or.representedOrganization.Addr</td>
<td></td>
<td>R</td>
<td></td>
</tr>
<tr>
<td>Telephone</td>
<td>The phone number of the person or facility that diagnosed the subject of the Case Report.</td>
<td>Facility</td>
<td></td>
<td>ClinicalDocument.author.assignedAuth or.representedOrganization.Name telecom</td>
<td></td>
<td>O</td>
<td></td>
</tr>
<tr>
<td>Data Element</td>
<td>Definition</td>
<td>CCD Description</td>
<td>Template ID</td>
<td>CCD XPATH</td>
<td>Mapping Constraints (CodeSystem and/or value sets)</td>
<td>CCD Code</td>
<td>Optionality</td>
</tr>
<tr>
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<td>----------</td>
<td>-------------</td>
</tr>
<tr>
<td>Contact Person</td>
<td>The name of the person to be contacted for further information</td>
<td>Facility</td>
<td></td>
<td>ClinicalDocument.author.assignedAuthor.representedOrganization.associatedEntity[classCode='CON'].assignedPerson.name</td>
<td></td>
<td></td>
<td>O</td>
</tr>
<tr>
<td>Contact Phone Number</td>
<td>The telephone number for the contact person</td>
<td>Facility</td>
<td></td>
<td>ClinicalDocument.author.assignedAuthor.representedOrganization.associatedEntity[classCode='CON'].assignedPerson.telecom</td>
<td></td>
<td></td>
<td>O</td>
</tr>
<tr>
<td>Responsible physician/Health care provider name</td>
<td>The name of the person that diagnosed the subject</td>
<td>Author</td>
<td></td>
<td>ClinicalDocument.author.assignedAuthor.assignedPerson.name</td>
<td></td>
<td></td>
<td>O</td>
</tr>
<tr>
<td>User Facility / Importer Report Number</td>
<td>The number of the report assigned by the reporting facility</td>
<td>Author</td>
<td></td>
<td>ClinicalDocument.author.assignedAuthor.assignedPerson.Id</td>
<td></td>
<td></td>
<td>O</td>
</tr>
<tr>
<td>Type of Report</td>
<td>The type of report (e.g., Drug Event Report, Healthcare Associated Infection Report, etc.)</td>
<td>TypeId</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>O</td>
</tr>
<tr>
<td>Report Date</td>
<td>The date that the Case Report is being sent</td>
<td>effectiveTime</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>O</td>
</tr>
<tr>
<td>Data Element</td>
<td>Definition</td>
<td>CCD Description</td>
<td>Template ID</td>
<td>CCD XPATH</td>
<td>Mapping Constraints (CodeSystem and/or value sets)</td>
<td>CCD Code</td>
<td>Optionality</td>
</tr>
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<td>---------------------------------------------------------------------------</td>
<td>-----------------------------------------------------</td>
<td>----------</td>
<td>-------------</td>
</tr>
<tr>
<td>Reported Previously</td>
<td>Indication if the information is supplemental to update in event already reported</td>
<td>versionNumber</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>O</td>
</tr>
<tr>
<td>Report sent to</td>
<td>The organization to which the report is submitted</td>
<td>informationRecipient</td>
<td></td>
<td>ClinicalDocument.informationRecipient.receivedOrganization</td>
<td></td>
<td></td>
<td>O</td>
</tr>
<tr>
<td>Report sent to FDA</td>
<td>Indication if the report is submitted to the Food and Drug Administration (FDA) – US</td>
<td>informationRecipient</td>
<td></td>
<td>ClinicalDocument.informationRecipient.receivedOrganization[&quot;id='FDA'&quot;]</td>
<td></td>
<td></td>
<td>O</td>
</tr>
<tr>
<td>Date User Facility/Importer Became Aware of Event</td>
<td>The date the event was first recognized by an observer</td>
<td>Event</td>
<td>2.16.840.1.113883.10.20.1.18</td>
<td>ClinicalDocument.component.structuredBody.component.section.entry.entryRelationship.observation[templateId.@root = 2.16.840.1.113883.10.20.1.18].effectiveTime.low.@value</td>
<td></td>
<td></td>
<td>O</td>
</tr>
<tr>
<td>Date report sent</td>
<td>The date the report is submitted</td>
<td>Not Known</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>O</td>
</tr>
<tr>
<td>Date sent to FDA</td>
<td>The date the report was submitted to the FDA – US</td>
<td>Not Known</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>O</td>
</tr>
<tr>
<td>Report Source</td>
<td>The originator of the report</td>
<td>Author</td>
<td></td>
<td>ClinicalDocument.author.assignedAuthor.representedOrganization.Name</td>
<td></td>
<td></td>
<td>O</td>
</tr>
<tr>
<td>Reporter Name</td>
<td>The name of the person or facility sending the Case Report</td>
<td>Author</td>
<td></td>
<td>ClinicalDocument.Author.assignedAuthor.assignedPerson.name</td>
<td></td>
<td></td>
<td>R</td>
</tr>
<tr>
<td>Data Element</td>
<td>Definition</td>
<td>CCD Description</td>
<td>Template ID</td>
<td>CCD XPATH</td>
<td>Mapping Constraints (CodeSystem and /or value sets)</td>
<td>CCD Code</td>
<td>Optionality</td>
</tr>
<tr>
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<td>---------------------------------------------------------------------------</td>
<td>-----------------------------------------------------</td>
<td>----------</td>
<td>-------------</td>
</tr>
<tr>
<td>Occupation of Reporter</td>
<td>The role of the reporter (e.g., physician, nurse, administrator, etc.)</td>
<td>no template</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>O</td>
</tr>
<tr>
<td>Telephone</td>
<td>The phone number of the person or facility sending the Case Report</td>
<td>no template</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>O</td>
</tr>
<tr>
<td>Reporter Email</td>
<td>The email contact information for the reporter</td>
<td>no template</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>O</td>
</tr>
<tr>
<td>Type of Reporter</td>
<td>The role of the reporter with respect to the patient (e.g., treating or consulting clinician, case manager, etc.)</td>
<td>no template</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>O</td>
</tr>
<tr>
<td>Reporter Address (street name, city, state, zip code)</td>
<td>The address of the reporter</td>
<td>Author</td>
<td>ClinicalDocument.author.assignedAuthor or.assignedPerson.addr</td>
<td></td>
<td></td>
<td></td>
<td>O</td>
</tr>
<tr>
<td>Patient identifier</td>
<td>The identifier for the patient, may be a pseudonymized identifier</td>
<td>Patient</td>
<td>ClinicalDocument.recordTarget.patient Role.id</td>
<td></td>
<td></td>
<td></td>
<td>R</td>
</tr>
<tr>
<td>Patient Name (first, MI, Last)</td>
<td>The name (preferably legal) of the subject of the case report.</td>
<td>Patient</td>
<td>ClinicalDocument.recordTarget.patient Role.patient.name</td>
<td></td>
<td></td>
<td></td>
<td>O</td>
</tr>
<tr>
<td>Data Element</td>
<td>Definition</td>
<td>CCD Description</td>
<td>Template ID</td>
<td>CCD XPATH</td>
<td>Mapping Constraints (CodeSystem and /or value sets)</td>
<td>CCD Code</td>
<td>Optionality</td>
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<td>----------</td>
<td>-------------</td>
</tr>
<tr>
<td>Date of Birth</td>
<td>Date of birth</td>
<td>Patient</td>
<td></td>
<td>ClinicalDocument.recordTarget.patientRole.patient.birthTime</td>
<td></td>
<td></td>
<td>O</td>
</tr>
<tr>
<td>Age</td>
<td>The age of the subject of the case report at time of diagnosis</td>
<td>no template</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>O</td>
</tr>
<tr>
<td>Gender</td>
<td>Patient sex</td>
<td>Patient</td>
<td></td>
<td>ClinicalDocument.recordTarget.patientRole.patient.administrativeGenderCode</td>
<td></td>
<td></td>
<td>O</td>
</tr>
<tr>
<td>Pregnancy Status</td>
<td>Whether the subject of the case report was pregnant at time of diagnosis.</td>
<td>no template</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>O</td>
</tr>
<tr>
<td>Estimated Deliver Date</td>
<td>Estimated date of delivery (or est. date of confinement [EDC])</td>
<td>Patient</td>
<td>EDD Observation 1.3.6.1.4.1.19376.1.5.3.1.1.13.1</td>
<td>EDD Observation 1.3.6.1.4.1.19376.1.5.3.1.1.13.1</td>
<td></td>
<td></td>
<td>O</td>
</tr>
<tr>
<td>Weight</td>
<td>The weight of the patient at the time of the report</td>
<td>Patient</td>
<td>Vital Signs Observation 1.3.6.1.4.1.19376.1.5.3.1.13.2</td>
<td>ClinicalDocument.component.structureBody.component.section.entry.entryRelationship.observation[templateId.@root = 1.3.6.1.4.1.19376.1.5.3.1.13.2].code.@displayName</td>
<td></td>
<td></td>
<td>O</td>
</tr>
<tr>
<td>Birth Weight</td>
<td>The weight of the patient at birth</td>
<td>Patient</td>
<td>Vital Signs Observation 1.3.6.1.4.1.19376.1.5.3.1.13.2</td>
<td>ClinicalDocument.component.structureBody.component.section.entry.entryRelationship.observation[templateId.@root = 1.3.6.1.4.1.19376.1.5.3.1.13.2].code.@displayName</td>
<td></td>
<td></td>
<td>O</td>
</tr>
<tr>
<td>Data Element</td>
<td>Definition</td>
<td>CCD Description</td>
<td>Template ID</td>
<td>CCD XPATH</td>
<td>Mapping Constraints (CodeSystem and/or value sets)</td>
<td>CCD Code</td>
<td>Optionality</td>
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<td>------------------------------------------</td>
<td>---------------------------------------------------------------------------</td>
<td>-----------------------------------------------------</td>
<td>----------</td>
<td>-------------</td>
</tr>
<tr>
<td>Number of Siblings</td>
<td>The number of siblings in a multiple birth</td>
<td>Patient</td>
<td>Pregnancy Observation 1.3.6.1.4.1.1.4.1.19376.1.5.3.1.4.13.5</td>
<td></td>
<td></td>
<td>O</td>
<td></td>
</tr>
<tr>
<td>Patient Address (street name, city, state, zip code)</td>
<td>The address of the subject of the case report.</td>
<td>Patient</td>
<td>ClinicalDocument.recordTarget.patient Role.addr</td>
<td></td>
<td></td>
<td>O</td>
<td></td>
</tr>
<tr>
<td>Patient Telephone</td>
<td>The telephone of the subject of the case report.</td>
<td>Patient</td>
<td>ClinicalDocument.recordTarget.patient Role.telecom</td>
<td></td>
<td></td>
<td>O</td>
<td></td>
</tr>
<tr>
<td>Patient County</td>
<td>The county of the address of the subject of the case report</td>
<td>no template</td>
<td>ClinicalDocument.recordTarget.patient Role.patient.raceCode</td>
<td></td>
<td></td>
<td>O</td>
<td></td>
</tr>
<tr>
<td>Patient Country</td>
<td>The country of the address of the subject of the case report</td>
<td>no template</td>
<td>ClinicalDocument.recordTarget.patient Role.patient.ethnicGroupCode</td>
<td></td>
<td></td>
<td>O</td>
<td></td>
</tr>
<tr>
<td>Race</td>
<td>The race(s) of the subject of the case report.</td>
<td>Patient</td>
<td>ClinicalDocument.recordTarget.patient Role.patient.raceCode</td>
<td></td>
<td></td>
<td>O</td>
<td></td>
</tr>
<tr>
<td>Ethnicity</td>
<td>The ethnicity of the subject of the case report</td>
<td>Patient</td>
<td>ClinicalDocument.recordTarget.patient Role.patient.ethnicGroupCode</td>
<td></td>
<td></td>
<td>O</td>
<td></td>
</tr>
<tr>
<td>Data Element</td>
<td>Definition</td>
<td>CCD Description</td>
<td>Template ID</td>
<td>CCD XPATH</td>
<td>Mapping Constraints (CodeSystem and/or value sets)</td>
<td>CCD Code</td>
<td>Optionality</td>
</tr>
<tr>
<td>--------------------</td>
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<td>--------------</td>
<td>---------------------------------------------------------------------------------------------------</td>
<td>----------------------------------------------------</td>
<td>----------</td>
<td>-------------</td>
</tr>
<tr>
<td>Occupation</td>
<td>The occupation of subject of the case report. Enter as much detail as possible (e.g., Teacher in Preschool facility)</td>
<td>no template</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>O</td>
</tr>
<tr>
<td>Date of Death</td>
<td>If patient has died, deceased date/time</td>
<td>no template</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>O</td>
</tr>
<tr>
<td>Date of Event</td>
<td>The date the event first occurred</td>
<td>no template</td>
<td></td>
<td></td>
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<tr>
<td>Description of Event</td>
<td>A textual description of the event</td>
<td>Event</td>
<td>originalText 1.3.6.1.4.1.19376.1.5.3.1.3.13 #XX= ClinicalDocument.component.structure dBody.component.section.entry[templateId/@root=1.3.6.1.4.1.19376.1.5.3.1.3.13].entryRelationship.observation[templateId/@root=2.16.840.1.113883.10.20.1.18].participant.playingEntity.code.origina...</td>
<td>originalText 1.3.6.1.4.1.19376.1.5.3.1.3.13 statusCode code='active'</td>
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<tr>
<td>Name of Condition</td>
<td>The name of the condition diagnosed for the subject of the Case Report</td>
<td>Event</td>
<td>displayName 1.3.6.1.4.1.19376.1.5.3.1.3.13 ClinicalDocument.component.structure dBody.component.section.entry[templateId/@root=1.3.6.1.4.1.19376.1.5.3.1.3.13].entryRelationship.observation[templateId/@root=2.16.840.1.113883.10.20.1.18].code.@displayName</td>
<td>displayName 1.3.6.1.4.1.19376.1.5.3.1.3.13 statusCode code='active'</td>
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<td>Optionality</td>
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<td>The locally determined code to identify the problem for subsequent follow up</td>
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<td>Type of Reportable Event</td>
<td>Seriousness of the event</td>
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<td>Type of Event and/or Issue</td>
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<td>no template</td>
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<td>Approximate Age of Device</td>
<td>The length of time the device has been in use for the patient</td>
<td>no template</td>
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<td>Outcome attributed to AE</td>
<td>Textual description of the outcome associated with the adverse event</td>
<td>no template</td>
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<td>Patient Recovered Diagnosis</td>
<td>Final determination of reaction – diagnosis</td>
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<td>Location where Event Occurred</td>
<td>The location of the event – e.g., home, hospital, other facility, etc.</td>
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<td>Adverse Event Terms</td>
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<td>Event Abated after use stopped or dose reduced?</td>
<td>Indication that the event resolved / abated after usage stopped or dose reduced</td>
<td>no template</td>
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<td>Event Reappeared after reintroduction</td>
<td>Indication if the reaction reoccurred after rechallenging the patient to the suspected substance</td>
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<td>Concomitant Medical Product Name</td>
