Integrating the Healthcare Enterprise

IHE Quality, Research and Public Health (QRPH)

Technical Framework

Volume 3

QRPH TF-3

Content Modules

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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®[1] V3 CDA®[2] Content Modules in detail.
- Section 7 defines QRPH DICOM®[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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[1] HL7 is the registered trademark of Health Level Seven International.

[2] CDA is the registered trademark of Health Level Seven International.

[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.

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1.8 History of Document Changes

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

Date	Document Revision	Change Summary
2011-09-02	0.1	Initial Trial Implementation Release (no Final Text profiles)
2018-10-19	1.0	Initial Final Text Release (includes CRD and DSC Final Text profiles). Volume 2 (of Rev. 0.1) split into Volume 2 and 3.
2019-07-05	2.0	Updated revision and date only to coincide with update of other TF Volumes.

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

4 Reserved

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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.

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

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

codeSystem	codeSystemName	Description
2.16.840.1.113883.6.1	LOINC	Logical Observation Identifier Names and Codes
2.16.840.1.113883.6.96	SNOMED-CT	SNOMED Controlled Terminology
2.16.840.1.113883.6.103	ICD-9CM (diagnosis codes)	International Classification of Diseases, Clinical Modifiers, Version 9
2.16.840.1.113883.6.104	ICD-9CM (procedure codes)	International Classification of Diseases, Clinical Modifiers, Version 9
2.16.840.1.113883.6.26	MEDCIN	A classification system from MEDICOMP Systems.
2.16.840.1.113883.6.88	RxNorm	RxNorm
2.16.840.1.113883.6.63	FDDC	First DataBank Drug Codes
2.16.840.1.113883.6.12	C4	Current Procedure Terminology 4 (CPT-4) codes.
2.16.840.1.113883.6.257	Minimum Data Set for Long Term Care	The root OID for Minimum Data Set Answer Lists

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.

Please see the IHEActCode Vocabulary at http://wiki.ihe.net/index.php/IHEActCode_Vocabulary.

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.

Please see the IHERoleCode Vocabulary at http://wiki.ihe.net/index.php/IHERoleCode_Vocabulary

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

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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 6.3.1-1: Constraints on the sub elements of the archiveContent data element

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

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

Code	Value
R	Required Section
R2	Required Section if data present
O	Optional section

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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
260 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

Template ID	1.3.6.1.4.1.19376.1.7.3.1.1.10			
Parent Template	CCD document: 2.16.840.1.113883.10.20.1			
General Description	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.			
Document Code	LOINC Code: 34133-9 "Summary of Episode Note"			
Opt	**Data Element or Section Name**	**Template ID**	**Specification Document**	**Constraint**
Header Elements				
R	Date of Birth	patientRole/patient/birthTime	1.3.6.1.4.1.19376.1.5.3.1.3.6	
R	Gender	patientRole/patient/administrativeGenderCode	1.3.6.1.4.1.19376.1.5.3.1.3.6	
O	Ethnicity	patientRole/patient/ethnicGroupCode	1.3.6.1.4.1.19376.1.5.3.1.3.6	
R2	Race	patientRole/patient/raceCode	1.3.6.1.4.1.19376.1.5.3.1.3.6	
Sections				
R	Active Problems	1.3.6.1.4.1.19376.1.5.3.1.3.6	PCC TF-2: 6.3.3.2.3	
R2	History of Past Illness	1.3.6.1.4.1.19376.1.5.3.1.3.8	PCC TF-2: 6.3.3.2.5	
R2	Procedures	2.16.840.1.113883.10.20.1.12	CCD specification: 3.14	

R2	Social History	1.3.6.1.4.1.19376.1.5.3.1.3.16	PCC TF-2: 6.3.3.2.14	
R	Medications	1.3.6.1.4.1.19376.1.5.3.1.3.19	PCC TF-2: 6.3.3.3.1	
R2	Coded Vital Signs	1.3.6.1.4.1.19376.1.5.3.1.1.5.3.2	PCC TF-2: 6.3.3.4.5	
R2	Detailed Physical Examination	1.3.6.1.4.1.19376.1.5.3.1.1.9.15	PCC TF-2: 6.3.3.4.2	
R	Allergies and Other Adverse Reactions	1.3.6.1.4.1.19376.1.5.3.1.3.13	PCC TF-2: 6.3.3.2.11	
R2	Coded Results	1.3.6.1.4.1.19376.1.5.3.1.3.28	PCC TF-2: 6.3.3.5.2	

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 6.3.1.2-1: "Context" data element constraints

Optionality	Data element	Data Location
R	context	workflowData/context
R	StudyID	workflowData/context/ StudyID
R	SiteID	workflowData/context/ SiteID
R	SubjID	workflowData/context/ SubjID
O	USubjID	workflowData/context/ USubjID

Optionality	Data element	Data Location
O	InvID	workflowData/context/ InvID
O	SpID	workflowData/context/ SpID
O	Visit	workflowData/context/ Visit
O	VisitNum	workflowData/context/ VisitNum
R	VisDatTim	workflowData/context/ VisDatTim
R2	PrePopArchiveID	workflowData/context/ PrePopArchiveID

