

**Integrating the Healthcare Enterprise**



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**IHE Quality, Research and Public Health  
(QRPH) Technical Framework  
Supplement 2008-2009**

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**Clinical Research Data Capture (CRD)**

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**Draft for Trial Implementation  
August 22, 2008**

## 1 Foreword

20 Integrating the Healthcare Enterprise (IHE) is an initiative designed to stimulate the integration  
of the information systems that support modern healthcare institutions. Its fundamental objective  
is to ensure that in the care of patients all required information for medical decisions is both  
correct and available to healthcare professionals. The IHE initiative is both a process and a  
forum for encouraging integration efforts. It defines a technical framework for the  
25 implementation of established messaging standards to achieve specific clinical goals. It includes  
a rigorous testing process for the implementation of this framework. And it organizes  
educational sessions and exhibits at major meetings of medical professionals to demonstrate the  
benefits of this framework and encourage its adoption by industry and users.

The approach employed in the IHE initiative is not to define new integration standards, but rather  
30 to support the use of existing standards, HL7, DICOM, IETF, and others, as appropriate in their  
respective domains in an integrated manner, defining configuration choices when necessary.  
IHE maintain formal relationships with several standards bodies including HL7, DICOM and  
refers recommendations to them when clarifications or extensions to existing standards are  
necessary.

35 This initiative has numerous sponsors and supporting organizations in different medical specialty  
domains and geographical regions. In North America the primary sponsors are the Healthcare  
Information and Management Systems Society (HIMSS) and the Radiological Society of North  
America (RSNA). IHE Canada has also been formed. IHE Europe (IHE-EUR) is supported by a  
large coalition of organizations including the European Association of Radiology (EAR) and  
40 European Congress of Radiologists (ECR), the Coordination Committee of the Radiological and  
Electromedical Industries (COCIR), Deutsche Röntngengesellschaft (DRG), the EuroPACS  
Association, Groupement pour la Modernisation du Système d'Information Hospitalier  
(GMSIH), Société Française de Radiologie (SFR), Società Italiana di Radiologia Medica  
(SIRM), the European Institute for health Records (EuroRec), and the European Society of  
45 Cardiology (ESC). In Japan IHE-J is sponsored by the Ministry of Economy, Trade, and  
Industry (METI); the Ministry of Health, Labor, and Welfare; and MEDIS-DC; cooperating  
organizations include the Japan Industries Association of Radiological Systems (JIRA), the  
Japan Association of Healthcare Information Systems Industry (JAHIS), Japan Radiological  
Society (JRS), Japan Society of Radiological Technology (JSRT), and the Japan Association of  
50 Medical Informatics (JAMI). Other organizations representing healthcare professionals are  
invited to join in the expansion of the IHE process across disciplinary and geographic  
boundaries.

The IHE Technical Frameworks for the various domains (IT Infrastructure, Cardiology,  
Laboratory, Radiology, etc.) defines specific implementations of established standards to achieve  
55 integration goals that promote appropriate sharing of medical information to support optimal  
patient care. It is expanded annually, after a period of public review, and maintained regularly  
through the identification and correction of errata. The current version for these Technical  
Frameworks may be found at [www.ihe.net/Technical\\_Framework](http://www.ihe.net/Technical_Framework).

60 The IHE Technical Framework identifies a subset of the functional components of the healthcare  
enterprise, called IHE Actors, and specifies their interactions in terms of a set of coordinated,  
standards-based transactions. It describes this body of transactions in progressively greater

65 depth. The volume I provides a high-level view of IHE functionality, showing the transactions organized into functional units called Integration Profiles that highlight their capacity to address specific clinical needs. The subsequent volumes provide detailed technical descriptions of each IHE transaction.

This IHE Quality, Research, and Public Health (QRPH) Technical Framework Supplement is issued for Trial Implementation through May 2009.

70 Comments and change proposals arising from Trial Implementation may be submitted to <http://forums.rsna.org> under the forum:  
***“Integrating the Healthcare Enterprise”***  
Select the sub-forum:  
***“IHE QRPH 2008 Supplements for Trial Implementation”***

75 The IHE IT Infrastructure Technical Committee will address these comments resulting from implementation, Connectathon testing and demonstrations. Final text is expected to be published in June 2009, dependent upon results of IHE validation process.