<td>Other medical products in use for the patient to determine proximal relationships</td>
<td>Admission Medication</td>
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<td>1.3.6.1.4.1.19376.1.5.3.1.3.20</td>
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<td>Therapy Dates</td>
<td>Dates of treatment with the suspected agent</td>
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<td>Pre-existing physician diagnosed allergies, birth defects. Medical conditions</td>
<td>Allergies, conditions existing prior to the use of the suspected agent</td>
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<td>Current Medications (Medwatch concomitant meds)</td>
<td>Other medications in use</td>
<td>Allergies and Other Adverse Reactions</td>
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<td>suspende</td>
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<td>Previous Vaccine Manufacturer</td>
<td>The manufacturer of the vaccine dose</td>
<td>substanceAdministration/text/reference/@value</td>
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<td>1.3.6.1.4.1.19376.1.5.3.1.4.12</td>
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<tr>
<td>Previous Vaccine Lot #</td>
<td>The lot number of the vaccine dose</td>
<td>consumable/administerableMaterial/administerableMaterial/asMedicineManufacturer.manufacturer.id</td>
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<td>Previous Vaccine Route/Site</td>
<td>The route of administration of the vaccine dose</td>
<td>Immunization</td>
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<td>manufacturedLabeledDrug 1.3.6.1.4.1.19376.1.5.3.1.3.23</td>
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<td>Vaccine # Previous Doses</td>
<td>The number of previous doses of the vaccine type</td>
<td>Immunization</td>
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<td>Previous Vaccine Date Given</td>
<td>The date the vaccination dose suspected was administered</td>
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<td>Vaccine Purchased With</td>
<td>Indication of vaccination source (e.g., special program such as Vaccine for Children, state or provincial programs, etc.)</td>
<td>Immunization</td>
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<td>effectiveTime 1.3.6.1.4.1.19376.1.5.3.1.3.23</td>
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<td>Suspect Product Name</td>
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<td>Product Dose</td>
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<tr>
<td>Product Frequency</td>
<td>The frequency with which the product was administered</td>
<td>Medications Administered</td>
<td></td>
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<td>Product 1.3.6.1.4.1.19376.1.5.3.1.3.21</td>
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<td>Product Route Used</td>
<td>The route of administration of the product (e.g., oral, intravenous, intramuscular, etc.)</td>
<td>Medications Administered</td>
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<td>Dose 1.3.6.1.4.1.19376.1.5.3.1.3.21</td>
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<td>Product Therapy Dates</td>
<td>Duration of therapy with the product</td>
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<td>O</td>
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<tr>
<td>Product Diagnosis for Use</td>
<td>The reason the product was initially used</td>
<td>Medications Administered</td>
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<td>Route 1.3.6.1.4.1.19376.1.5.3.1.3.21</td>
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<td>Expiration Date</td>
<td>The expiration date of the product</td>
<td>Medications Administered</td>
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<td></td>
<td>Indication 1.3.6.1.4.1.19376.1.5.3.1.3.21</td>
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<tr>
<td>NDC# or Unique ID</td>
<td>The unique identifier for the product</td>
<td>Medications Administered</td>
<td></td>
<td></td>
<td>Lot #</td>
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<tr>
<td>Event Abated after use</td>
<td>Indication that the event resolved / abated after usage stopped or dose reduced</td>
<td>Medications Administered</td>
<td></td>
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<td>Event Reappeared after reintroduction?</td>
<td>Indication if the reaction reoccurred after rechallenging the patient to the suspected substance</td>
<td>Medications Administered</td>
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<td>Suspect Medical Device Brand Name</td>
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<td>Manuf. name, City and State</td>
<td>Manufacturer of the device</td>
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<td>Medical Device Other #</td>
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<td>Operator of Device</td>
<td>The individual managing the device</td>
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<td>Template ID</td>
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<td>If implanted give date</td>
<td>Date of implantation of the device (if implanted)</td>
<td>no template</td>
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<td>If explanted give date</td>
<td>Date device was removed (if removed)</td>
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<td>Is this a single use device that</td>
<td>Indication if the device is a single-use device that was cleaned/reprocessed and is reused on the affected patient</td>
<td>no template</td>
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<tr>
<td>was reprocessed and reused on</td>
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<td>patient?</td>
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<td>Name and Address of Reprocessor</td>
<td>Name and address of the individual / organization reprocessing the single use device</td>
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<td>Product available for evaluation?</td>
<td>Indication if the product is still available to be evaluated</td>
<td>no template</td>
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<tr>
<td>Date product returned to manuf.</td>
<td>If returned to the manufacturer, date of return</td>
<td>no template</td>
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<tr>
<td>Concomitant Medical Products &amp;</td>
<td>Other medical products and treatment used proximal to the event</td>
<td>no template</td>
<td></td>
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<td>Therapy Dates</td>
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<tr>
<td>Signs and Symptoms</td>
<td>The signs and symptoms experienced by the patient</td>
<td>no template</td>
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<tr>
<td>Symptom/Illness Onset Date/Time</td>
<td>This is the range of time of which the problem was active for the patient; for PH: The date that the subject began having symptoms of condition being reported</td>
<td>Admission Medication</td>
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<td>1.3.6.1.4.1.19376.1.5.3.1.3.20</td>
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<tr>
<td>Patient Class</td>
<td>General type of patient, e.g., Inpatient, Outpatient, Emergency</td>
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<td>Reporting Laboratory Identifier</td>
<td>Identifier for laboratory that is sending the result. This laboratory may be sending results received back from reference laboratories</td>
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<td></td>
<td></td>
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<tr>
<td>Performing Laboratory</td>
<td>Laboratory that produced the test result. This may be a reference laboratory identifier.</td>
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<td></td>
<td></td>
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<td>Data Element</td>
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<tr>
<td>Report Date/Time</td>
<td>Date/time of report</td>
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<td>O</td>
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<tr>
<td>Results Status</td>
<td>Status of report (preliminary, final, corrected)</td>
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<td>Ordered Test Code</td>
<td>The identifier code for the requested observation/test/battery</td>
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<td>Resulted Test</td>
<td>“The identifier code for the specific test component resulted”</td>
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</tr>
<tr>
<td>Result Unit</td>
<td>Unit for numeric result context</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>O</td>
</tr>
<tr>
<td>Test Interpretation</td>
<td>Interpretation of test result, including the susceptibility test interpretation</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>O</td>
</tr>
<tr>
<td>Test Status</td>
<td>Status of the test result</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>C</td>
</tr>
<tr>
<td>Date of Test</td>
<td>The date that the laboratory test was performed for the subject of the Case Report.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>O</td>
</tr>
<tr>
<td>Data Element</td>
<td>Definition</td>
<td>CCD Description</td>
<td>Template ID</td>
<td>CCD XPATH</td>
<td>Mapping Constraints (CodeSystem and/or value sets)</td>
<td>CCD Code</td>
<td>Optionality</td>
</tr>
<tr>
<td>----------------------------------------------</td>
<td>------------------------------------------------------------------------------</td>
<td>------------------</td>
<td>-------------</td>
<td>-----------</td>
<td>---------------------------------------------------</td>
<td>----------</td>
<td>-------------</td>
</tr>
<tr>
<td>Test Method</td>
<td>Testing method used to arrive at the specific result: The name of the laboratory test.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>O</td>
</tr>
<tr>
<td>Test Result</td>
<td>The test result of the laboratory test including any applicable result units of measure</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>O</td>
</tr>
<tr>
<td>Specimen Collection Date</td>
<td>The date that the specimen for the laboratory test was taken from the subject of the Case Report</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>O</td>
</tr>
<tr>
<td>Source of Specimen</td>
<td>The physical body location from where the specimen for the lab report was taken from the subject</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>O</td>
</tr>
<tr>
<td>Name of Organization Collecting Specimen</td>
<td>Name of organization collecting specimen which may be different from the organization performing the laboratory analysis</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>O</td>
</tr>
<tr>
<td>Data Element</td>
<td>Definition</td>
<td>CCD Description</td>
<td>Template ID</td>
<td>CCD XPATH</td>
<td>Mapping Constraints (CodeSystem and/or value sets)</td>
<td>CCD Code</td>
<td>Optionality</td>
</tr>
<tr>
<td>-----------------------</td>
<td>----------------------------------------------------------------------------</td>
<td>-----------------</td>
<td>-------------</td>
<td>-----------</td>
<td>---------------------------------------------------</td>
<td>----------</td>
<td>-------------</td>
</tr>
<tr>
<td>Diagnosis/Injury Code</td>
<td>Diagnosis or diagnoses assigned as a result of the encounter</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>O;</td>
</tr>
<tr>
<td>Diagnosis Type</td>
<td>Type of diagnosis being sent (admitting, working, final)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>O;</td>
</tr>
<tr>
<td>Diagnosis Date/Time</td>
<td>The date that the subject of the Case Report was diagnosed with Condition above</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>O;</td>
</tr>
<tr>
<td>Previous Event Report Details</td>
<td>Definitions pending - see appendix for detail to be considered</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>O</td>
</tr>
<tr>
<td>Reason for Non-Evaluation</td>
<td>Definitions pending - see appendix for detail to be considered</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>O</td>
</tr>
<tr>
<td>Type of Follow-Up</td>
<td>Definitions pending - see appendix for detail to be considered</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>O</td>
</tr>
<tr>
<td>Type of Remedial Action</td>
<td>Definitions pending - see appendix for detail to be considered</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>O</td>
</tr>
<tr>
<td>Administration of Treatment</td>
<td>Was treatment administered?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>R</td>
</tr>
<tr>
<td>Data Element</td>
<td>Definition</td>
<td>CCD Description</td>
<td>Template ID</td>
<td>CCD XPATH</td>
<td>Mapping Constraints (CodeSystem and/or value sets)</td>
<td>CCD Code</td>
<td>Optionality</td>
</tr>
<tr>
<td>-----------------------------</td>
<td>-----------------------------------------------------------------------------</td>
<td>------------------</td>
<td>-------------</td>
<td>-----------</td>
<td>-----------------------------------------------------</td>
<td>----------</td>
<td>-------------</td>
</tr>
<tr>
<td>Date of Admin of Treatment</td>
<td>The date treatment was administered. For HepB, Date HBV vaccine administered</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>R</td>
<td></td>
</tr>
<tr>
<td>Name of Treatment</td>
<td>Name of the treatment</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>R</td>
<td></td>
</tr>
<tr>
<td>Hospitalization</td>
<td>If the subject of the case report was hospitalized</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>R</td>
<td></td>
</tr>
<tr>
<td>Admission Date</td>
<td>Enter the date that the subject of the Case Report was Admitted to the hospital.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>O</td>
<td></td>
</tr>
<tr>
<td>Discharge Date</td>
<td>Enter the date that the subject of the Case Report was Discharged from the hospital.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>R</td>
<td></td>
</tr>
<tr>
<td>Hospital Name</td>
<td>Name of hospital the case was admitted.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>O</td>
<td></td>
</tr>
<tr>
<td>Recovered</td>
<td>Did the subject recover from the disease?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>R</td>
<td></td>
</tr>
<tr>
<td>Death</td>
<td>Did the subject die as a result of the disease?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>R</td>
<td></td>
</tr>
</tbody>
</table>
6.3.1.3.4 Document Sample