Table 6.3.1.2-2: Data elements CDASH reference

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

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 >
```



```
        <SubjID> a String identifying the Subject Identifier </ SubjID >
          <VisDatTim>
            <effectiveTime xsi:type='TS'>
              <low value=' '/>
              <high value=' '/>
            </effectiveTime>
            </ VisDatTim >
            < PrePopArchiveID> a String identifying the Prepopulation Archive
            XDSDocumentEntry.uniqueId </ PrePopArchiveID>
  </context>
</workflowData>
```

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 prepopData Document Content Module

6.3.1.3.1 Standards

CDAR2: Clinical Document Architecture, Release 2, 2005 HL7

CRS: Implementation Guide for CDA Release 2 – Level 1 and 2 – Care Record Summary (US realm), 2006, 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

365 **Table 6.3.1.3.3-1: Form Data Element Mapping Specification**

Data Element	Definition	CCD Description	Template ID	CCD XPATH	Mapping Constraints (CodeSystem and /or value sets)	CCD Code	Optionality
Facility/ Importer Name	The name of the facility that the health care provider diagnosed the subject of the Case Report.	Facility		ClinicalDocument.author.assignedAuthor.representedOrganization.Name			R
Facility Identifier	Unique facility identifier.	Facility		ClinicalDocument.author.assignedAuthor.representedOrganization.Id			O
Address	The address (Street, City, State, Zip Code) of the person or facility that diagnosed the subject of the Case Report	Facility		ClinicalDocument.author.assignedAuthor.representedOrganization.Addr			R
Telephone	The phone number of the person or facility that diagnosed the subject of the Case Report.	Facility		ClinicalDocument.author.assignedAuthor.representedOrganization.Name telecom			O

Data Element	Definition	CCD Description	Template ID	CCD XPATH	Mapping Constraints (CodeSystem and /or value sets)	CCD Code	Optionality
Contact Person	The name of the person to be contacted for further information We assume this is the organizations contact	Facility		ClinicalDocument.author.assignedAuthor.representedOrganization.associatedEntity[classCode='CON'].assignedPerson.name			O
Contact Phone Number	The telephone number for the contact person We assume this is the organizations contact	Facility		ClinicalDocument.author.assignedAuthor.representedOrganization.associatedEntity[classCode='CON'].assignedPerson.telecom			O
Responsible physician/Health care provider name	The name of the person that diagnosed the subject	Author		ClinicalDocument.author.assignedAuthor.assignedPerson.name			O
User Facility / Importer Report Number	The number of the report assigned by the reporting facility	Author		ClinicalDocument.author.assignedAuthor.assignedPerson.Id			O
Type of Report	The type of report (e.g., Drug Event Report, Healthcare Associated Infection Report, etc.)	TypeId					O
Report Date	The date that the Case Report is being sent	effectiveTime					O

Data Element	Definition	CCD Description	Template ID	CCD XPATH	Mapping Constraints (CodeSystem and /or value sets)	CCD Code	Optionality
Reported Previously	Indication if the information is supplemental to update in event already reported	versionNumber					O
Report sent to	The organization to which the report is submitted	informationRecipient		ClinicalDocument.informationRecipient.intendedRecipient.receivedOrganization			O
Report sent to FDA	Indication if the report is submitted to the Food and Drug Administration (FDA) – US	informationRecipient		ClinicalDocument.informationRecipient.intendedRecipient.receivedOrganization[id='*FDA*']			O
Date User Facility/Importer Became Aware of Event	The date the event was first recognized by an observer	Event	2.16.840.1.113883.10.20.1.18	ClinicalDocument.component.structuredBody.component.section.entry.entryRelationship.observation[templateId.@root = 2.16.840.1.113883.10.20.1.18].effectiveTime.low.@value			O
Date report sent	The date the report is submitted	Not Known					O
Date sent to FDA	The date the report was submitted to the FDA – US	Not Known					O
Report Source	The originator of the report	Author		ClinicalDocument.author.assignedAuthor.representedOrganization.Name			O
Reporter Name	The name of the person or facility sending the Case Report	Author		ClinicalDocument. Author.assignedAuthor.assignedPerson.name			R

Data Element	Definition	CCD Description	Template ID	CCD XPATH	Mapping Constraints (CodeSystem and /or value sets)	CCD Code	Optionality
Occupation of Reporter	The role of the reporter (e.g., physician, nurse, administrator, etc.)	no template					O
Telephone	The phone number of the person or facility sending the Case Report	no template					O
Reporter Email	The email contact information for the reporter	no template					O
Type of Reporter	The role of the reporter with respect to the patient (e.g., treating or consulting clinician, case manager, etc.)	no template					O
Reporter Address (street name, city, state, zip code)	The address of the reporter	Author		ClinicalDocument.author.assignedAuthor.assignedPerson.addr			O
Patient identifier	The identifier for the patient, may be a pseudonymized identifier	Patient		ClinicalDocument.recordTarget.patientRole.id			R
Patient Name (first, MI, Last)	The name (preferably legal) of the subject of the case report.	Patient		ClinicalDocument.recordTarget.patientRole.patient.name			O

Data Element	Definition	CCD Description	Template ID	CCD XPATH	Mapping Constraints (CodeSystem and /or value sets)	CCD Code	Optionality
Date of Birth	Date of birth	Patient		ClinicalDocument.recordTarget.patientRole.patient.birthTime			O
Age	The age of the subject of the case report at time of diagnosis	no template					O
Gender	Patient sex	Patient		ClinicalDocument.recordTarget.patientRole.patient.administrativeGenderCode			O
Pregnancy Status	Whether the subject of the case report was pregnant at time of diagnosis.	no template					O
Estimated Deliver Date	Estimated date of delivery (or est. date of confinement [EDC])	Patient	EDD Observation 1.3.6.1.4.1.19376.1.5.3.1.1.11.2.3.1			EDD Observation 1.3.6.1.4.1.19376.1.5.3.1.1.11.2.3.1	O
Weight	The weight of the patient at the time of the report	Patient	Vital Signs Observation 1.3.6.1.4.1.19376.1.5.3.1.4.13.2	ClinicalDocument.component.structuredBody.component.section.entry.entryRelationship.observation[templateId.@root = 1.3.6.1.4.1.19376.1.5.3.1.4.13.2].code.@displayName		Vital Signs Observation 1.3.6.1.4.1.19376.1.5.3.1.4.13.2	O
Birth Weight	The weight of the patient at birth	Patient	Vital Signs Observation 1.3.6.1.4.1.19376.1.5.3.1.4.13.2	ClinicalDocument.component.structuredBody.component.section.entry.entryRelationship.observation[templateId.@root = 1.3.6.1.4.1.19376.1.5.3.1.4.13.2].code.@displayName			O

Data Element	Definition	CCD Description	Template ID	CCD XPATH	Mapping Constraints (CodeSystem and /or value sets)	CCD Code	Optionality
Number of Siblings	The number of siblings in a multiple birth	Patient	Pregnancy Observation 1.3.6.1.4.1. 19376.1.5.3 .1.4.13.5				O
Patient Address (street name, city, state, zip code)	The address of the subject of the case report.	Patient		ClinicalDocument.recordTarget.patient Role.addr			O
Patient Telephone	The telephone of the subject of the case report.	Patient		ClinicalDocument.recordTarget.patient Role.telecom			O
Patient County	The county of the address of the subject of the case report	no template					O
Patient Country	The country of the address of the subject of the case report.	no template					O
Race	The race(s) of the subject of the case report.	Patient		ClinicalDocument.recordTarget.patient Role.patient.raceCode			O
Ethnicity	The ethnicity of the subject of the case report	Patient		ClinicalDocument.recordTarget.patient Role.patient.ethnicGroupCode			O

Data Element	Definition	CCD Description	Template ID	CCD XPATH	Mapping Constraints (CodeSystem and /or value sets)	CCD Code	Optionality
Occupation	The occupation of subject of the case report. Enter as much detail as possible (e.g., Teacher in Pre-School facility)	no template					O
Date of Death	If patient has died, deceased date/time	no template					O
Date of Event	The date the event first occurred	no template					R
Description of Event	A textual description of the event	Event	originalText 1.3.6.1.4.1.19376.1.5.3.1.3.13	#XX= ClinicalDocument.component.structuredBody.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].particpant.participantrole.playingEntity.code.originalText.reference.@value //*[@ID='XX']		originalText 1.3.6.1.4.1.19376.1.5.3.1.3.13 statusCode code='active'	O
Name of Condition	The name of the condition diagnosed for the subject of the Case Report	Event	displayName 1.3.6.1.4.1.19376.1.5.3.1.3.13	ClinicalDocument.component.structuredBody.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		displayName 1.3.6.1.4.1.19376.1.5.3.1.3.13 statusCode code='active'	R

Data Element	Definition	CCD Description	Template ID	CCD XPATH	Mapping Constraints (CodeSystem and /or value sets)	CCD Code	Optionality
Event Patient Problem Code	The locally determined code to identify the problem for subsequent follow up	no template					O
Event Device Problem Code	The locally determined code to identify the problem for subsequent follow up	no template					O
Type of Reportable Event	Seriousness of the event	no template					O
Type of Event and/or Issue		no template					O
Approximate Age of Device	The length of time the device has been in use for the patient	no template					O
Outcome attributed to AE	Textual description of the outcome associated with the adverse event	no template					O
Patient Recovered Diagnosis	Final determination of reaction – diagnosis	no template					O