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## **2 Introduction**

### **2.1 Open Issues**

### **100 2.2 Closed Issues**

### 3 Profile Abstract

#### Clinical Research Data Capture Profile (CRD)

105 CRD describes the content and format to be used within the Prepopulation Data transaction described within the RFD Integration Profile. The purpose of this profile is to support a standard set of data in CCD format which the Form Filler provides for use in Clinical Research. In addition this profile will reference the ability to convert this output into a standard case report form (Standard CRF) consisting of ODM and CDASH.

## 4 Glossary

**CCD** – ASTM/HL7 Continuity of Care Document (CCD)

110 **CDASH** – Clinical Data Acquisition Standards Harmonization (CDASH)

**Clinical Research CCD** – Refers to the CCD constrained within the Clinical Research Data Capture (CRD) profile.

**Form Manager** – The Form Manager actor provides the store of forms ready for use by a Form Filler.

115 **Form Filler** – The Form Filler actor retrieves forms from a Form Manager as and when required. When requesting a form, the Form Filler actor can optionally provide context information by providing pre-population xml data in the request for use by the Form Manager. The Form Filler may also specify a Form Archiver actor. The Form Archiver actor specified by the Form Filler is in addition to any Form Archiver actors specified by the Form Manager.

120 **Form Receiver** – The Form Receiver actor receives and processes completed or partially completed forms instance data from a Form Filler. Form Receiver processing is out of the scope of the profile.

**Form Archiver** – The Form Archiver actor receives completed or partially completed forms instance data and stores these for archival purposes.

125 **ODM** – Operational Data Model (ODM)

**Retrieve Form** – The Retrieve Form transaction carries the form identifier from a Form Filler to a Form Manager. The transaction also allows a Form Filler to optionally specify a Form Archiver actor as well as optionally containing context information in the form of xml data to be used in the selection and pre-population of the requested form prior to the form being returned to the Form Filler.

130

**RFD** – Retrieve Form for Data Capture Profile (RFD)

**Standard CRF** – Refers to a Standard Case Report Form in a ODM format which is mapped to CDASH

Also refer to Glossary of CDISC Terms at <http://www.cdisc.org/glossary/index.html>

# Volume I – Integration Profiles

## 5 Clinical Research Data Capture (CRD)

### 5.1 Dependencies

Content Profile	Dependency	Dependency Type	Purpose
Clinical Research Data Capture	RFD	Integration Profile	This is a content profile that will be used in the context of the RFD Integration profile.

### 5.2 Profile Name

The Clinical Research Data Capture Profile (CRD)

140 CRD describes the content and format to be used within the Prepopulation Data transaction described within the RFD Integration Profile. The purpose of this profile is to support a standard set of data in CCD format which the Form Filler provides for use in Clinical Research. In addition this profile will reference the ability to convert this output into a standard case report form (Standard CRF) consisting of ODM and CDASH.

### 145 5.3 Use Case

The setting for the clinical research use case is a physicians’ practice where patient care is delivered side-by-side with clinical research activities. The site, Holbin Medical Group, is a multi-site physician practice, employing over 100 physicians in a variety of specialties. Holbin’s CEO encourages the physicians to participate as site investigators for pharmaceutical-sponsored clinical trials; Holbin provides support for clinical research activities in the form of a Research Department of twelve dedicated study coordinators, mostly RNs, along with clerical and data-entry support personnel. Holbin Medical Group uses an Electronic Health Record (EHR) and a number of sponsor-provided Electronic Data Capture (EDC) systems for documenting clinical trial activities. EDC is a system for documenting clinical trial activities. EDC is a remote data entry system, provided by the research sponsor, which uses either a laptop (thick or thin client) or a web site. For our purposes, an EHR is any application which is the primary site for documenting patient care, and retrieving patient care information. Thus we include in our span of interest many systems installed today that are not quite EHRs in the strictest sense, but which would still benefit from this approach.