6.3.1.3.4.1 Immunizations Example

```xml
<component>
  <section>
    <templateId root='2.16.840.1.113883.10.20.1.6'/>
    <templateId root='1.3.6.1.4.1.19376.1.5.3.1.3.23'/>
    <id root='' extension=''/>
    <code code='11369-6' displayName='HISTORY OF IMMUNIZATIONS'
      codeSystem='2.16.840.1.113883.6.1' codeSystemName='LOINC'/>
    <text>
      Text as described above
    </text>
    <entry>
      <!-- Required Immunization element -->
      <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.12'/>
    </entry>
  </section>
</component>
```

6.3.1.3.4.2 Allergies and Other Adverse Reactions Samples

```xml
<component>
  <section>
    <templateId root='2.16.840.1.113883.10.20.1.2'/>
    <templateId root='1.3.6.1.4.1.19376.1.5.3.1.3.13'/>
    <id root='' extension=''/>
    <code code='48765-2' displayName='Allergies, adverse reactions, alerts'
      codeSystem='2.16.840.1.113883.6.1' codeSystemName='LOINC'/>
    <text>
      Text as described above
    </text>
    <entry>
      <!-- Required Allergies and Intolerances Concern element -->
      <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.5.3'/>
    </entry>
  </section>
</component>
```
6.3.1.3.4.3 Admission Medication History Example

```xml
<component>
  <section>
    <templateId root='1.3.6.1.4.1.19376.1.5.3.1.3.20'/>
    <id root='' extension=' '/>
    <code code='42346-7' codeSystem='2.16.840.1.113883.6.1' codeSystemName='LOINC'/>
    <text>
      Text as described above
    </text>
  </section>
</component>
```

6.3.1.3.4.4 ClinicalDocument Header Example

```xml
<ClinicalDocument xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
  xmlns="urn:hl7-org:v3"
  xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd">
  <realmCode code="US" codeSystem="2.16.1" codeSystemName="ISO3166-1"
    displayName="US"/>
  <typeId extension="POCD_HD000040" root="2.16.840.1.113883.1.3"/>
  <templateId extension="Lab.Report.Clinical.Document" root="1.3.6.1.4.1.19376.1.3.3"/>
  <id root="1.19.6.11.13.103000012000025132.1181266627192.1"/>
  <code code="18725-2" codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC"
    displayName="Microbiology Studies"/>
  <title>Public Health Laboratory Report</title>
  <effectiveTime value="20070607183707.0222-0700"/>
  <confidentialityCode code="N" codeSystem="2.16.840.1.113883.5.25"
    displayName="Normal"/>
  <languageCode code="en-US" codeSystem="2.16.840.1.113883.6.99"
    codeSystemName="ISO639-1" displayName="en-US"/>
  <setId extension="07SR012345" root="2.16.840.1.113883.1.3"/>
  <versionNumber value="1"/>
</ClinicalDocument>
```

6.3.1.3.4.5 Medications Administered Example

```xml
<component>
  <section>
    <templateId root='1.3.6.1.4.1.19376.1.5.3.1.3.21'/>
  </section>
</component>
```
6.3.1.3.4.6 Author Example

```xml
<author>
  <time value="19990522"/>
  <assignedAuthor>
    <id extension="1111111" root="1.3.5.35.1.4436.7"/>
    <assignedPerson>
      <name>
        <prefix>Dr.</prefix>
        <given>Bernard</given>
        <family>Wiseman</family>
        <suffix>Sr.</suffix>
      </name>
    </assignedPerson>
    <representedOrganization>
      <id extension="aaaaabbbbb" root="1.3.5.35.1.4436.7"/>
      <name>Dr. Wiseman’s Clinic</name>
    </representedOrganization>
  </assignedAuthor>
</author>
```

6.3.1.3.4.7 Patient Example

```xml
<recordTarget>
  <patientRole classCode="PAT">
    <id root="27143B24-E580-4F47-9405-3D0DC2BF1223" extension="1022"/>
    <addr>
      <streetAddressLine/>
      <city/>
      <state>FM</state>
      <postalCode/>
      <country>Canada</country>
    </addr>
  </patientRole>
</recordTarget>
```
6.3.1.3.4.8 Vital Signs Observation Example

```xml
<observation classCode='OBS' moodCode='EVN'>
  <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.13' />
  <templateId root='2.16.840.1.113883.10.20.1.31' />
  <id root=' ' extension=' '/>
  <code code=' ' codeSystem='2.16.840.1.113883.6.1' codeSystemName='LOINC' />
  <text><reference value='#xxx'/></text>
  <statusCode code='completed' />
  <effectiveTime value=' '/>
  <repeatNumber value=' '/>
  <value xsi:type='PQ' value=' ' unit=' '/>
  <interpretationCode code=' ' codeSystem=' ' codeSystemName=' '/>
  <methodCode code=' ' codeSystem=' ' codeSystemName=' '/>
  <targetSiteCode code=' ' codeSystem=' ' codeSystemName=' '/>
</observation>
```

6.3.1.3.4.9 Pregnancy Observation Example

```xml
<observation typeCode='OBS' moodCode='EVN'>
  <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.13' />
  <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.13.5' />
  <id root=' ' extension=' '/>
  <code code=' ' displayName=' ' codeSystem='2.16.840.1.113883.6.1' codeSystemName='LOINC' />
  <text><reference value='#xxx'/></text>
</observation>
```
6.3.1.3.4.10 EDD Observation Example

```xml
<observation classCode='OBS' moodCode='EVN'>
  <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.13'/>
  <templateId root='1.3.6.1.4.1.19376.1.5.3.1.1.11.2.3.1'/>
  <statusCode code='completed'/>
  <effectiveTime value=' '/>
  <author typeCode='AUT'>
    <time value=' '/>
    <assignedAuthor>
      <id root=' ' extension=' '/>
    </assignedAuthor>
  </author>
  <id root=' ' extension=' '/>
  <code code='11778-8' displayName='DELIVERY DATE-TMSTP-PT-^PATIENT-QN-CLINICAL.ESTIMATED' codeSystem='2.16.840.1.113883.6.1' codeSystemName='LOINC'/>
  <text>
    <reference value='id-foo'/>
  </text>
  <value xsi:type='TS' value=' '/>
  <entryRelationship typeCode='SPRT'>
    <observation classCode='OBS' moodCode='EVN'>
      <id root=' ' extension=' '/>
      <statusCode code='completed'/>
      <effectiveTime value=' '/>
      <author typeCode='AUT'>
        <time value=' '/>
        <assignedAuthor classCode=' '>
          <id root=' ' extension=' '/>
        </assignedAuthor>
      </author>
      <id root=' ' extension=' '/>
      <code code='[11779-6|(xx-EDD-by-PE)|11781-2|(xx-EDD-by-Qck)|(xx-EDD-by-Fund)]' codeSystem='2.16.840.1.113883.6.1' codeSystemName='LOINC'/>
      <value type='TS' value=' '/>
      <entryRelationship typeCode='DRIV'>
        <observation classCode='OBS' moodCode='EVN'>
          <id root=' ' extension=' '/>
          <statusCode code='completed'/>
          <effectiveTime value=' '/>
          <author typeCode='AUT'>
            <time value=' '/>
            <assignedAuthor>
              <id root=' ' extension=' '/>
            </assignedAuthor>
          </author>
          <id root=' ' extension=' '/>
        </observation>
      </entryRelationship>
    </observation>
  </entryRelationship>
</observation>
```
6.4 Section not applicable
This heading is not used in a CDA document.

6.5 QRPH Value Sets
This section intentionally left blank.
7 QRPH DICOM Content Modules

The structure for the DICOM Content section has not yet been defined. Authors utilizing this section are encouraged to provide input to development of the template structure for this Technical Framework Volume 3 section to the Documentation Workgroup at http://ihe.net/Templates_Public_Comments.
8 QRPH Content Modules (Type other than CDA or DICOM)

The structure for other types of “Content” sections has not yet been defined. Authors utilizing this section are encouraged to provide input to development of the template structure for this Technical Framework Volume 3 section at http://ihe.net/Templates_Public_Comments.
Appendices
### Appendix A – CCD-ODM/CDASH mapping and CRD constraints

This appendix is informative.