Data Element	Definition	CCD Description	Template ID	CCD XPATH	Mapping Constraints (CodeSystem and /or value sets)	CCD Code	Optionality
Location where Event Occurred	The location of the event – e.g., home, hospital, other facility, etc.	no template					O
Adverse Event Terms		no template					O
Event Abated after use stopped or dose reduced?	Indication that the event resolved / abated after usage stopped or dose reduced	no template					O
Event Reappeared after reintroduction	Indication if the reaction reoccurred after rechallenging the patient to the suspected substance	no template					O
Concomitant Medical Product Name	Other medical products in use for the patient to determine proximal relationships	Admission Medication				1.3.6.1.4.1.19376.1.5.3.1.3.20	O
Therapy Dates	Dates of treatment with the suspected agent	no template					O

Data Element	Definition	CCD Description	Template ID	CCD XPATH	Mapping Constraints (CodeSystem and /or value sets)	CCD Code	Optionality
Pre-existing physician diagnosed allergies, birth defects. Medical conditions	Allergies, conditions existing prior to the use of the suspected agent	no template					O
Current Medications (Medwatch concomitant meds)	Other medications in use	Allergies and Other Adverse Reactions				1.3.6.1.4.1.19376.1.5.3.1.3.13 statusCode code='active|suspended|aborted|completed'	O
Previous Vaccine Type	The type of vaccine	no template					O
Previous Vaccine Manufacturer	The manufacturer of the vaccine dose	substanceAdministration/text/reference/@value				1.3.6.1.4.1.19376.1.5.3.1.4.12	O
Previous Vaccine Lot #	The lot number of the vaccine dose	consumable/administerableMaterial/ administerableMaterial/ asMedicineManufacturer.manufacturer.id				1.3.6.1.4.1.19376.1.5.3.1.4.12	O

Data Element	Definition	CCD Description	Template ID	CCD XPATH	Mapping Constraints (CodeSystem and /or value sets)	CCD Code	Optionality
Previous Vaccine Route/Site	The route of administration of the vaccine dose	Immunization				manufacturedLabeledDrug 1.3.6.1.4.1.19376.1.5.3.1.3.23	O
Vaccine # Previous Doses	The number of previous doses of the vaccine type	Immunization				lotNumberText 1.3.6.1.4.1.19376.1.5.3.1.3.23	O
Previous Vaccine Date Given	The date the vaccination dose suspected was administered	Immunization				routeCode 1.3.6.1.4.1.19376.1.5.3.1.3.23	O
AE Following Prior Vaccination	Description of the adverse event	no template					O
Vaccine Purchased With	Indication of vaccination source (e.g., special program such as Vaccine for Children, state or provincial programs, etc.)	Immunization				effectiveTime 1.3.6.1.4.1.19376.1.5.3.1.3.23	O
Suspect Product Name	Product name	no template					O
Product Dose	The dose of the product administered	no template					O

Data Element	Definition	CCD Description	Template ID	CCD XPATH	Mapping Constraints (CodeSystem and /or value sets)	CCD Code	Optionality
Product Frequency	The frequency with which the product was administered	Medications Administered				Product 1.3.6.1.4.1.19376.1.5.3.1.3.21	O
Product Route Used	The route of administration of the product (e.g., oral, intravenous, intramuscular, etc.)	Medications Administered				Dose 1.3.6.1.4.1.19376.1.5.3.1.3.21	O
Product Therapy Dates	Duration of therapy with the product	no template					O
Product Diagnosis for Use	The reason the product was initially used	Medications Administered				Route 1.3.6.1.4.1.19376.1.5.3.1.3.21	O
Product Lot #	The product lot number	no template					O
Expiration Date	The expiration date of the product	Medications Administered				Indication 1.3.6.1.4.1.19376.1.5.3.1.3.21	O
NDC# or Unique ID	The unique identifier for the product	Medications Administered				Lot #	O
Event Abated after use stopped or dose reduced?	Indication that the event resolved / abated after usage stopped or dose reduced	Medications Administered				expiration Time	O

Data Element	Definition	CCD Description	Template ID	CCD XPATH	Mapping Constraints (CodeSystem and /or value sets)	CCD Code	Optionality
Event Reappeared after reintroduction ?	Indication if the reaction reoccurred after rechallenging the patient to the suspected substance	Medications Administered				Code 1.3.6.1.4.1.19376.1.5.3.1.3.21	O
Suspect Medical Device Brand Name	Brand name of the suspect device	no template					O
Common Device Name	Common name of the device	no template					O
Manuf. name, City and State	Manufacturer of the device	no template					O
Medical Device Model #	Model number of the device	no template					O
Medical Device Catalog #	Catalog number of the device	no template					O
Medical Device Serial #	Serial number of the device	no template					O
Medical Device Lot #	Lot number of the device	no template					O
Medical Device Other #	Other identifiers for the device	no template					O
Operator of Device	The individual managing the device	no template					O

Data Element	Definition	CCD Description	Template ID	CCD XPATH	Mapping Constraints (CodeSystem and /or value sets)	CCD Code	Optionality
If implanted give date	Date of implantation of the device (if implanted)	no template					O
If explanted give date	Date device was removed (if removed)	no template					O
Is this a single use device that was reprocessed and reused on patient?	Indication if the device is a single-use device that was cleaned/reprocessed and is reused on the affected patient	no template					O
Name and Address of Reprocessor	Name and address of the individual / organization reprocessing the single use device	no template					O
Product available for evaluation?	Indication if the product is still available to be evaluated	no template					O
Date product returned to manuf.	If returned to the manufacturer, date of return	no template					O
Concomitant Medical Products & Therapy Dates	Other medical products and treatment used proximal to the event	no template					O

Data Element	Definition	CCD Description	Template ID	CCD XPATH	Mapping Constraints (CodeSystem and /or value sets)	CCD Code	Optionality
Signs and Symptoms	The signs and symptoms experienced by the patient	no template					O;
Symptom/ Illness Onset Date/Time	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	Admission Medication				1.3.6.1.4.1.19376.1.5.3.1.3.20	O
Patient Class	General type of patient, e.g., Inpatient, Outpatient, Emergency						O
Reporting Laboratory Identifier	Identifier for laboratory that is sending the result. This laboratory may be sending results received back from reference laboratories						O
Performing Laboratory	Laboratory that produced the test result. This may be a reference laboratory identifier.						O

Data Element	Definition	CCD Description	Template ID	CCD XPATH	Mapping Constraints (CodeSystem and /or value sets)	CCD Code	Optionality
Report Date/Time	Date/time of report						O
Results Status	Status of report (preliminary, final, corrected)						O
Ordered Test Code	The identifier code for the requested observation/test/battery						O
Resulted Test	"The identifier code for the specific test component resulted						O
Result Unit	Unit for numeric result context						O
Test Interpretation	Interpretation of test result, including the susceptibility test interpretation						O
Test Status	Status of the test result						C
Date of Test	The date that the laboratory test was performed for the subject of the Case Report.						O

Data Element	Definition	CCD Description	Template ID	CCD XPATH	Mapping Constraints (CodeSystem and /or value sets)	CCD Code	Optionality
Test Method	Testing method used to arrive at the specific result: The name of the laboratory test.						O
Test Result	The test result of the laboratory test including any applicable result units of measure						O
Specimen Collection Date	The date that the specimen for the laboratory test was taken from the subject of the Case Report						O
Source of Specimen	The physical body location from where the specimen for the lab report was taken from the subject						O
Name of Organization Collecting Specimen	Name of organization collecting specimen which may be different from the organization performing the laboratory analysis						O

Data Element	Definition	CCD Description	Template ID	CCD XPATH	Mapping Constraints (CodeSystem and /or value sets)	CCD Code	Optionality
Diagnosis/Injury Code	Diagnosis or diagnoses assigned as a result of the encounter						O;
Diagnosis Type	Type of diagnosis being sent (admitting, working, final)						O;
Diagnosis Date/Time	The date that the subject of the Case Report was diagnosed with Condition above						O;
Previous Event Report Details	Definitions pending - see appendix for detail to be considered						O
Reason for Non-Evaluation	Definitions pending - see appendix for detail to be considered						O
Type of Follow-Up	Definitions pending - see appendix for detail to be considered						O
Type of Remedial Action	Definitions pending - see appendix for detail to be considered						O
Administration of Treatment	Was treatment administered?						R

Data Element	Definition	CCD Description	Template ID	CCD XPATH	Mapping Constraints (CodeSystem and /or value sets)	CCD Code	Optionality
Date of Admin of Treatment	The date treatment was administered. For HepB, Date HBV vaccine administered						R
Name of Treatment	Name of the treatment						R
Hospitalizatio n	If the subject of the case report was hospitalized						R
Admission Date	Enter the date that the subject of the Case Report was Admitted to the hospital.						O
Discharge Date	Enter the date that the subject of the Case Report was Discharged from the hospital						R
Hospital Name	Name of hospital the case was admitted.						O
Recovered	Did the subject recover from the disease?						R
Death	Did the subject die as a result of the disease?						R

6.3.1.3.4 Document Sample

6.3.1.3.4.1 Immunizations Example