160 Holbin’s involvement in a clinical study begins when the Research Department receives a request for proposal (RFP) or a request for a feasibility assessment (EU) from a study Sponsor. The Investigator or the Study Coordinator, Patricia Zone, RN, evaluates the RFP to assess if their facility has the required patient population (clinical condition and required numbers required by the study protocol) as specified in the clinical study protocol, as well as the business viability. A major issue that must be addressed is the time needed to perform the clinical study and whether or not the site has the time to perform the study appropriately. Once these concerns are addressed satisfactorily and the site is selected for the trial, the financial aspects are addressed and the site then sends the required regulatory documentation to the Sponsor. The Sponsor then provides Protocol-specific training to the Physician Investigator and other study personnel.

170 During the trial set-up period, Patricia, together with the Investigator ensures that the appropriate system security is in place for this protocol, recruits patients to participate as subjects according to inclusion and exclusion criteria described in the study protocol schedules patient visits, manages data capture and data entry, ensures that IRB approval has been obtained, maintains required regulatory documents and performs all the attendant financial tasks.

175 Patricia, under the supervision of the Investigator contacts Corey Jones, a patient at Holbin, about participating in the trial, and Corey agrees to participate as a subject. Patricia registers Corey in the EHR as a subject in trial #1234, using the EHR's patient index. She schedules Corey's study visits using the EHR scheduling module, and flags the visits as pertaining to the trial #1234. After the set-up stage, the site initiates clinical trial care and trial-specific  
180 documentation.

The use case continues with current state and desired state scenarios, which describe data capture utilizing EDC technology during a patient clinical trial visit before and after the RFD implementation.

#### 5.4 Current State

185 Corey Jones arrives at the clinic for a scheduled trial visit and meets with Patricia Zone for a face-to-face interview. Patricia logs into the EHR and documents the visit with a terse entry: 'Mrs. Jones comes in for a clinical trial visit associated with study #1234.' Patricia interviews Mrs. Jones, makes some observations, and records her observation on a source paper document. She looks up recent lab results in the EHR and records them in the Case Report Form (CRF).

190 The EHR provides only a portion of the data required to complete the form, the rest comes from the interview and observations. (Estimates on the percentage of data required for a clinical trial that would be available in an EHR vary from 5% to 40%. Even in the best case, the EHR typically captures only a subset of the data required by a study protocol.)

The completed source document is forwarded to Bob, the data entry person. Bob identifies the  
195 CRF as belonging to trial #1234, and selects the trial #1234 EDC system, which may be housed on a dedicated laptop provided by the sponsor or may be accessible via a browser session connected to the Sponsor's EDC system via the Internet. He takes a three ring binder off the shelf and refers to his 'crib sheet' to get the instructions for how to use this particular system. He logs into the EDC application, using a user name and password unique to this system, and enters  
200 the data into the correct electronic case report form (eCRF) for that trial visit. Once the source document has been processed, Bob files it in a 'banker's box' as part of the permanent source record of the trial (in order to meet the requirements of the Federal Code of Regulations 21CFR 312:62).

In addition to trial #1234, Bob performs data entry on eight additional EDC systems, five on  
205 dedicated laptops and three that are web-based. The web-based EDC systems save on table space, but still require entries in the three ring binders where Bob puts his 'crib sheets'. It is a chore to make sure that data from a particular trial gets entered into the corresponding laptop with its unique login ritual and data capture form, so Bob experiences much frustration in dealing with this unwieldy set of systems. Bob is a conscientious employee, and stays current in his  
210 work. But in many other sites the data entry person holds the CRF for a period of time before entering the data, perhaps entering data twice a month, or entering the data the week before the monitor visit occurs.