#### Table A-1: CCD-CDASH Mapping and CRD Constraints

<table>
<thead>
<tr>
<th>CRD Reference</th>
<th>CDASH Domain</th>
<th>Clinical Database Variable Name</th>
<th>Optionality</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td><strong>Common Identifiers</strong></td>
<td>STUDYID</td>
<td>R2</td>
<td>Unique Identifier for a study within a submission.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>SITEID</td>
<td>R2</td>
<td>Unique identifier for the site.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>SUBJID</td>
<td>R2</td>
<td>Subject identifier.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>INVID</td>
<td>O</td>
<td>Investigator identifier.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>VISIT</td>
<td>O</td>
<td>Visit Name.</td>
</tr>
<tr>
<td></td>
<td><strong>Header Information</strong></td>
<td>BRTHYR</td>
<td>R</td>
<td>Year of subject’s birth.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>BRTHMO</td>
<td>R</td>
<td>Month of subject’s birth.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>BRTHDY</td>
<td>R2</td>
<td>Day of subject’s birth.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>BRTHTM</td>
<td>O</td>
<td>Time of subject’s birth,</td>
</tr>
<tr>
<td></td>
<td></td>
<td>SEX</td>
<td>R</td>
<td>The assemblage of physical properties or qualities by which male is distinguished from female; the physical difference between male and female; the distinguishing peculiarity of male or female. (NCI – CDISC Definition).</td>
</tr>
<tr>
<td></td>
<td></td>
<td>AGE</td>
<td>O</td>
<td>Numeric Age of Subject.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>AGEU</td>
<td>O</td>
<td>Age units.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>DMDAT</td>
<td>R2</td>
<td>Date of collection.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>DMTM (Note: If collected, will be derived into DMDTC.)</td>
<td>O</td>
<td>Time of collection.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>ETHNIC</td>
<td>O</td>
<td>A social group characterized by a distinctive social and cultural tradition maintained from generation to generation, a common history and origin and a sense of identification with the group; members of the group have distinctive features in their way of life, shared experiences and often a common genetic heritage; these features MAY be reflected in their experience of health and disease.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>RACE</td>
<td>R2</td>
<td>An arbitrary classification based on physical characteristics; a group of persons related by common descent or heredity.</td>
</tr>
<tr>
<td>CRD Reference</td>
<td>CDASH Domain</td>
<td>Clinical Database Variable Name</td>
<td>Optionality</td>
<td>Definition</td>
</tr>
<tr>
<td>---------------</td>
<td>--------------</td>
<td>---------------------------------</td>
<td>-------------</td>
<td>------------</td>
</tr>
<tr>
<td></td>
<td>Subject Characteristics</td>
<td>SCDTC</td>
<td>R2</td>
<td>Date of collection.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>SCTM (Note: If collected, will be derived into SCDTC.)</td>
<td>O</td>
<td>Time of collection.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>O</td>
<td>The age (in weeks) of the newborn infant, counted from the first day of the woman’s last menstrual period (LMP) or health status indicators / Clinical Estimate (CE).</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>SCTESTCD</td>
<td>O</td>
<td>Natural eye color</td>
</tr>
<tr>
<td></td>
<td></td>
<td>SCTESTCD</td>
<td>O</td>
<td>Subject’s childbearing potential</td>
</tr>
<tr>
<td></td>
<td></td>
<td>SCTESTCD</td>
<td>O</td>
<td>Education level achieved at start of study (Reference date)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>SCTESTCD</td>
<td>O</td>
<td>Sub-study participation information.</td>
</tr>
<tr>
<td></td>
<td>Medical History</td>
<td>MHTERM</td>
<td>R</td>
<td>Verbatim or preprinted CRF term for the medical condition or event.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>MHONGO</td>
<td>R</td>
<td>Identifies the end of the event as ONGOING or RESOLVED.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>MHYN</td>
<td>O</td>
<td>Lead prompt for the Medical History (e.g., “Has the subject experienced any past and / or concomitant diseases or past surgeries?”).</td>
</tr>
<tr>
<td></td>
<td></td>
<td>MHSPID</td>
<td>O</td>
<td>O sponsor-defined reference number (e.g., Preprinted line number).</td>
</tr>
<tr>
<td></td>
<td></td>
<td>MHCAT</td>
<td>O</td>
<td>Used to define a category of related records (e.g., CARDIAC or GENERAL).</td>
</tr>
<tr>
<td></td>
<td></td>
<td>MHSCAT</td>
<td>O</td>
<td>A categorization of the condition or event pre-printed on the CRF or instructions.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>MHOCCUR</td>
<td>O</td>
<td>A pre-printed prompt used to indicate whether or not a medical condition has occurred.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>MHSTDTC</td>
<td>O</td>
<td>Start Date of Medical History Event.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>MHENDTC</td>
<td>O</td>
<td>End Date/Time of Medical History Event.</td>
</tr>
<tr>
<td></td>
<td>Concomitant Medication</td>
<td>CMYN</td>
<td>O</td>
<td>General prompt question to aid in monitoring and data cleaning.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>CMSPID</td>
<td>O</td>
<td>A sponsor-defined reference number.</td>
</tr>
<tr>
<td>CRD Reference</td>
<td>CDASH Domain</td>
<td>Clinical Database Variable Name</td>
<td>Optionality</td>
<td>Definition</td>
</tr>
<tr>
<td>---------------</td>
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<td>---------------------------------</td>
<td>-------------</td>
<td>------------</td>
</tr>
<tr>
<td></td>
<td></td>
<td>CMTRT</td>
<td>R</td>
<td>Verbatim drug name that is either pre-printed or collected on a CRF.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>CMINGRD</td>
<td>O</td>
<td>Medication Ingredients.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>CMINDC</td>
<td>R2</td>
<td>The reason for administration of a concomitant (non-study) medication. (e.g., Nausea, Hypertension) This is not the pharmacological/therapeutic classification of an agent (e.g., antibiotic, analgesic, etc.), but the reason for its administration to the subject.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>AESPID</td>
<td>O</td>
<td>Identifier for the adverse event that is the indication for this medication.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>CMDOSTOT</td>
<td>R2</td>
<td>Total daily dose taken.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>CMDOSFRM</td>
<td>O</td>
<td>Name of the pharmaceutical dosage form (e.g., tablets, capsules, syrup) of delivery for the drug.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>CMDOSFRQ</td>
<td>O</td>
<td>How often the medication was taken (e.g., BID, every other week, PRN).</td>
</tr>
<tr>
<td></td>
<td></td>
<td>CMDSTXT (Note: If collected, will be derived into CMDOSTXT or CMDOSE.)</td>
<td>O</td>
<td>The dose of medication taken per administration.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>CMDOSU</td>
<td>O</td>
<td>Within structured dosage information, the unit associated with the dose (e.g., &quot;mg&quot; in &quot;2mg three times per day).</td>
</tr>
<tr>
<td></td>
<td></td>
<td>CMDOSRGM</td>
<td>O</td>
<td>Within structured dosage information, the number of units for the interval (e.g., in oncology where drug is given 1 week on, and 3 weeks off).</td>
</tr>
<tr>
<td></td>
<td></td>
<td>CMROUTE</td>
<td>R2</td>
<td>Identifies the route of administration of the drug.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>CMSTDTC</td>
<td>R</td>
<td>Date when the medication was first taken.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>CMSTRF</td>
<td>O</td>
<td>Relative time frame that the medication was first taken with respect to the sponsor-defined reference period.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>CMSTTM (Note: If collected, will be derived into CMSTDTC.)</td>
<td>R2</td>
<td>Time the medication was started.</td>
</tr>
<tr>
<td>CRD Reference</td>
<td>CDASH Domain</td>
<td>Clinical Database Variable Name</td>
<td>Optionality</td>
<td>Definition</td>
</tr>
<tr>
<td>---------------</td>
<td>--------------</td>
<td>---------------------------------</td>
<td>-------------</td>
<td>------------</td>
</tr>
<tr>
<td></td>
<td>Social History</td>
<td>CMENDTC</td>
<td>R2</td>
<td>Date that the subject stopped taking the medication.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>CMENRF</td>
<td>O</td>
<td>Indicates medication is ongoing when no End/Stop Date is provided.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>CMONGO (Note: If collected, will be derived into CMENRF.)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>CMENTM (Note: If collected, will be derived into CMENDTC.)</td>
<td>R2</td>
<td>Time when the subject stopped taking the medication.</td>
</tr>
<tr>
<td></td>
<td>Social History</td>
<td>SUTRT</td>
<td>R</td>
<td>The type of substance (e.g., TOBACCO, ALCOHOL, CAFFEINE, etc. Or CIGARETTES, CIGARS, COFFEE, etc.).</td>
</tr>
<tr>
<td></td>
<td>Social History</td>
<td>SUNCF</td>
<td>R2</td>
<td>Substance Use Occurrence.</td>
</tr>
<tr>
<td></td>
<td>Social History</td>
<td>SUCAT</td>
<td>O</td>
<td>Used to define a category of related records (e.g., TOBACCO, ALCOHOL, CAFFEINE, etc.).</td>
</tr>
<tr>
<td></td>
<td>Social History</td>
<td>SUDOSTXT</td>
<td>O</td>
<td>Substance use consumption amounts or a range of consumption information collected in text form [e.g., 1-2 (packs), 8 (ounces), etc.].</td>
</tr>
<tr>
<td></td>
<td>Social History</td>
<td>SUDOSU</td>
<td>O</td>
<td>Units for SUDOSTXT (e.g., PACKS, OUNCES, etc.).</td>
</tr>
<tr>
<td></td>
<td>Social History</td>
<td>SUDOSFRQ</td>
<td>O</td>
<td>Usually expressed as the number of uses consumed per a specific interval (e.g., PER DAY, PER WEEK, OCCASIONAL).</td>
</tr>
<tr>
<td></td>
<td>Social History</td>
<td>SUSTDTC</td>
<td>O</td>
<td>Date substance use started.</td>
</tr>
<tr>
<td></td>
<td>Social History</td>
<td>SUSTTM (Note: If collected, will be derived into SUSTDTC.)</td>
<td>O</td>
<td>Time substance use started.</td>
</tr>
<tr>
<td></td>
<td>Social History</td>
<td>SUENDTC</td>
<td>O</td>
<td>Date substance use ended.</td>
</tr>
<tr>
<td></td>
<td>Social History</td>
<td>SUENTM (Note: If collected, will be derived into SUENDTC.)</td>
<td>O</td>
<td>Time substance use ended.</td>
</tr>
<tr>
<td></td>
<td>Social Signs</td>
<td>SUDUR</td>
<td>O</td>
<td>The duration of the substance use.</td>
</tr>
<tr>
<td></td>
<td>Vital Signs</td>
<td>VS HTC</td>
<td>R2</td>
<td>Date of measurements</td>
</tr>
<tr>
<td></td>
<td>Vital Signs</td>
<td>VSSPID</td>
<td>O</td>
<td>Sponsor defined reference number</td>
</tr>
<tr>
<td></td>
<td>Vital Signs</td>
<td>VISITDY</td>
<td>O</td>
<td>Study day of measurements, measured as integer days</td>
</tr>
<tr>
<td>CRD Reference</td>
<td>CDASH Domain</td>
<td>Clinical Database Variable Name</td>
<td>Optionality</td>
<td>Definition</td>
</tr>
<tr>
<td>---------------</td>
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<td>------------</td>
</tr>
<tr>
<td></td>
<td></td>
<td>VSTPT</td>
<td>O</td>
<td>Text description of time when measurement SHOULD be taken.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>VSTM (Note: If collected, will be derived into VSDTC.)</td>
<td>O</td>
<td>Time of measurements.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>VTEST</td>
<td>R2</td>
<td>Verbatim name of the test or examination used to obtain the measurement or finding.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>VSTAT</td>
<td>R2</td>
<td>Used to indicate that a vital signs measurement was not done.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>ORRES</td>
<td>R</td>
<td>Result of the vital signs measurement as originally received or collected.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>ORRESU</td>
<td>R</td>
<td>Original units in which the data were collected.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>LOC</td>
<td>R2</td>
<td>Location on body where measurement was performed.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>POS</td>
<td>R2</td>
<td>Position of the subject during a measurement or examination.</td>
</tr>
<tr>
<td></td>
<td>Physical Exam</td>
<td>PESTAT</td>
<td>O</td>
<td>Used to indicate if exam was not done as scheduled.</td>
</tr>
<tr>
<td></td>
<td>Physical Exam - Best Practice Approach</td>
<td>PEDTC</td>
<td>O</td>
<td>Date of examination.</td>
</tr>
<tr>
<td></td>
<td>Physical Exam - Best Practice Approach</td>
<td>PETM (Note: If collected, will be derived into PEDTC.)</td>
<td>O</td>
<td>Time of examination.</td>
</tr>
<tr>
<td></td>
<td>Physical Exam - Traditional Approach</td>
<td>PEDONE</td>
<td>O</td>
<td>Used to indicate if exam was not done as scheduled.</td>
</tr>
<tr>
<td></td>
<td>Physical Exam - Traditional Approach</td>
<td>PEDTC</td>
<td>R2</td>
<td>Date of examination.</td>
</tr>
<tr>
<td></td>
<td>Physical Exam - Traditional Approach</td>
<td>PETM (Note: If collected, will be derived into PEDTC.)</td>
<td>O</td>
<td>Time of examination.</td>
</tr>
<tr>
<td></td>
<td>Allergies and Other Adverse Reactions</td>
<td>AEYN</td>
<td>O</td>
<td>General prompt question to aid in monitoring and data cleaning.</td>
</tr>
<tr>
<td></td>
<td>Allergies and Other Adverse Reactions</td>
<td>AESPID</td>
<td>O</td>
<td>A sponsor-defined reference number.</td>
</tr>
<tr>
<td></td>
<td>Allergies and Other Adverse Reactions</td>
<td>AETERM</td>
<td>R2</td>
<td>Verbatim (i.e., investigator reported term) description of the adverse event.</td>
</tr>
<tr>
<td></td>
<td>Allergies and Other Adverse Reactions</td>
<td>AESER</td>
<td>R2</td>
<td>Indicates whether or not the adverse event is determined to be “serious” according to the protocol.</td>
</tr>
<tr>
<td>CRD Reference</td>
<td>CDASH Domain</td>
<td>Clinical Database Variable Name</td>
<td>Optionality</td>
<td>Definition</td>
</tr>
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</tr>
<tr>
<td></td>
<td></td>
<td>AESERTP Or AESCAN AESCONG AESDISAB AESDTH AESHOSP AESLIFE AESOD AESMIE (see below)</td>
<td>O</td>
<td>Captures the criteria required by protocol for determining why an event is “Serious”.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>AESCAN</td>
<td>O</td>
<td>Captures the criteria required by protocol for determining why an event is “Serious”.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>AESCONG</td>
<td>O</td>
<td>Captures the criteria required by protocol for determining why an event is “Serious”.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>AESDISAB</td>
<td>O</td>
<td>Captures the criteria required by protocol for determining why an event is “Serious”.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>AESDTH</td>
<td>O</td>
<td>Captures the criteria required by protocol for determining why an event is “Serious”.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>AESHOSP</td>
<td>O</td>
<td>Captures the criteria required by protocol for determining why an event is “Serious”.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>AESLIFE</td>
<td>O</td>
<td>Captures the criteria required by protocol for determining why an event is “Serious”.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>AESOD</td>
<td>O</td>
<td>Captures the criteria required by protocol for determining why an event is “Serious”.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>AESMIEIE</td>
<td>O</td>
<td>Captures the criteria required by protocol for determining why an event is “Serious”.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>AESTDTC</td>
<td>R2</td>
<td>Date when the adverse event started.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>AESTTM (Note: If collected, will be derived into AESTDTC.)</td>
<td>R2</td>
<td>Time when the adverse event started.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>AEENDTC</td>
<td>R2</td>
<td>Date when the adverse event resolved.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>AEENRF AEONGO</td>
<td>O</td>
<td>Indicates AE is ongoing when no End/Stop date is provided.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>AEENTM (Note: If collected, will be derived into AEENDTC.)</td>
<td>R2</td>
<td>Time when the adverse event resolved.</td>
</tr>
<tr>
<td>CRD Reference</td>
<td>CDASH Domain</td>
<td>Clinical Database Variable Name</td>
<td>Optionality</td>
<td>Definition</td>
</tr>
<tr>
<td>---------------</td>
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<td>---------------------------------</td>
<td>-------------</td>
<td>------------</td>
</tr>
<tr>
<td></td>
<td></td>
<td>AESEV And/or AETOXGR</td>
<td>R2</td>
<td>Description of the severity of the adverse event.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>AEREL</td>
<td>R2</td>
<td>Indication of whether the investigational product had a causal effect on the adverse event, as reported by the clinician/investigator.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>AERELTP</td>
<td>R2</td>
<td>Captures a category for an investigational product to which an adverse event is related.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>AEACN</td>
<td>R2</td>
<td>Action(s) taken with the investigational product in response to the adverse event.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>AEACNOTH</td>
<td>O</td>
<td>Describes Other Action(s) taken in response to the adverse event. (Does not include investigational products)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>AEOOUT</td>
<td>R2</td>
<td>Description of the subject’s status associated with an event.</td>
</tr>
<tr>
<td></td>
<td>Coded Results</td>
<td>Lab Test Results - Scenario 1: Central processing</td>
<td>LBBDTC</td>
<td>R</td>
</tr>
<tr>
<td></td>
<td></td>
<td>LBBDTC</td>
<td>R2</td>
<td>Time of collection.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>LBBDTC</td>
<td>R2</td>
<td>Status of whether or not lab was done.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>LBCAT LBSCAT</td>
<td>R2</td>
<td>Type of draw / category / panel name. Used to define a category of related records.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>LBBDTC</td>
<td>R2</td>
<td>Relative time for use when multiple sequential assessments are done.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>LBBDTC</td>
<td>R2</td>
<td>Conditions for sampling defined in the protocol.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>LBBDTC</td>
<td>R2</td>
<td>Internal or external specimen identifier.</td>
</tr>
<tr>
<td></td>
<td>Lab Test Results - Scenario 2: Local processing</td>
<td>LBBDTC</td>
<td>R</td>
<td>Date of sample collection.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>LBBDTC</td>
<td>R2</td>
<td>Time of collection.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>LBBDTC</td>
<td>R2</td>
<td>Status of whether or not lab was done.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>LBCAT LBSCAT</td>
<td>R2</td>
<td>Type of draw / category / panel name. Used to define a category of related records.</td>
</tr>
<tr>
<td>CRD Reference</td>
<td>CDASH Domain</td>
<td>Clinical Database Variable Name</td>
<td>Optionality</td>
<td>Definition</td>
</tr>
<tr>
<td>---------------</td>
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</tr>
<tr>
<td></td>
<td></td>
<td>LBPTT</td>
<td>R2</td>
<td>Relative time for use when multiple sequential assessments are done.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>LBFAST (for example)</td>
<td>R2</td>
<td>Conditions for sampling defined in the protocol.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>LBSPCCND</td>
<td>R2</td>
<td>Free or standardized text describing the condition of the specimen.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>LBTESTCD And/or LBTEST</td>
<td>R2</td>
<td>Verbatim name of the test or examination used to obtain the measurement or finding. Note any test normally performed by a clinical laboratory is considered a lab test.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>LBORRES</td>
<td>R</td>
<td>Result of the measurement or finding as originally received or collected.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>LBORRESU</td>
<td>R</td>
<td>Original units in which the data were collected.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>LBORNRLO LBORNRIH LBSTNRC</td>
<td>R2</td>
<td>Normal range for continuous measurements in original units. Normal values for non-continuous measurements in original units.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>LBNRIND</td>
<td>R2</td>
<td>Reference Range Indicator Indicates where value falls with respect to reference range defined by high and low ranges.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>LBCLSG (Note: If collected will be mapped to SUPPQUAL domain.)</td>
<td>R2</td>
<td>Whether lab test results were clinically significant.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>LBNAM</td>
<td>R2</td>
<td>Name of lab analyzing sample.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>LBREFID</td>
<td>R2</td>
<td>Internal or external specimen identifier.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>LBDTC</td>
<td>R</td>
<td>Date of sample collection.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>LBTM (Note: If collected will be derived into LBDTC.)</td>
<td>R2</td>
<td>Time of collection.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>LBSTAT</td>
<td>R2</td>
<td>Status of whether or not lab was done.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>LBCAT LBSCAT</td>
<td>R2</td>
<td>Type of draw / category / panel name. Used to define a category of related records.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>LBPTT</td>
<td>R2</td>
<td>Relative time for use when multiple sequential assessments are done,</td>
</tr>
</tbody>
</table>