```
<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

```
<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

```
<component>
  <section>
    <templateId root='1.3.6.1.4.1.19376.1.5.3.1.3.20'/>
    <id root=' ' extension=' '/>
    <code code='42346-7' displayName='MEDICATIONS ON ADMISSION'
      codeSystem='2.16.840.1.113883.6.1' codeSystemName='LOINC'/>
    <text>
      Text as described above
    </text>
    <entry>
         :
      <!-- Required Medications element -->
        <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.7'/>
         :
    </entry>

  </section>
</component>
```

6.3.1.3.4.4 ClinicalDocument Header Example

```
<ClinicalDocument xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
                  xmlns="urn:hl7-org:v3"
xmnls:lab="urn:oid:1.3.6.1.4.1.19376.1.3.2"
                  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"/>
```

6.3.1.3.4.5 Medications Administered Example

```
<component>
  <section>
    <templateId root='1.3.6.1.4.1.19376.1.5.3.1.3.21'/>
```



```
    <id root=' ' extension=' '/>
    <code code='18610-6' displayName='MEDICATION ADMINISTERED'
      codeSystem='2.16.840.1.113883.6.1' codeSystemName='LOINC'/>
    <text>
      Text as described above
    </text>
    <entry>
         :
      <!-- Required Medications element -->
        <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.7'/>
         :
    </entry>

  </section>
</component>
```

6.3.1.3.4.6 Author Example

```
  <author>
    <time value="19990522"/>
    <assignedAuthor>
      <id extension="11111111" 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

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



```
      <telecom nullFlavor="UNK" use="HP"/>
      <patient classCode="PSN" determinerCode="INSTANCE">
        <name>
          <prefix/>
          <given>Christine</given>
          <family>Smith</family>
          <suffix/>
        </name>
        <ethnicGroupCode code="364699009" displayName="ethnic group"
          codeSystem="2.16.840.1.113883.6.96" codeSystemName="SNOMED CT"/>
        <administrativeGenderCode code="F"
codeSystem="2.16.840.1.113883.5.1"/>
        <birthTime value="20040725"/>
        <raceCode code=”2106-3” codeSystem=”2.16.840.1.113883.5.104”/>
      </patient>
      <providerOrganization classCode="ORG" determinerCode="INSTANCE">
        <id root="2.16.840.1.113883.19.5"/>
      </providerOrganization>
    </patientRole>
  </recordTarget>
```

6.3.1.3.4.8 Vital Signs Observation Example

```
<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'/>
 <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.13.2'/>
 <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

```
<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>
 <statusCode code='completed'/>
 <effectiveTime value=' '/>
</observation>
```

6.3.1.3.4.10 EDD Observation Example

```
<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>
     <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>
```



```
          <informant typeCode='INF'>
            <relatedEntity classCode=' '>
              <id root=' ' extension=' '/>
            </relatedEntity>
          </informant>
          <code code='[8655-2|(xx-ga-by-pe)|11888-5|(xx-date-of-qck)|(xx-date-
of-fund-umb) ]' codeSystem='2.16.840.1.113883.6.1' codeSystemName='LOINC'/>
          <value type='[PQ|TS]' value=' ' units='week'/>
        </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.

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Appendices

Appendix A – CCD-ODM/CDASH mapping and CRD constraints

This appendix is informative.

635 **Table A-1: CCD-CDASH Mapping and CRD Constraints**

CRD Reference	CDASH Domain	Clinical Database Variable Name	Optionality	Definition
	Common Identifiers	STUDYID	R2	Unique Identifier for a study within a submission.
		SITEID	R2	Unique identifier for the site.
		SUBJID	R2	Subject identifier.
		INVID	O	Investigator identifier.
		VISIT	O	Visit Name.
Header Information	**Demography**	BRTHYR	R	Year of subject's birth.
		BRTHMO	R	Month of subject's birth.
		BRTHDY	R2	Day of subject's birth.
		BRTHTM	O	Time of subject's birth,
		SEX	R	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).
		AGE	O	Numeric Age of Subject.
		AGEU	O	Age units.
		DMDAT	R2	Date of collection.
		DMTM (Note: If collected, will be derived into DMDTC.)	O	Time of collection.
		ETHNIC	O	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.
		RACE	R2	An arbitrary classification based on physical characteristics; a group of persons related by common descent or heredity.

CRD Reference	CDASH Domain	Clinical Database Variable Name	Optionality	Definition
	Subject Characteristics	SCDTC	R2	Date of collection.
		SCTM (Note: If collected, will be derived into SCDTC.)	O	Time of collection.
			O	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).
		SCTESTCD	O	Natural eye color
		SCTESTCD	O	Subject's childbearing potential
		SCTESTCD	O	Education level achieved at start of study (Reference date)
		SCTESTCD	O	Sub-study participation information.
Active Problems, Past Medical History, and Procedures and Interventions	**Medical History**	MHTERM	R	Verbatim or preprinted CRF term for the medical condition or event.
		MHONGO	R	Identifies the end of the event as being ONGOING or RESOLVED.
		MHYN	O	Lead prompt for the Medical History (e.g., "Has the subject experienced any past and / or concomitant diseases or past surgeries?").
		MHSPID	O	O sponsor-defined reference number (e.g., Preprinted line number).
		MHCAT	O	Used to define a category of related records (e.g., CARDIAC or GENERAL).
		MHSCAT	O	A categorization of the condition or event pre-printed on the CRF or instructions.
		MHOCCUR	O	A pre-printed prompt used to indicate whether or not a medical condition has occurred.
		MHSTDTC	O	Start Date of Medical History Event.
		MHENDTC	O	End Date/Time of Medical History Event.
Current Medications	**Concomitant Medication**	CMYN	O	General prompt question to aid in monitoring and data cleaning.
		CMSPID	O	A sponsor-defined reference number.

CRD Reference	CDASH Domain	Clinical Database Variable Name	Optionality	Definition
		CMTRT	R	Verbatim drug name that is either pre-printed or collected on a CRF.
		CMINGRD	O	Medication Ingredients.
		CMINDC	R2	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.
		AESPID	O	Identifier for the adverse event that is the indication for this medication.
		CMDOSTOT	R2	Total daily dose taken.
		CMDOSFRM	O	Name of the pharmaceutical dosage form (e.g., tablets, capsules, syrup) of delivery for the drug.
		CMDOSFRQ	O	How often the medication was taken (e.g., BID, every other week, PRN).
		CMDSTXT (Note: If collected, will be derived into CMDOSTXT or CMDOSE.)	O	The dose of medication taken per administration.
		CMDOSU	O	Within structured dosage information, the unit associated with the dose (e.g., "mg" in "2mg three times per day).
		CMDOSRGM	O	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).
		CMROUTE	R2	Identifies the route of administration of the drug.
		CMSTDTC	R	Date when the medication was first taken.
		CMSTRF	O	Relative time frame that the medication was first taken with respect to the sponsor-defined reference period.
		CMSTTM (Note: If collected, will be derived into CMSTDTC.)	R2	Time the medication was started.

CRD Reference	CDASH Domain	Clinical Database Variable Name	Optionality	Definition
		CMENDTC	R2	Date that the subject stopped taking the medication.
		CMENRF CMONGO (Note: If collected, will be derived into CMENRF.)	O	Indicates medication is ongoing when no End/Stop Date is provided.
		CMENTM (Note: If collected, will be derived into CMENDTC.)	R2	Time when the subject stopped taking the medication.
Social History	**Substance Use**	SUTRT	R	The type of substance (e.g., TOBACCO, ALCOHOL, CAFFEINE, etc. Or CIGARETTES, CIGARS, COFFEE, etc.).
		SUNCF	R2	Substance Use Occurrence.
		SUCAT	O	Used to define a category of related records (e.g., TOBACCO, ALCOHOL, CAFFEINE, etc.).
		SUDOSTXT	O	Substance use consumption amounts or a range of consumption information collected in text form [e.g., 1-2 (packs), 8 (ounces), etc.].
		SUDOSU	O	Units for SUDOSTXT (e.g., PACKS, OUNCES, etc.).
		SUDOSFRQ	O	Usually expressed as the number of uses consumed per a specific interval (e.g., PER DAY, PER WEEK, OCCASIONAL).
		SUSTDTC	O	Date substance use started.
		SUSTTM (Note: If collected, will be derived into SUSTDTC.)	O	Time substance use started.
		SUENDTC	O	Date substance use ended.
		SUENTM (Note: If collected, will be derived into SUENDTC.)	O	Time substance use ended.
		SUDUR	O	The duration of the substance use.
Vital Signs	**Vital Signs**	VSDTC	R2	Date of measurements
		VSSPID	O	Sponsor defined reference number
		VISITDY	O	Study day of measurements, measured as integer days

CRD Reference	CDASH Domain	Clinical Database Variable Name	Optionality	Definition
		VSTPT	O	Text description of time when measurement SHOULD be taken
		VSTM (Note: If collected, will be derived into VSDTC.)	O	Time of measurements.
		VSTEST	R2	Verbatim name of the test or examination used to obtain the measurement or finding.
		VSSTAT	R2	Used to indicate that a vital signs measurement was not done.
		VSORRES	R	Result of the vital signs measurement as originally received or collected.
		VSORRESU	R	Original units in which the data were collected.
		VSLOC	R2	Location on body where measurement was performed.
		VSPOS	R2	Position of the subject during a measurement or examination.
Physical Exam	**Physical Exam - Best Practice Approach**	PESTAT	O	Used to indicate if exam was not done as scheduled.
		PEDTC	O	Date of examination.
		PETM (Note: If collected, will be derived into PEDTC.)	O	Time of examination.
	Physical Exam - Traditional Approach	PEDONE	O	Used to indicate if exam was not done as scheduled.
		PEDTC	R2	Date of examination.
		PETM (Note: If collected, will be derived into PEDTC.)	O	Time of examination.
		PESPID	O	Sponsor defined reference number.
Allergies and Other Adverse Reactions	**Adverse Events**	AEYN	O	General prompt question to aid in monitoring and data cleaning.
		AESPID	O	A sponsor-defined reference number.
		AETERM	R2	Verbatim (i.e., investigator reported term) description of the adverse event.
		AESER	R2	Indicates whether or not the adverse event is determined to be “serious” according to the protocol.

CRD Reference	CDASH Domain	Clinical Database Variable Name	Optionality	Definition
		AESERTP Or AESCAN AESCONG AESDISAB AESDTH AESHOSP AESLIFE AESOD AESMIE (see below)	O	Captures the criteria required by protocol for determining why an event is “Serious”.
		AESCAN	O	Captures the criteria required by protocol for determining why an event is “Serious”.
		AESCONG	O	Captures the criteria required by protocol for determining why an event is “Serious”.
		AESDISAB	O	Captures the criteria required by protocol for determining why an event is “Serious”.
		AESDTH	O	Captures the criteria required by protocol for determining why an event is “Serious”.
		AESHOSP	O	Captures the criteria required by protocol for determining why an event is “Serious”.
		AESLIFE	O	Captures the criteria required by protocol for determining why an event is “Serious”.
		AESOD	O	Captures the criteria required by protocol for determining why an event is “Serious”.
		AESMIE	O	Captures the criteria required by protocol for determining why an event is “Serious”.
		AESTDTC	R2	Date when the adverse event started.
		AESTTM (Note: If collected, will be derived into AESTDTC.)	R2	Time when the adverse event started.
		AEENDTC	R2	Date when the adverse event resolved.
		AEENRF AEONGO	O	Indicates AE is ongoing when no End/Stop date is provided.
		AEENTM (Note: If collected, will be derived into AEENDTC.)	R2	Time when the adverse event resolved.

CRD Reference	CDASH Domain	Clinical Database Variable Name	Optionality	Definition
		AESEV And/or AETOXGR	R2	Description of the severity of the adverse event.
		AEREL	R2	Indication of whether the investigational product had a causal effect on the adverse event, as reported by the clinician/investigator.
		AERELTP	R2	Captures a category for an investigational product to which an adverse event is related.
		AEACN	R2	Action(s) taken with the investigational product in response to the adverse event.
		AEACNOTH	O	Describes Other Action(s) taken in response to the adverse event. (Does not include investigational products)
		AEOUT	R2	Description of the subject's status associated with an event.
Coded Results	**Lab Test Results - Scenario 1: Central processing**	LBDTC	R	Date of sample collection.
		LBTM (Note: If collected, will be derived into LBDTC.)	R2	Time of collection.
		LBSTAT	R2	Status of whether or not lab was done.
		LBCAT LBSCAT	R2	Type of draw / category / panel name. Used to define a category of related records.
		LBTPT	R2	Relative time for use when multiple sequential assessments are done.
		LBFAST (for example)	R2	Conditions for sampling defined in the protocol.
		LBREFID	R2	Internal or external specimen identifier.
	Lab Test Results - Scenario 2: Local processing	LBDTC	R	Date of sample collection.
		LBTM (Note: If collected, will be derived into LBDTC.)	R2	Time of collection.
		LBSTAT	R2	Status of whether or not lab was done.
		LBCAT LBSCAT	R2	Type of draw / category / panel name. Used to define a category of related records.