Lab Test Results - Scenario 3: Central processing but CRF includes site assessment...
<table>
<thead>
<tr>
<th>CRD Reference</th>
<th>CDASH Domain</th>
<th>Clinical Database Variable Name</th>
<th>Optionality</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>LBFAST (for example)</td>
<td>R2</td>
<td>Conditions for sampling defined in the protocol.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>LBTEST</td>
<td>R</td>
<td>Verbatim name of the test or examination used to obtain the measurement or finding. Note: any test normally performed by a clinical laboratory is considered a lab test.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>LBORRES</td>
<td>R2</td>
<td>Result of the measurement or finding as originally received or collected.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>LBCLSG (Note: If collected will be mapped to SUPPQUAL domain.)</td>
<td>R2</td>
<td>Whether lab test results were clinically significant.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>LBNAM</td>
<td>R2</td>
<td>Name of lab analyzing sample.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>LBREFID</td>
<td>R2</td>
<td>Internal or external specimen identifier.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>ECG Test Results - Scenario 1: Central reading...</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>LBDTC</td>
<td>R</td>
<td>Date of sample collection.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>LBTM (Note: If collected, will be derived into LBDTC.)</td>
<td>O</td>
<td>Time of collection.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>SBSTAT</td>
<td>R2</td>
<td>Status of whether or not lab was done.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>LBCAT, LBSCAT</td>
<td>R2</td>
<td>Type of draw / category / panel name. Used to define a category of related records.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>LBTPT</td>
<td>R2</td>
<td>Relative time for use when multiple sequential assessments are done.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>LBFAST (for example)</td>
<td>O</td>
<td>Conditions for sampling defined in the protocol.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>LBREFID</td>
<td>O</td>
<td>Internal or external specimen identifier.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>ECG Test Results - Scenario 2: Local reading: ECGs...</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>EGSTAT</td>
<td>R2</td>
<td>Status of whether or not ECG was done.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>EGREASND</td>
<td>O</td>
<td>Describes why the ECG was not done (e.g., BROKEN EQUIPMENT, SUBJECT REFUSED).</td>
</tr>
<tr>
<td></td>
<td></td>
<td>EGDTC</td>
<td>R2</td>
<td>Date of ECG.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>EGTM (Note: If collected, will be derived into EGDTC.)</td>
<td>R2</td>
<td>Time of ECG.</td>
</tr>
<tr>
<td>CRD Reference</td>
<td>CDASH Domain</td>
<td>Clinical Database Variable Name</td>
<td>Optionality</td>
<td>Definition</td>
</tr>
<tr>
<td>---------------</td>
<td>--------------</td>
<td>---------------------------------</td>
<td>-------------</td>
<td>------------</td>
</tr>
<tr>
<td></td>
<td></td>
<td>EGTPT</td>
<td>R2</td>
<td>Text description of planned time point when measurements SHOULD be taken for use when multiple sequential assessments are done.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>EGTESTCD And/or EGTEST</td>
<td>R</td>
<td>Verbatim name of the test or examination used to obtain the measurement or finding.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>EGORRES</td>
<td>R</td>
<td>Result of the measurement or finding as originally received or collected.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>EGORRESU</td>
<td>R2</td>
<td>Original units in which the data were collected.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>EGCLSG (Note: If collected will be mapped to SUPPQUAL domain.)</td>
<td>O</td>
<td>Whether ECG results were clinically significant.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>EGPOS, EGMETHOD (for example)</td>
<td>O</td>
<td>Condition for testing defined in the protocol.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>EGEVAL</td>
<td>O</td>
<td>Role of the person who provided the evaluation. This SHOULD only be used for results that are subjective (e.g., assigned by a person or a group) and do not apply to quantitative results (i.e., ADJUDICATION COMMITTEE, INVESTIGATOR).</td>
</tr>
<tr>
<td></td>
<td></td>
<td>EGREFID</td>
<td>O</td>
<td>Internal or external identifier.</td>
</tr>
</tbody>
</table>

**ECG Test Results - Scenario 3: Central reading**

<table>
<thead>
<tr>
<th>CRD Reference</th>
<th>CDASH Domain</th>
<th>Clinical Database Variable Name</th>
<th>Optionality</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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<td>EGSTAT</td>
<td>R2</td>
<td>Status of whether or not ECG was done.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>EGREASND</td>
<td>O</td>
<td>Describes why the ECG was not done (e.g., BROKEN EQUIPMENT, SUBJECT REFUSED).</td>
</tr>
<tr>
<td></td>
<td></td>
<td>EGDTC</td>
<td>R2</td>
<td>Date of ECG.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>EGTPT</td>
<td>R2</td>
<td>Text description of planned time point when measurements SHOULD be taken for use when multiple sequential assessments are done.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>EGTPT</td>
<td>R2</td>
<td>Text description of planned time point when measurements SHOULD be taken for use when multiple sequential assessments are done.</td>
</tr>
<tr>
<td>CRD Reference</td>
<td>CDASH Domain</td>
<td>Clinical Database Variable Name</td>
<td>Optionality</td>
<td>Definition</td>
</tr>
<tr>
<td>---------------</td>
<td>--------------</td>
<td>---------------------------------</td>
<td>-------------</td>
<td>------------</td>
</tr>
<tr>
<td></td>
<td></td>
<td>EGTEST</td>
<td>R</td>
<td>Verbatim name of the test or examination used to obtain the measurement or finding.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>EGORRESU</td>
<td>R2</td>
<td>Original units in which the data were collected.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>EGCLSG (Note: If collected, will be mapped to SUPPQUAL domain.)</td>
<td>R2</td>
<td>Whether ECG results were clinically significant.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>EGORRES</td>
<td>R2</td>
<td>Result of the measurement or finding as originally received or collected.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>EGORRESU</td>
<td>R2</td>
<td>Original units in which the data were collected.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>EGNAM</td>
<td>R2</td>
<td>Name of vendor providing ECG data.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>EGPOS, EGMETHOD (for example)</td>
<td>O</td>
<td>Conditions for testing defined in the protocol.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>EGREFID</td>
<td>O</td>
<td>Internal or external ECG identifier.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Optionality Key</th>
</tr>
</thead>
<tbody>
<tr>
<td>R</td>
</tr>
<tr>
<td>R2</td>
</tr>
<tr>
<td>O</td>
</tr>
</tbody>
</table>
Appendix B – Clinical Research Document to Standard CRF (ODM/CDASH) Crosswalk

This section is intended to be a guide as to how a Form Manager would crosswalk a Clinical Research Document prepopulation and workflow data structure into a CDASH compliant ODM structure (Standard CRF). The adopted format for this transformation from one structure to the other is an XSLT. The intent is to have this XSLT not be presented here within the CRD Profile and remain static, but to further develop and refine this XSLT as supplemental material. The goal is to allow additional Use Cases to drive different flavors of transformations all of which might be available to be referenced.