CRD Reference	CDASH Domain	Clinical Database Variable Name	Optionality	Definition
		LBTPT	R2	Relative time for use when multiple sequential assessments are done.
		LBFAST (for example)	R2	Conditions for sampling defined in the protocol.
		LBSPCCND	R2	Free or standardized text describing the condition of the specimen.
		LBTESTCD And/or LBTEST	R2	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.
		LBORRES	R	Result of the measurement or finding as originally received or collected.
		LBORRESU	R	Original units in which the data were collected.
		LBORNRLO LBORNRHI LBSTNRC	R2	Normal range for continuous measurements in original units. Normal values for non-continuous measurements in original units.
		LBNRIND	R2	Reference Range Indicator Indicates where value falls with respect to reference range defined by high and low ranges.
		LBCLSG (Note: If collected will be mapped to SUPPQUAL domain.)	R2	Whether lab test results were clinically significant.
		LBNAM	R2	Name of lab analyzing sample.
		LBREFID	R2	Internal or external specimen identifier.
	Lab Test Results - Scenario 3: Central processing but CRF includes site assessment…	LBDTC	R	Date of sample collection.
		LBTM (Note: If collected, will be derived into LBDTC.)	R2	Time of collection.
		LBSTAT	R2	Status of whether or not lab was done.
		LBCAT LBSCAT	R2	Type of draw / category / panel name. Used to define a category of related records.
		LBTPT	R2	Relative time for use when multiple sequential assessments are done,

CRD Reference	CDASH Domain	Clinical Database Variable Name	Optionality	Definition
		LBFAST (for example)	R2	Conditions for sampling defined in the protocol.
		LBTEST	R	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.
		LBORRES	R2	Result of the measurement or finding as originally received or collected.
		LBCLSG (Note: If collected will be mapped to SUPPQUAL domain.)	R2	Whether lab test results were clinically significant.
		LBNAM	R2	Name of lab analyzing sample.
		LBREFID	R2	Internal or external specimen identifier.
Coded Results	**ECG Test Results - Scenario 1: Central reading…**	LBDTC	R	Date of sample collection.
		LBTM (Note: If collected, will be derived into LBDTC.)	O	Time of collection.
		SBSTAT	R2	Status of whether or not lab was done.
		LBCAT LBSCAT	R2	Type of draw / category / panel name. Used to define a category of related records.
		LBTPT	R2	Relative time for use when multiple sequential assessments are done.
		LBFAST (for example)	O	Conditions for sampling defined in the protocol.
		LBREFID	O	Internal or external specimen identifier.
	ECG Test Results - Scenario 2: Local reading: ECGs…	EGSTAT	R2	Status of whether or not ECG was done.
		EGREASND	O	Describes why the ECG was not done (e.g., BROKEN EQUIPMENT, SUBJECT REFUSED).
		EGDTC	R2	Date of ECG.
		EGTM (Note: If collected, will be derived into EGDTC.)	R2	Time of ECG.

CRD Reference	CDASH Domain	Clinical Database Variable Name	Optionality	Definition
		EGTPT	R2	Text description of planned time point when measurements SHOULD be taken for use when multiple sequential assessments are done
		EGTESTCD And/or EGTEST	R	Verbatim name of the test or examination used to obtain the measurement or finding.
		EGORRES	R	Result of the measurement or finding as originally received or collected.
		EGORRESU	R2	Original units in which the data were collected.
		EGCLSG (Note: If collected will be mapped to SUPPQUAL domain.)	O	Whether ECG results were clinically significant.
		EGPOS, EGMETHOD (for example)	O	Condition for testing defined in the protocol.
		EGEVAL	O	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).
		EGREFID	O	Internal or external identifier.
	ECG Test Results - Scenario 3: Central reading	EGSTAT	R2	Status of whether or not ECG was done.
		EGREASND	O	Describes why the ECG was not done (e.g., BROKEN EQUIPMENT, SUBJECT REFUSED).
		EGDTC	R2	Date of ECG.
		EGTM (Note: If collected, will be derived into EGDTC.)	R2	Time of ECG.
		EGTPT	R2	Text description of planned time point when measurements SHOULD be taken for use when multiple sequential assessments are done.

CRD Reference	CDASH Domain	Clinical Database Variable Name	Optionality	Definition
		EGTEST	R	Verbatim name of the test or examination used to obtain the measurement or finding.
		EGORRESU	R2	Original units in which the data were collected.
		EGCLSG (Note: If collected, will be mapped to SUPPQUAL domain.)	R2	Whether ECG results were clinically significant.
		EGORRES	R2	Result of the measurement or finding as originally received or collected.
		EGORRESU	R2	Original units in which the data were collected.
		EGNAM	R2	Name of vendor providing ECG data.
		EGPOS, EGMETHOD (for example)	O	Conditions for testing defined in the protocol.
		EGREFID	O	Internal or external ECG identifier.

Optionality Key	
R	Required Section
R2	Required Section if data present
O	Optional section

Appendix B – Clinical Research Document to Standard CRF (ODM/CDASH) Crosswalk

This appendix is informative.

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 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"-->
            <!-- TODO: add attributes for the following
                  AsOfDateTime="2008-04-28T14:03:56"
                  CreationDateTime="2008-04-28T14:03:56"
            -->
      <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>
            <!-- ClinicalData element -->
            <xsl:element name="ClinicalData"
namespace="http://www.cdisc.org/ns/odm/v1.3">
                  <xsl:attribute name="StudyOID">CLL.001</xsl:attribute>
```



```
                    <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>
                        <!-- 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>
                        <!-- multiple FormData Elements, representing CDASH
Domains -->
                        <!-- demography -->
                        <xsl:call-template name="demography"/>
                        <!-- medical history -->
                        <xsl:call-template name="medicalHistory"/>
                        <!-- conMeds -->
                        <xsl:call-template name="conMeds"/>
                        <!-- substance use -->
                        <xsl:call-template name="substanceAbuse"/>
                        <!-- vitals -->
                        <xsl:call-template name="vitalSigns"/>
                        <!-- physical exam -->
                        <!-- AE -->
                        <xsl:call-template name="adverseEvents"/>
                        <!-- lab results -->
                        <!-- ECG results -->
                        </xsl:element>
            </xsl:element>
      </xsl:element>
      </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:element name="FormData"
namespace="http://www.cdisc.org/ns/odm/v1.3">
                    <xsl:attribute
name="FormOID">DemographicsForm</xsl:attribute>
```



```
                  <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="$ISODATE"/>
                                    <!--xsl:value-of
select="$patientNode/cda:birthTime/@value"/-->
                              </xsl:attribute>
                        </xsl:element>
                  </xsl:element>
            </xsl:element>
      </xsl:template>


<!-- 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: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>
</xsl:template>


<!-- 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="$ccdMedication/cda:entry">
                  <!-- we MAY be pointed to the text of the med, or we MAY
just have the text-->
                  <xsl:variable name="originalTextRef"
select="cda:substanceAdministration/cda:consumable/cda:manufacturedProduct/cd
a:manufacturedMaterial/cda:code/cda:originalText/cda:reference/@value"/>
                  <xsl:variable name="originalText"
select="cda:substanceAdministration/cda:consumable/cda:manufacturedProduct/cd
a:manufacturedMaterial/cda:code/cda:originalText"/>
                  <!--ItemGroupData ItemGroupOID='CM'-->
                  <xsl:element name="ItemGroupData"
namespace="http://www.cdisc.org/ns/odm/v1.3">
                        <xsl:attribute name="ItemGroupOID">CM</xsl:attribute>
                        <!-- CMTRT -->
                        <!--ItemData ItemDataOID='CMTRT'-->
                        <xsl:element name="ItemData"
namespace="http://www.cdisc.org/ns/odm/v1.3">
                              <xsl:attribute
name="ItemOID">CMTRT</xsl:attribute>
                              <xsl:attribute name="Value">
                                    <xsl:choose>
                                          <xsl:when
test="$originalTextRef"><xsl:value-of select="//*[@ID=substring-
after($originalTextRef,'#')]"/></xsl:when>
                                          <xsl:otherwise><xsl:value-of
select="$originalText"/></xsl:otherwise>
                                    </xsl:choose>
                              </xsl:attribute>
                        </xsl:element>
                        <!-- CMDOSFREQ -->
                        <xsl:comment>need table to translate HL7 frequency,
e.g., 6h to BID</xsl:comment>
                        <!-- CMROUTE -->
                        <xsl:variable name="routeCode"
select="cda:substanceAdministration/cda:routeCode/@displayName"/>
                        <xsl:if test="$routeCode">
```



```
                              <!--ItemData ItemDataOID='CMROUTE'-->
                              <xsl:element name="ItemData"
namespace="http://www.cdisc.org/ns/odm/v1.3">
                                    <xsl:attribute
name="ItemOID">CMROUTE</xsl:attribute>
                                    <xsl:attribute name="Value"><xsl:value-of
select="$routeCode"/></xsl:attribute>
                              </xsl:element><!--/ItemData-->
                        </xsl:if>
                        <!-- CMSTDTC -->
                        <xsl:variable name="medStartDate"
select="cda:substanceAdministration/cda:effectiveTime[@xsi:type='IVL_TS']/cda
:low/@value"/>
                        <xsl:if test="$medStartDate">
                              <!--ItemData ItemDataOID='CMSTDTC'-->
                              <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="$medStartDate"/>
                                          </xsl:call-template>
                                    </xsl:variable>
                                    <xsl:attribute
name="ItemOID">CMSTDTC</xsl:attribute>
                                    <!--xsl:attribute
name="Value"><xsl:value-of select="$medStartDate"/></xsl:attribute-->
                                    <xsl:attribute name="Value"><xsl:value-of
select="$ISODATE"/></xsl:attribute>
                              </xsl:element><!--/ItemData-->
                        </xsl:if>
                        <!-- CMENDTC -->
                        <xsl:variable name="medEndDate"
select="cda:substanceAdministration/cda:effectiveTime[@xsi:type='IVL_TS']/cda
:high/@value"/>
                        <xsl:if test="$medEndDate">
                              <!--ItemData ItemDataOID='CMENDDTC'-->
                              <xsl:element name="ItemData"
namespace="http://www.cdisc.org/ns/odm/v1.3">
                                    <xsl:attribute
name="ItemOID">CMENDDTC</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="$medEndDate"/>
                                          </xsl:call-template>
```



```
                                        </xsl:variable>
                                        <!--xsl:attribute
name="Value"><xsl:value-of select="$medEndDate"/></xsl:attribute-->
                                        <xsl:attribute name="Value"><xsl:value-of
select="$ISODATE"/></xsl:attribute>
                                    </xsl:element><!--/ItemData-->
                                </xsl:if>
                            </xsl:element>
                            <!--/ItemGroupData-->
                        </xsl:for-each>
                        </xsl:element>
                </xsl:if>
</xsl:template>

<!-- 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"/>
                  <!--ItemGroupData ItemGroupDataOID='VS'-->
                  <xsl:element name="ItemGroupData"
namespace="http://www.cdisc.org/ns/odm/v1.3">
                        <xsl:attribute name="ItemGroupOID">VS</xsl:attribute>
                        <!-- VSDTC -->
                        <!--ItemData ItemDataOID='VSDTC'-->
                        <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="$vitalsDateTime"/>
                                          </xsl:call-template>
                                    </xsl:variable>
                                    <xsl:attribute
name="ItemOID">VSDTC</xsl:attribute>
                                    <!--xsl:attribute name="Value"><xsl:value-of
select="$vitalsDateTime"/></xsl:attribute-->
                                    <xsl:attribute name="Value"><xsl:value-of
select="$ISODATE"/></xsl:attribute>
                              </xsl:element><!--/ItemData-->
                        <!-- now go get all of the components from this recording -
->
                        <xsl:for-each select="cda:component">
                              <xsl:variable name="vitalsResultNode"
select="cda:observation/cda:value"/>
                              <!-- VSTEST -->
                              <!--ItemData ItemDataOID='VSTEST'-->
                              <xsl:element name="ItemData"
namespace="http://www.cdisc.org/ns/odm/v1.3">
                                    <xsl:attribute
name="ItemOID">VSTEST</xsl:attribute>
                                    <xsl:attribute name="Value"><xsl:value-of
select="cda:observation/cda:code/@displayName"/></xsl:attribute>
                              </xsl:element>
                                    <xsl:choose>
                                          <xsl:when
test="$vitalsResultNode/@xsi:type='PQ'">
                                          <!-- VSORRES -->
                                                <!--ItemData ItemDataOID='VSORRES'-
->
                                                <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="$vitalsResultNode/@value"/></xsl:attribute>
                                                </xsl:element><!--/ItemData-->
                                                <!-- VSORRESU -->
                                                <!--ItemData
ItemDataOID='VSORRESU'-->
                                                <xsl:element name="ItemData"
namespace="http://www.cdisc.org/ns/odm/v1.3">
                                                      <xsl:attribute
name="ItemOID">VSORRESU</xsl:attribute>
                                                      <xsl:attribute
name="Value"><xsl:value-of select="$vitalsResultNode/@unit"/></xsl:attribute>
                                                </xsl:element><!--/ItemData-->
```



```
                                    </xsl:when>
                                    <xsl:otherwise>
                                          <!-- VSORRES ...no units -->
                                          <!--ItemData ItemDataOID='VSORRES'-
->
                                          <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:par
ticipantRole/cda:playingEntity/cda:code/cda:originalText/cda:reference/@value
"/>
                        <xsl:variable name="codedDisplayName"
select="cda:act/cda:entryRelationship/cda:observation/cda:participant/cda:par
ticipantRole/cda:playingEntity/cda:code/@displayName"/>
                        <!--ItemData ItemDataOID='AETERM'-->
                        <xsl:element name="ItemData"
namespace="http://www.cdisc.org/ns/odm/v1.3">
                              <xsl:attribute
name="ItemOID">AETERM</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="$codedDisplayName"/></xsl:otherwise>
                                        </xsl:choose>
                                  </xsl:attribute>
                            </xsl:element><!--/ItemData-->
                            <!-- AESTDTC -->
                            <xsl:variable name="aeStartDateTime"
select="cda:act/cda:entryRelationship/cda:observation/cda:effectiveTime/@valu
e"/>
                            <xsl:if test="$aeStartDateTime">
                                  <!--ItemData ItemDataOID='AESTDTC'-->
                                  <xsl:element name="ItemData"
namespace="http://www.cdisc.org/ns/odm/v1.3">
                                        <xsl:attribute
name="ItemOID">AESTDTC</xsl:attribute>
                                        <xsl:attribute name="value"><xsl:value-of
select="$aeStartDateTime"/></xsl:attribute>
                                  </xsl:element><!--/ItemData-->
                            </xsl:if>
                      </xsl:element><!--/ItemDataGroup-->
                </xsl:for-each>
          </xsl:element><!--/FormData-->
</xsl:if>

</xsl:template>

<!-- helper templates -->

<!-- CDASH a med history item -->
<xsl:template name="problemItemData">
<xsl:param name="theNode"/>
      <!-- we MAY be pointed to the text of the condition, or we MAY just
have a coded value display name -->
      <xsl:variable name="originalTextRef"
select="$theNode/cda:act/cda:entryRelationship/cda:observation/cda:text/cda:r
eference/@value"/>
      <xsl:variable name="codedValue"
select="$theNode/cda:act/cda:entryRelationship/cda:observation/cda:value/@dis
playName"/>
      <!-- problem status translates into the CDASH MHONG -->
      <xsl:variable name="problemStatusNode"
select="$theNode/cda:act/cda:entryRelationship/cda:observation/cda:entryRelat
ionship/cda:observation[cda:code/@code='33999-4']"/>
      <!-- can have status coded or by reference -->
      <xsl:variable name="problemStatusRef"
select="$problemStatusNode/cda:text/cda:reference/@value"/>
      <!-- onset and end dates for problems -->
```