B.1 XSLT Sample

```xml
<?xml version="1.0" encoding="UTF-8"?>
<!-- mapping CCD to CDASH elements -->
<xsl:stylesheet version="1.0"
    xmlns:xsl="http://www.w3.org/1999/XSL/Transform"
    xmlns:cda="urn:hl7-org:v3"
    xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
    xmlns:odm="http://www.cdisc.org/ns/odm/v1.3"
    xmlns:ds="http://www.w3.org/2000/09/xmldsig#"
    exclude-result-prefixes="cda">
    <xsl:output method="xml" version="1.0" encoding="UTF-8" indent="yes"
        omit-xml-declaration="no"/>

    <!-- kick off the transformation with this default template -->
    <xsl:template match="cda:ClinicalDocument">
        <!--odm:ODM xmlns:ds="http://www.w3.org/2000/09/xmldsig#"
            xmlns:xsi=http://www.w3.org/2001/XMLSchema-instance" ODMVersion="1.3"
        FileOID="CLL.003" PriorFileOID="CRF_CLL_v1.6" FileType="SnapShot"
        Description="IHE CDASH from CCD"-->
        <xsl:element name="ODM" namespace="http://www.cdisc.org/ns/odm/v1.3">
            <xsl:attribute name="AsOfDateTime"><xsl:value-of select="current-dateTime()"/></xsl:attribute>
            <xsl:attribute name="ODMVersion">1.3</xsl:attribute>
            <xsl:attribute name="FileType">Transactional</xsl:attribute>
            <xsl:attribute name="FileOID">TEST</xsl:attribute>
            <xsl:attribute name="CreationDateTime"><xsl:value-of select="current-dateTime()"/></xsl:attribute>
            <xsl:element name="ClinicalData" namespace="http://www.cdisc.org/ns/odm/v1.3">
                <xsl:attribute name="StudyOID">CLL.001</xsl:attribute>
            </xsl:element>
        </xsl:element>
    </xsl:template>
</xsl:stylesheet>
```
<xsl:attribute name="MetaDataVersionOID">001</xsl:attribute>

<!-- SubjectData element -->
<xsl:element name="SubjectData" namespace="http://www.cdisc.org/ns/odm/v1.3">
  <xsl:attribute name="SubjectKey">1038</xsl:attribute>
</xsl:element>

<!-- SiteRef element -->
<xsl:element name="SiteRef" namespace="http://www.cdisc.org/ns/odm/v1.3">
  <xsl:attribute name="LocationOID">100</xsl:attribute>
</xsl:element>

<!-- StudyEventData element -->
<xsl:element name="StudyEventData" namespace="http://www.cdisc.org/ns/odm/v1.3">
  <xsl:attribute name="StudyEventOID">CLL_CRF</xsl:attribute>
</xsl:element>

<!-- multiple FormData Elements, representing CDASH Domains -->
  <!-- demography -->
  <xsl:element name="FormData" namespace="http://www.cdisc.org/ns/odm/v1.3">
    <xsl:attribute name="FormOID">DemographicsForm</xsl:attribute>
  </xsl:element>
  <!-- medical history -->
  <xsl:element name="FormData" namespace="http://www.cdisc.org/ns/odm/v1.3">
    <xsl:attribute name="FormOID">MedicalHistoryForm</xsl:attribute>
  </xsl:element>
  <!-- conMeds -->
  <xsl:element name="FormData" namespace="http://www.cdisc.org/ns/odm/v1.3">
    <xsl:attribute name="FormOID">ConMedsForm</xsl:attribute>
  </xsl:element>
  <!-- substance use -->
  <xsl:element name="FormData" namespace="http://www.cdisc.org/ns/odm/v1.3">
    <xsl:attribute name="FormOID">SubstanceUseForm</xsl:attribute>
  </xsl:element>
  <!-- vitals -->
  <xsl:element name="FormData" namespace="http://www.cdisc.org/ns/odm/v1.3">
    <xsl:attribute name="FormOID">VitalsForm</xsl:attribute>
  </xsl:element>
  <!-- physical exam -->
  <xsl:element name="FormData" namespace="http://www.cdisc.org/ns/odm/v1.3">
    <xsl:attribute name="FormOID">PhysicalExamForm</xsl:attribute>
  </xsl:element>
  <!-- AE -->
  <xsl:element name="FormData" namespace="http://www.cdisc.org/ns/odm/v1.3">
    <xsl:attribute name="FormOID">AdverseEventsForm</xsl:attribute>
  </xsl:element>
  <!-- lab results -->
  <xsl:element name="FormData" namespace="http://www.cdisc.org/ns/odm/v1.3">
    <xsl:attribute name="FormOID">LabResultsForm</xsl:attribute>
  </xsl:element>
  <!-- ECG results -->
  <xsl:element name="FormData" namespace="http://www.cdisc.org/ns/odm/v1.3">
    <xsl:attribute name="FormOID">ECGResultsForm</xsl:attribute>
  </xsl:element>
</xsl:template>

<!-- ODM Templates -->
<!-- demography -->
<xsl:template name="demography">
  <!-- get the patient node, from which we can get the sex and date of birth -->
  <xsl:variable name="patientNode" select="cda:recordTarget/cda:patientRole/cda:patient"/>
</xsl:template>
<xsl:comment>check on whether or not we can get Ethnicity and Race</xsl:comment>

<xsl:element name="ItemGroupData"
    namespace="http://www.cdisc.org/ns/odm/v1.3">
    <xsl:attribute name="ItemGroupOID">DM</xsl:attribute>
    <!-- SEX -->
    <xsl:element name="ItemData"
        namespace="http://www.cdisc.org/ns/odm/v1.3">
        <xsl:attribute
            name="ItemOID">SEX</xsl:attribute>
        <xsl:attribute
            name="Value"><xsl:value-of
            select="$patientNode/cda:administrativeGenderCode/@code"/></xsl:attribute>
    </xsl:element>
    <!-- BRTHDTC -->
    <xsl:element name="ItemData"
        namespace="http://www.cdisc.org/ns/odm/v1.3">
        <xsl:attribute
            name="ItemOID">BRTHDTC</xsl:attribute>
        <!-- transform stupid non-ISO8601-XML date to ISO8601 date -->
        <xsl:variable name="ISODATE">
            <xsl:call-template name="HL7DateToISO8601">
                <xsl:with-param name="HL7Date" select="$patientNode/cda:birthTime/@value"/>
            </xsl:call-template>
        </xsl:variable>
        <xsl:attribute
            name="Value">"<xsl:value-of select="$ISODATE"/>
    </xsl:element>
</xsl:element>

<!-- Medical History
looking for entries in any of the following CDA sections:
Conditions
Past Medical History
Procedures-->
<xsl:template name="medicalHistory">
    <xsl:variable name="ccdConditions"
        select="cda:component/cda:structuredBody/cda:component/cda:section[cda:code/@code='11450-4']"/>
    <xsl:variable name="ccdPMH"
        select="cda:component/cda:structuredBody/cda:component/cda:section[cda:code/@code='11348-0']"/>
</xsl:template>
<xsl:variable name="ccdProcedures" select="cda:component/cda:structuredBody/cda:component/cda:section[cda:code/@code='47519-4']"/>
<xsl:variable name="conditionsCount" select="count($ccdConditions/cda:entry)"/>
<xsl:variable name="pmhCount" select="count($ccdPMH/cda:entry)"/>
<xsl:variable name="proceduresCount" select="count($ccdProcedures/cda:entry)"/>

<!-- if we have any of the above then we output this section, i.e., FormData element -->
<xsl:if test="($conditionsCount+$pmhCount+$proceduresCount)>0">
  <xsl:element name="FormData" namespace="http://www.cdisc.org/ns/odm/v1.3">
    <xsl:attribute name="FormOID">MedicalHistory</xsl:attribute>
    <!-- just loop thru the entry elements in each of the sections -->
    <!-- NOTE: we're making up the ItemGroupOID's....these SHOULD be standardized; it also might be that all med history items SHOULD be in one ItemGroup -->
    <xsl:for-each select="$ccdConditions/cda:entry">
      <xsl:element name="ItemGroupData" namespace="http://www.cdisc.org/ns/odm/v1.3">
        <xsl:attribute name="ItemGroupOID">CONDITION</xsl:attribute>
        <xsl:call-template name="problemItemData"><xsl:with-param name="theNode" select="."/></xsl:call-template>
      </xsl:element>
    </xsl:for-each>
    <xsl:for-each select="$ccdPMH/cda:entry">
      <xsl:element name="ItemGroupData" namespace="http://www.cdisc.org/ns/odm/v1.3">
        <xsl:attribute name="ItemGroupOID">PASTCONDITION</xsl:attribute>
        <xsl:call-template name="problemItemData"><xsl:with-param name="theNode" select="."/></xsl:call-template>
      </xsl:element>
    </xsl:for-each>
    <xsl:for-each select="$ccdProcedures/cda:entry">
      <xsl:element name="ItemGroupData" namespace="http://www.cdisc.org/ns/odm/v1.3">
        <xsl:attribute name="ItemGroupOID">PROCEDURE</xsl:attribute>
        <xsl:call-template name="procedureItemData"><xsl:with-param name="theNode" select="."/></xsl:call-template>
      </xsl:element>
    </xsl:for-each>
  </xsl:element>
</xsl:if>
<!-- CON MEDS -->
<xsl:template name="conMeds">
  <xsl:variable name="ccdMedication"
    select="cda:component/cda:structuredBody/cda:component/cda:section[cda:code/@code='10160-0']"/>
  <xsl:variable name="conMedCount"
    select="count($ccdMedication/cda:entry)"/>
  <xsl:if test="$conMedCount>0">
    <!--FormData FormDataOID='ConMedForm'-->
    <xsl:element name="(formData"
      namespace="http://www.cdisc.org/ns/odm/v1.3">
      <xsl:attribute name="FormOID">ConMedForm</xsl:attribute>
      <xsl:for-each select="$ccdMedication/cda:entry">
        <!-- we MAY be pointed to the text of the med, or we MAY just have the text-->
        <xsl:variable name="originalTextRef"
          select="cda:substanceAdministration/cda:consumable/cda:manufacturedProduct/cda:manufacturedMaterial/cda:code/cda:originalText/cda:reference/@value"/>
        <xsl:variable name="originalText"
          select="cda:substanceAdministration/cda:consumable/cda:manufacturedProduct/cda:manufacturedMaterial/cda:code/cda:originalText"/>
        <xsl:if test="$originalTextRef">
          <!--CMTRT -->
          <xsl:element name="ItemData"
            namespace="http://www.cdisc.org/ns/odm/v1.3">
            <xsl:attribute name="ItemOID">CMTRT</xsl:attribute>
            <xsl:attribute name="Value">
              <xsl:choose>
                <xsl:when test="$originalTextRef">
                  <xsl:value-of select="/[@ID=substring-after($originalTextRef,'#')]"></xsl:when>
                <xsl:otherwise>
                  <xsl:value-of select="/[@ID='originalText']"/>
                </xsl:otherwise>
              </xsl:choose>
            </xsl:attribute>
          </xsl:element>
        </xsl:if>
        <!-- CMDOSFREQ -->
        <xsl:comment>need table to translate HL7 frequency, e.g., 6h to BID</xsl:comment>
        <xsl:if test="$routeCode">
          <xsl:variable name="routeCode"
            select="cda:substanceAdministration/cda:routeCode/@displayName"/>
          <xsl:element name="ItemData"
            namespace="http://www.cdisc.org/ns/odm/v1.3">
            <xsl:attribute name="ItemOID">CMDOSFREQ</xsl:attribute>
            <xsl:attribute name="Value">
              <xsl:choose>
                <xsl:when test="$routeCode">
                  <!-- need table to translate HL7 frequency, e.g., 6h to BID -->
                  <xsl:element name="ItemData"
                    namespace="http://www.cdisc.org/ns/odm/v1.3">
                    <xsl:attribute name="ItemOID">CMDOSFREQ</xsl:attribute>
                    <xsl:attribute name="Value">
                      <xsl:choose>
                        <xsl:when test="$routeCode">
                          <xsl:value-of select="/[@ID='originalText']"/>
                        </xsl:when>
                      </xsl:choose>
                    </xsl:attribute>
                  </xsl:element>
                </xsl:when>
              </xsl:choose>
            </xsl:attribute>
          </xsl:element>
        </xsl:if>
      </xsl:for-each>
    </xsl:element>
  </xsl:if>
</xsl:template>
<!-- ItemData ItemDataOID='CMROUTE' -->
<xs1:element name="ItemData"
namespace="http://www.cdisc.org/ns/odm/v1.3">
  <xs1:attribute name="ItemOID">CMROUTE</xs1:attribute>
  <xs1:attribute name="Value"><xs1:value-of select="$routeCode"/></xs1:attribute>
</xs1:element>

<!-- CMSTDTC -->
<xs1:variable name="medStartDate">
  <xs1:if test="$medStartDate">
    <!-- transform stupid non-ISO8601-XML date to ISO8601 date -->
    <xs1:variable name="ISODATE">
      <xs1:call-template name="HL7DateToISO8601">
        <xs1:with-param name="HL7Date" select="$medStartDate"/>
      </xs1:call-template>
    </xs1:variable>
    <xs1:attribute name="ItemOID">CMSTDTC</xs1:attribute>
    <xs1:attribute name="Value"><xs1:value-of select="$medStartDate"/></xs1:attribute>
  </xs1:if>
</xs1:variable>

<!-- CMENDTC -->
<xs1:variable name="medEndDate">
  <xs1:if test="$medEndDate">
    <!-- transform stupid non-ISO8601-XML date to ISO8601 date -->
    <xs1:variable name="ISODATE">
      <xs1:call-template name="HL7DateToISO8601">
        <xs1:with-param name="HL7Date" select="$medEndDate"/>
      </xs1:call-template>
    </xs1:variable>
    <xs1:attribute name="ItemOID">CMENDDTC</xs1:attribute>
    <xs1:attribute name="Value"><xs1:value-of select="$medEndDate"/></xs1:attribute>
  </xs1:if>
</xs1:variable>
<!-- SUBSTANCE ABUSE -->
<xsl:template name="substanceAbuse">
  <!-- we could look into the social history for any of a specific list
  of substance abuse entries...if any are present then we emit the section -->
  <!-- however, there are probably too many codes to consider....just
  quickly looking we see several SNOMED codes for smoking, cigarette smoking,
  .... -->
</xsl:template>

<!-- Vital Signs -->
<xsl:template name="vitalSigns">
  <!-- if we have a vitals section with at least one organizer then we're going
  for all organizers -->
  <xsl:variable name="vitalsSection"
    select="cda:component/cda:structuredBody/cda:component/cda:section["cda:code/@code='8716-3']"/>
  <xsl:if test="$vitalsSection/cda:entry/cda:organizer">
    <!--FormData FormDataOID='VSForm'-->
    <xsl:element name="FormData"
      namespace="http://www.cdisc.org/ns/odm/v1.3">
      <xsl:attribute name="FormOID">VSFORM</xsl:attribute>
      <!-- for each organizer -->
      <xsl:for-each select="$vitalsSection/cda:entry/cda:organizer">
        <!-- at the organizer level we have the date (and MAY be
        the time) -->
        <xsl:variable name="vitalsDateTime"
          select="cda:effectiveTime/@value"/>
        <xsl:element name="ItemGroupData"
          namespace="http://www.cdisc.org/ns/odm/v1.3">
          <xsl:attribute name="ItemGroupOID">VS</xsl:attribute>
          <!-- VSDTC -->
          <xsl:element name="ItemData"
            namespace="http://www.cdisc.org/ns/odm/v1.3">
            <xsl:attribute name="ItemDataOID">VSDTC</xsl:attribute>
          </xsl:element>
        </xsl:element>
      </xsl:for-each>
    </xsl:element>
  </xsl:if>
</xsl:template>
<xsl:variable name="ISODATE">
<xsl:call-template
name="HL7DateToISO8601">
<xsl:with-param name="HL7Date"
select="$vitalsDateTime"/>
</xsl:call-template>
</xsl:variable>

<xsl:attribute
name="ItemOID">VSTEST</xsl:attribute>
</xsl:element>

<xsl:element
name="ItemData"
namespace="http://www.cdisc.org/ns/odm/v1.3">
<xsl:attribute
name="ItemOID">VSORRES</xsl:attribute>
<xsl:attribute
name="Value"><xsl:value-of
select="$vitalsResultNode/@value"/></xsl:attribute>
</xsl:element>

<xsl:element
name="ItemData"
namespace="http://www.cdisc.org/ns/odm/v1.3">
<xsl:attribute
name="ItemOID">VSORRESU</xsl:attribute>
<xsl:attribute
name="Value"><xsl:value-of
select="$vitalsResultNode/@unit"/></xsl:attribute>
</xsl:element>
<xsl:element name="ItemData" namespace="http://www.cdisc.org/ns/odm/v1.3">
  <xsl:attribute name="ItemOID">VSORRES</xsl:attribute>
  <xsl:attribute name="Value"><xsl:value-of select="$vitalsResultNode"/></xsl:attribute>
</xsl:element><!--/ItemData-->
</xsl:otherwise>
</xsl:choose>
</xsl:for-each>
</xsl:element><!--/ItemGroupData-->
</xsl:for-each>
</xsl:element><!--/FormData-->
</xsl:if>
</xsl:template>
<!-- AE -->
<xsl:template name="adverseEvents">
  <xsl:variable name="aeSection" select="cda:component/cda:structuredBody/cda:component/cda:section[cda:code/@code='48765-2']"/>
  <xsl:if test="$aeSection/cda:entry/cda:act">
    <!--FormData FormDataOID='AEForm'-->
    <xsl:element name="FormData" namespace="http://www.cdisc.org/ns/odm/v1.3">
      <xsl:attribute name="FormOID">AEForm</xsl:attribute>
      <xsl:for-each select="$aeSection/cda:entry">
        <!--ItemDataGroup ItemDataGroupOID='AE'-->
        <xsl:element name="ItemGroupData" namespace="http://www.cdisc.org/ns/odm/v1.3">
          <xsl:attribute name="ItemGroupOID">AE</xsl:attribute>
          <!-- AETERM -->
          <xsl:variable name="originalTextRef" select="cda:act/cda:entryRelationship/cda:observation/cda:participant/cda:participantRole/cda:playingEntity/cda:code/cda:originalText/cda:reference/@value"/>
          <xsl:variable name="codedDisplayName" select="cda:act/cda:entryRelationship/cda:observation/cda:participant/cda:participantRole/cda:playingEntity/cda:code/@displayName"/>
          <xsl:element name="ItemData" namespace="http://www.cdisc.org/ns/odm/v1.3">
            <xsl:attribute name="ItemOID">AETERM</xsl:attribute>
            <xsl:attribute name="Value">
              <!-- AE -->
            </xsl:attribute>
          </xsl:element><!--/ItemData-->
        </xsl:for-each>
      </xsl:element><!--/ItemGroupData-->
    </xsl:for-each>
  </xsl:element><!--/FormData-->
</xsl:template>
<xsl:variable name="problemOnset" select="$theNode/cda:act/cda:entryRelationship/cda:observation/cda:effectiveTime/cda:low/@value然/">
<xsl:variable name="problemResolved" select="$theNode/cda:act/cda:entryRelationship/cda:observation/cda:effectiveTime/cda:high/@value然/">
<!-- MHTERM -->
<!--ItemData ItemOID='MHTERM'-->
<xsl:element name="ItemData" namespace="http://www.cdisc.org/ns/odm/v1.3">
<xsl:attribute name="ItemOID">MHTERM</xsl:attribute>
<xsl:attribute name="Value">
<xsl:choose>
<xsl:when test="string-length($originalTextRef)>0"><xsl:value-of select="//*[@ID=substring-after($originalTextRef,'#')]"/></xsl:when>
<xsl:when test="string-length($codedValue)>0"><xsl:value-of select="$codedValue"/></xsl:when>
<xsl:otherwise>???</xsl:otherwise>
</xsl:choose>
</xsl:attribute>
</xsl:element><!--/ItemData-->
<!-- MHONG -->
<!--ItemData ItemOID='MHONG'-->
<xsl:element name="ItemData" namespace="http://www.cdisc.org/ns/odm/v1.3">
<xsl:attribute name="ItemOID">MHONG</xsl:attribute>
<xsl:attribute name="Value">
<xsl:choose>
<xsl:when test="$problemStatusNode/cda:value/@displayName='Active'">ONGOING</xsl:when>
<xsl:when test="//*[ID=substring-after($problemStatusRef,'#')]='Active'">ONGOING</xsl:when>
<xsl:otherwise>RESOLVED</xsl:otherwise>
</xsl:choose>
</xsl:attribute>
</xsl:element><!--/ItemData-->
<xsl:comment>research adding type and category (MHCAT, MHSCAT)</xsl:comment>
<!-- NOTE: might need a more generic template to handle the multiple ways that time can be reported in ccd -->
<!-- MSSTDTC -->
<xsl:if test="$problemOnset">
<!--ItemData ItemDataOID='MHSTDTC'-->
<xsl:element name="ItemData" namespace="http://www.cdisc.org/ns/odm/v1.3">
<!-- transform stupid non-ISO8601-XML date to ISO8601 date -->
<xsl:variable name="ISODATE">
<xsl:call-template name="HL7DateToISO8601">

<xsl:with-param name="HL7Date" select="$problemOnset"/>
</xsl:call-template>
<xsl:variable name="ItemOID" select="MHSTDTC"></xsl:variable>
</xsl:attribute><!-- ItemData -->
</xsl:if>
<!-- MHENDDTC -->
<xsl:if test="$problemResolved">
<!--ItemData ItemDataOID='MHENDDTC'-->
<xsl:element name="ItemData"
namespace="http://www.cdisc.org/ns/odm/v1.3">
<xsl:attribute name="ItemOID">MHENDDTC</xsl:attribute>
<xsl:attribute name="Value"><xsl:value-of
select="$problemResolved"/></xsl:attribute>
</xsl:element><!--/ItemData-->
</xsl:if>
</xsl:if>
</xsl:template>
<xsl:template name="procedureItemData">
<xsl:param name="theNode"/>
<xsl:variable name="originalTextRef" select="$theNode/cda:procedure/cda:code/cda:originalText/cda:reference/@value"/>
<xsl:variable name="codedValue" select="$theNode/cda:procedure/cda:code/@displayName"/>
<!-- MHTERM -->
<xsl:element name="ItemData"
namespace="http://www.cdisc.org/ns/odm/v1.3">
<xsl:attribute name="ItemOID">MHTERM</xsl:attribute>
<xsl:attribute name="Value">
<xsl:choose>
<xsl:when test="string-length($originalTextRef)>0"">"<xsl:value-of select="/*[@ID=substring-after($originalTextRef,'#')]/""/></xsl:when>
<xsl:when test="string-length($codedValue)>0"">"<xsl:value-of select="$codedValue"/></xsl:when>
<xsl:otherwise>???</xsl:otherwise>
</xsl:choose>
</xsl:attribute>
</xsl:element><!--/ItemData-->
<!-- NOTE: is this true = procedures are RESOLVED -->
<!-- MHONG -->
<xsl:element name="ItemData" ItemDataOID='MHONG'
namespace="http://www.cdisc.org/ns/odm/v1.3">
<xsl:attribute name="ItemOID">MHONG</xsl:attribute>
<xsl:attribute name="Value">RESOLVED</xsl:attribute>
</xsl:element><!--/ItemData-->
<xsl:attribute name="Value">RESOLVED</xsl:attribute>
</xsl:element>