```
      <xsl:variable name="problemOnset"
select="$theNode/cda:act/cda:entryRelationship/cda:observation/cda:effectiveT
ime/cda:low/@value"/>
      <xsl:variable name="problemResolved"
select="$theNode/cda:act/cda:entryRelationship/cda:observation/cda:effectiveT
ime/cda:high/@value"/>
      <!-- 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="$problemOnset"/>
                                          </xsl:call-template>
                              </xsl:variable>
                  <xsl:attribute name="ItemOID">MHSTDTC</xsl:attribute>
                  <!--xsl:attribute name="Value"><xsl:value-of
select="$problemOnset"/></xsl:attribute-->
                  <xsl:attribute name="Value"><xsl:value-of
select="$ISODATE"/></xsl:attribute>
            </xsl:element><!--/ItemData-->
      </xsl:if>
      <!-- MHENDDTC -->
      <xsl:if test="$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: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 -->
      <!--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-->
      <!-- NOTE: is this true = procedures are RESOLVED -->
      <!-- MHONG -->
      <!--ItemData ItemDataOID='MHONG' value='RESOLVED'/-->
      <xsl:element name="ItemData"
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>
      <xsl:comment>??? what to do about an effectiveTime of center
???</xsl:comment>
</xsl:template>

<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',$HOUR,':',$MINUTE)"/>
            </xsl:when>
            <xsl:when test="string-length($HL7Date) = 14">
```



```
                    <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($HL7Date,11,2)"/>
                    <xsl:variable name="SECOND"
select="substring($HL7Date,13,2)"/>
                    <xsl:value-of select="concat($YEAR,'-',$MONTH,'-
',$DAY,'T',$HOUR,':',$MINUTE,':',$SECOND)"/>
                </xsl:when>
                <!-- can still be extended for the case milliseconds are given --
>
                <!-- CASE NOT FOUND -->
                <xsl:otherwise><xsl:value-of select="$HL7Date"/></xsl:otherwise>
            </xsl:choose>

</xsl:template>
</xsl:stylesheet>
```

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"/>
```



```
            <!--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"/>
            <!--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"/>
            <!--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"/>
            <!--??? what to do about an effectiveTime of center ???-->
          </ItemGroupData>
        </FormData>
        <FormData FormOID="ConMedForm">
          <ItemGroupData ItemGroupOID="CM">
            <ItemData ItemOID="CMTRT" Value="Albuterol inhalant"/>
            <!--need table to translate HL7 frequency, e.g., 6h to BID-->
            <ItemData ItemOID="CMROUTE" Value="Inhalation, oral"/>
          </ItemGroupData>
          <ItemGroupData ItemGroupOID="CM">
            <ItemData ItemOID="CMTRT" Value="Clopidogrel"/>
            <!--need table to translate HL7 frequency, e.g., 6h to BID-->
          </ItemGroupData>
          <ItemGroupData ItemGroupOID="CM">
            <ItemData ItemOID="CMTRT" Value="Metoprolol"/>
            <!--need table to translate HL7 frequency, e.g., 6h to BID-->
          </ItemGroupData>
          <ItemGroupData ItemGroupOID="CM">
            <ItemData ItemOID="CMTRT" Value="Prednisone"/>
            <!--need table to translate HL7 frequency, e.g., 6h to BID-->
            <ItemData ItemOID="CMSTDTC" Value="2000-03-28"/>
          </ItemGroupData>
          <ItemGroupData ItemGroupOID="CM">
            <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>
        </FormData>
        <FormData FormOID="VSFORM">
          <ItemGroupData ItemGroupOID="VS">
            <ItemData ItemOID="VSDTC" Value="1999-11-14"/>
            <ItemData ItemOID="VSTEST" Value="Body height"/>
            <ItemData ItemOID="VSORRES" Value="177"/>
```



```
            <ItemData ItemOID="VSORRESU" Value="cm"/>
            <ItemData ItemOID="VSTEST" Value="Body weight"/>
            <ItemData ItemOID="VSORRES" Value="86"/>
            <ItemData ItemOID="VSORRESU" Value="kg"/>
            <ItemData ItemOID="VSTEST" Value="Systolic BP"/>
            <ItemData ItemOID="VSORRES" Value="132"/>
            <ItemData ItemOID="VSORRESU" Value="mm[Hg]"/>
            <ItemData ItemOID="VSTEST" Value="Diastolic BP"/>
            <ItemData ItemOID="VSORRES" Value="86"/>
            <ItemData ItemOID="VSORRESU" Value="mm[Hg]"/>
          </ItemGroupData>
          <ItemGroupData ItemGroupOID="VS">
            <ItemData ItemOID="VSDTC" Value="2000-04-07"/>
            <ItemData ItemOID="VSTEST" Value="Body height"/>
            <ItemData ItemOID="VSORRES" Value="177"/>
            <ItemData ItemOID="VSORRESU" Value="cm"/>
            <ItemData ItemOID="VSTEST" Value="Body weight"/>
            <ItemData ItemOID="VSORRES" Value="88"/>
            <ItemData ItemOID="VSORRESU" Value="kg"/>
            <ItemData ItemOID="VSTEST" Value="Systolic BP"/>
            <ItemData ItemOID="VSORRES" Value="145"/>
            <ItemData ItemOID="VSORRESU" Value="mm[Hg]"/>
            <ItemData ItemOID="VSTEST" Value="Diastolic BP"/>
            <ItemData ItemOID="VSORRES" Value="88"/>
            <ItemData ItemOID="VSORRESU" Value="mm[Hg]"/>
          </ItemGroupData>
        </FormData>
        <FormData FormOID="AEForm">
          <ItemGroupData ItemGroupOID="AE">
            <ItemData ItemOID="AETERM" Value="Penicillin"/>
          </ItemGroupData>
          <ItemGroupData ItemGroupOID="AE">
            <ItemData ItemOID="AETERM" Value="Aspirin"/>
          </ItemGroupData>
          <ItemGroupData ItemGroupOID="AE">
            <ItemData ItemOID="AETERM" Value="Codeine"/>
          </ItemGroupData>
        </FormData>
      </StudyEventData>
    </SubjectData>
  </ClinicalData>
</ODM>
```


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]
2. Rozich JD, Haraden CR, Resar RK. Adverse drug event trigger tool: a practical methodology for measuring medication related harm, Qual Saf Health Care. 2003;12:194-200. - Lists 24 clinical triggers to identify potential adverse drug events. *** See Table Below for 24 Triggers
3. Resar RK, Rozich JK, Classen D. Methodology and rationale for the measurement of harm with trigger tools, Qual Saf Health Care. 2003;12:ii30-ii45.
4. Takata GS, Mason W, Taketomo C, Logsdon T and Sharek PJ. Development, Testing, and Findings of a Pediatric-Focused Trigger Tool to Identify Medication-Related Harm in US Children's Hospitals. Pediatrics 2008;121:927-935. Full Text of Article

Table C-1: Clinical Triggers

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

[5] Rozich JD, Haraden CR, Resar RK. Adverse drug event trigger tool: a practical methodology for measuring medication related harm, Qual Saf Health Care. 2003;12:194-200. - Lists 24 clinical triggers to identify potential adverse drug events.

Rozich, Haraden, Resar - Clinical Triggers[5]			
Trigger #	**Trigger**	**Concern**	**EMR Trigger Type (added)**
T22	Abrupt medication stop	Adverse drug event	Order to discontinue
T23	Transfer to higher level of care	Adverse event	Order
T24	Customized to individual institution	Adverse event	Local determinant Acronyms: PTT=prothrombin time; INR=international normalized ratio; WBC=white blood cells

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.