??? what to do about an effectiveTime of center
</xsl:comment>

<xsl:template name="HL7DateToISO8601">
  <xsl:param name="HL7Date"></xsl:param>
  <xsl:choose>
    <xsl:when test="string-length($HL7Date) = 4">
      <xsl:value-of select="$HL7Date"/>
    </xsl:when>
    <xsl:when test="string-length($HL7Date) = 6">
      <xsl:variable name="YEAR" select="substring($HL7Date,1,4)"/>
      <xsl:variable name="MONTH" select="substring($HL7Date,5,2)"/>
      <xsl:value-of select="concat($YEAR,'-',$MONTH)"/>
    </xsl:when>
    <xsl:when test="string-length($HL7Date) = 8">
      <xsl:variable name="YEAR" select="substring($HL7Date,1,4)"/>
      <xsl:variable name="MONTH" select="substring($HL7Date,5,2)"/>
      <xsl:variable name="DAY" select="substring($HL7Date,7,2)"/>
      <xsl:value-of select="concat($YEAR,'-',$MONTH,'-',$DAY)"/>
    </xsl:when>
    <xsl:when test="string-length($HL7Date) = 10">
      <xsl:variable name="YEAR" select="substring($HL7Date,1,4)"/>
      <xsl:variable name="MONTH" select="substring($HL7Date,5,2)"/>
      <xsl:variable name="DAY" select="substring($HL7Date,7,2)"/>
      <xsl:variable name="HOUR" select="substring($HL7Date,9,2)"/>
      <xsl:value-of select="concat($YEAR,'-',$MONTH,'-',$DAY,'T',$HOUR)"/>
    </xsl:when>
    <xsl:when test="string-length($HL7Date) = 12">
      <xsl:variable name="YEAR" select="substring($HL7Date,1,4)"/>
      <xsl:variable name="MONTH" select="substring($HL7Date,5,2)"/>
      <xsl:variable name="DAY" select="substring($HL7Date,7,2)"/>
      <xsl:variable name="HOUR" select="substring($HL7Date,9,2)"/>
      <xsl:variable name="MINUTE" select="substring($HL7Date,11,2)"/>
      <xsl:value-of select="concat($YEAR,'-',$MONTH,'-',$DAY,'T',$HOUR,'Z')"/>
    </xsl:when>
  </xsl:choose>
B.2 Sample Standard CRF output from the Sample XSLT

<?xml version="1.0" encoding="UTF-8"?>
<ODM xmlns="http://www.cdisc.org/ns/odm/v1.3" AsOfDateTime="2008-09-23T22:28:40.739+02:00" ODMVersion="1.3" FileType="Transactional" FileOID="TEST" CreationDateTime="2008-09-23T22:28:40.739+02:00">
  <ClinicalData StudyOID="CLL.001" MetaDataVersionOID="001">
    <SubjectData SubjectKey="1038">
      <SiteRef LocationOID="100"/>
      <StudyEventData StudyEventOID="CLL_CRF">
        <FormData FormOID="DemographicsForm">
          <!--check on whether or not we can get Ethnicity and Race-->
          <ItemGroupData ItemGroupOID="DM">
            <ItemData ItemOID="SEX" Value="M"/>
            <ItemData ItemOID="BRTHDTC" Value="1932-09-24"/>
          </ItemGroupData>
        </FormData>
        <FormData FormOID="MedicalHistory">
          <ItemGroupData ItemGroupOID="CONDITION">
            <ItemData ItemOID="MHTERM" Value="Asthma"/>
            <ItemData ItemOID="MHONG" Value="ONGOING"/>
            <!--research adding type and category (MHCAT, MHSCAT)-->
            <ItemData ItemOID="MHSTDTC" Value="1950"/>
          </ItemGroupData>
          <ItemGroupData ItemGroupOID="CONDITION">
            <ItemData ItemOID="MHTERM" Value="Pneumonia"/>
            <ItemData ItemOID="MHONG" Value="RESOLVED"/>
          </ItemGroupData>
        </FormData>
      </StudyEventData>
    </SubjectData>
  </ClinicalData>
</ODM>
<!--research adding type and category (MHCAT, MHSCAT)-->  
<ItemData ItemOID="MHSTDTC" Value="1997-01"/>
</ItemGroupData>
<ItemGroupData ItemGroupOID="CONDITION">
<ItemData ItemOID="MHTERM" Value="Pneumonia"/>
<ItemData ItemOID="MHONG" Value="RESOLVED"/>
</ItemGroupData>
<!--research adding type and category (MHCAT, MHSCAT)-->  
<ItemData ItemOID="MHSTDTC" Value="1999-03"/>
</ItemGroupData>
<ItemGroupData ItemGroupOID="CONDITION">
<ItemData ItemOID="MHTERM" Value="Myocardial infarction"/>
<ItemData ItemOID="MHONG" Value="RESOLVED"/>
</ItemGroupData>
<!--research adding type and category (MHCAT, MHSCAT)-->  
<ItemData ItemOID="MHSTDTC" Value="1997-01"/>
</ItemGroupData>
<ItemGroupData ItemGroupOID="PROCEDURE">
<ItemData ItemOID="MHTERM" Value="Total hip replacement, left"/>
<ItemData ItemOID="MHONG" Value="RESOLVED"/>
</ItemGroupData>
<!--research adding type and category (MHCAT, MHSCAT)-->  
<ItemData ItemOID="CMTRT" Value="Albuterol inhalant"/>
<!--need table to translate HL7 frequency, e.g., 6h to BID-->  
<ItemData ItemOID="CMROUTE" Value="Inhalation, oral"/>
</ItemGroupData>
<ItemData ItemOID="CMTRT" Value="Clopidogrel"/>
<!--need table to translate HL7 frequency, e.g., 6h to BID-->  
</ItemGroupData>
<ItemData ItemOID="CMTRT" Value="Metoprolol"/>
<!--need table to translate HL7 frequency, e.g., 6h to BID-->  
</ItemGroupData>
<ItemData ItemOID="CMTRT" Value="Prednisone"/>
<!--need table to translate HL7 frequency, e.g., 6h to BID-->  
<ItemData ItemOID="CMSTDTC" Value="2000-03-28"/>
</ItemGroupData>
<ItemData ItemOID="CMTRT" Value="Cephalexin"/>
<!--need table to translate HL7 frequency, e.g., 6h to BID-->  
<ItemData ItemOID="CMSTDTC" Value="2000-03-28"/>
<ItemData ItemOID="CMENDDTC" Value="2000-04-04"/>
</ItemGroupData>
<ItemData ItemOID="VSTEST" Value="Body height"/>
<ItemData ItemOID="VSORRES" Value="177"/>
Appendix C – Triggers

This appendix is informative.

Management of triggers for generating drug safety content

Triggers are generally managed within the electronic medical record (EMR) workflow to request from a clinician a determination as to whether or not an adverse event has occurred. Some triggers that have been used include:

1. In the EMR used in the ASTER project, a question each time a medication is discontinued for the ordering physician to enter if the discontinuation is due to an adverse event

2. Automated triggers based on specific medication orders or laboratory results or clinical events as listed in Minutes_Drugs_Safety_Content_Profile_June_5,_2008

3. Regardless, triggers require clinician determination before a drug safety content report can be initiated and, therefore, triggers are the responsibility / expectation of the originating EMR.

Sources for triggers:

1. Institute for Healthcare Improvement [(IHI) http://www.ihi.org/ihi/workspace/tools/trigger/ ADE Trigger Tools]


### Table C-1: Clinical Triggers

<table>
<thead>
<tr>
<th>Trigger #</th>
<th>Trigger</th>
<th>Concern</th>
<th>EMR Trigger Type (added)</th>
</tr>
</thead>
<tbody>
<tr>
<td>T1</td>
<td>Diphenhydramine</td>
<td>Hypersensitivity reaction or drug effect</td>
<td>Order</td>
</tr>
<tr>
<td>T2</td>
<td>Vitamin K</td>
<td>Over-anticoagulation with warfarin</td>
<td>Order</td>
</tr>
<tr>
<td>T3</td>
<td>Flumazenil</td>
<td>Oversedation with benzodiazepine</td>
<td>Order</td>
</tr>
<tr>
<td>T4</td>
<td>Droperidol</td>
<td>Nausea/emesis related to drug use</td>
<td>Order</td>
</tr>
<tr>
<td>T5</td>
<td>Naloxone</td>
<td>Oversedation with narcotic</td>
<td>Order</td>
</tr>
<tr>
<td>T6</td>
<td>Antidiarrheals</td>
<td>Adverse drug event</td>
<td>Order</td>
</tr>
<tr>
<td>T7</td>
<td>Sodium polystyrene</td>
<td>Hyperkalemia related to renal impairment or drug effect</td>
<td>Order</td>
</tr>
<tr>
<td>T8</td>
<td>PTT &gt;100 seconds</td>
<td>Over-anticoagulation with heparin</td>
<td>Result occurrence</td>
</tr>
<tr>
<td>T9</td>
<td>INR &gt;6</td>
<td>Over-anticoagulation with warfarin</td>
<td>Result occurrence</td>
</tr>
<tr>
<td>T10</td>
<td>WBC &lt;3000 × 10⁶/μl</td>
<td>Neutropenia related to drug or disease</td>
<td>Result occurrence</td>
</tr>
<tr>
<td>T11</td>
<td>Serum glucose &lt;50 mg/dl</td>
<td>Hypoglycemia related to insulin use</td>
<td>Result occurrence</td>
</tr>
<tr>
<td>T12</td>
<td>Rising serum creatinine</td>
<td>Renal insufficiency related to drug use</td>
<td>Result occurrence (calculated delta)</td>
</tr>
<tr>
<td>T13</td>
<td>Clostridium difficile positive stool</td>
<td>Exposure to antibiotics</td>
<td>Result occurrence (perhaps order for stool C difficile)</td>
</tr>
<tr>
<td>T14</td>
<td>Digoxin level &gt;2 ng/ml</td>
<td>Toxic digoxin level</td>
<td>Result occurrence</td>
</tr>
<tr>
<td>T15</td>
<td>Lidocaine level &gt;5 ng/ml</td>
<td>Toxic lidocaine level</td>
<td>Result occurrence</td>
</tr>
<tr>
<td>T16</td>
<td>Gentamicin or tobramycin levels peak &gt;10 μg/ml, trough &gt;2 μg/ml</td>
<td>Toxic levels of antibiotics</td>
<td>Result occurrence</td>
</tr>
<tr>
<td>T17</td>
<td>Amikacin levels peak &gt;30 μg/ml, trough &gt;10 μg/ml</td>
<td>Toxic levels of antibiotics</td>
<td>Result occurrence</td>
</tr>
<tr>
<td>T18</td>
<td>Vancomycin level &gt;26 μg/ml</td>
<td>Toxic levels of antibiotics</td>
<td>Result occurrence</td>
</tr>
<tr>
<td>T19</td>
<td>Theophylline level &gt;20 μg/ml</td>
<td>Toxic levels of drug</td>
<td>Result occurrence</td>
</tr>
<tr>
<td>T20</td>
<td>Oversedation, lethargy, falls</td>
<td>Related to overuse of medication</td>
<td>Occurrence of finding/observation</td>
</tr>
<tr>
<td>T21</td>
<td>Rash</td>
<td>Drug related/adverse drug event</td>
<td>Occurrence of finding/observation</td>
</tr>
</tbody>
</table>

### Rozich, Haraden, Resar - Clinical Triggers

<table>
<thead>
<tr>
<th>Trigger #</th>
<th>Trigger</th>
<th>Concern</th>
<th>EMR Trigger Type (added)</th>
</tr>
</thead>
<tbody>
<tr>
<td>T22</td>
<td>Abrupt medication stop</td>
<td>Adverse drug event</td>
<td>Order to discontinue</td>
</tr>
<tr>
<td>T23</td>
<td>Transfer to higher level of care</td>
<td>Adverse event</td>
<td>Order</td>
</tr>
<tr>
<td>T24</td>
<td>Customized to individual institution</td>
<td>Adverse event</td>
<td>Local determinant</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Acronyms:</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>PTT=prothrombin time;</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>INR=international normalized ratio;</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>WBC=white blood cells</td>
</tr>
</tbody>
</table>

Note: Retrieved from "http://wiki.ihe.net/index.php?title=Minutes_Drugs_Safety_Content_Profile_June_5%2C_2008"
Glossary

The IHE Glossary, an appendix to the *IHE Technical Frameworks General Introduction* can be found [here](#).