## 5.5 Desired State

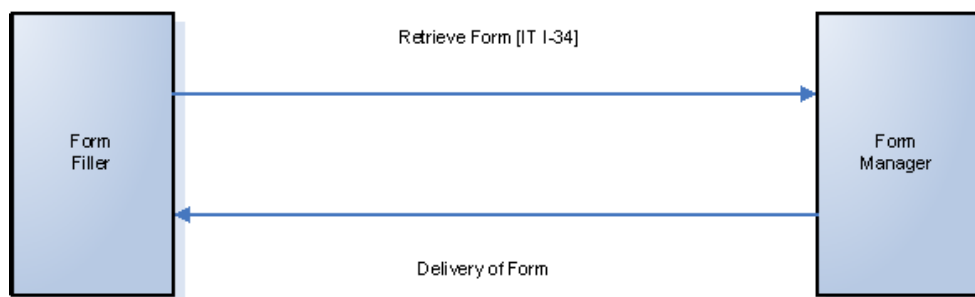
215 Mrs. Jones arrives for a visit and Patricia logs into the EHR, pulls up Mrs. Jones's record, and identifies the scheduled clinical trial visit. Because of the patient identification and scheduling steps that took place in the set-up stage, the EHR recognizes Mrs. Jones as a subject in Trial 1234, and requests an electronic case report form from trial #1234's, using RFD. If the trial is sufficiently complex, the retrieved form may contain a list of relevant forms from the RFD Forms Manager system from which Patricia may choose. Patricia selects the appropriate form, 220 the EHR checks Patricia's credentials, confirms that she is empowered to view the form, and displays the form. (The data capture form is essentially the same form that an EDC system would offer for this visit, and its presentation may take on some of the look and feel of the EHR's user interface.)

225 Nurse Patricia interviews Mrs. Jones and enters data into the clinical trial form as presented in the EHR. The clinical site personnel will be well acquainted with the basic data collection variables\* that appear on the clinical trial form as they are consistently collected in all types/phases of clinical trials. Applicable data from the EHR database are now used to pre-populate some of the clinical trial data fields. Additional data may need to be captured interactively via the forms (which may have built-in edit checks). Upon completing the form, 230 Patricia hits the submit button, and the EHR returns the complete form to the EDC system, using RFD. A copy of the document is archived in the site clinical trial document vault as part of the permanent source record of the trial.

\*These clinical trial forms or domain modules are comprised of data collection variables identified by the Clinical Data Acquisition Standards Harmonization (CDASH) Initiative. The 235 CDASH initiative identifies data collection fields that are applicable to all clinical trials regardless of therapeutic area or phase of trial. Additional data collection fields will have been added to the CDASH collection variables to capture the required therapeutic area or required fields by the study Sponsor.

## 5.6 Actors/Transaction

240 This content profile addresses the Retrieve Form [IT I-34] transaction with the Pre-population argument between the two actors, Form Filler and Form Manager. The Form Filler can request that the Form Filler context information be used by the Form Manager in the selection and/or creation of the returned form. The sharing of content from one actor to the other is addressed by the appropriate use of IHE profiles described below, and is out of scope of this profile. The 245 [Retrieve Form for Data Capture](#) embodies the Form Filler Actor and Form Manager Actor. The sharing of content or updates from one actor to the other is addressed by the use of appropriate IHE profiles described by the 2007-2008 Trial Implementation Supplements to ITI-TF v. 4.0 specifically the Retrieve Form for Data Capture (RFD) supplement.



250 **Clinical Research Data Capture Actor Diagram**

## 5.7 Grouping

### 5.7.1 Content Bindings with RFD

255 The Retrieve Form for Data Capture Profile (RFD) provides a method for gathering data within a user’s current application to meet the requirements of an external system. RFD supports the retrieval of forms by a Form Filler from a Form Manager optionally using prepopulation data sent from the Form Filler and then further describes display and completion of a form, and return of instance data from the Form Filler to the Form Receiver as well as optionally to a Form Archiver. This content profile will be bound to the prepopulation data transaction described in RFD.

260 For more details on these profiles, see the [IHE IT Infrastructure Technical Framework](#).

Content profiles may impose additional requirements on the transactions used when grouped with actors from other IHE Profiles.

### 5.7.2 Options

Clinical Research Data Capture Options	
Actor	Option <sup>(1)</sup>
Form Filler	CCD Option ODM/CDASH Option
Form Manager	CCD Option ODM/CDASH Option

Note <sup>1</sup>: Each Actor shall support at least one of these options.

### 265 5.7.3 Form Filler Options

#### 5.7.3.1 CCD Option

This option defines that the Form Filler can produce a valid CCD as content for the prepopulation data transaction as defined in RFD. This valid CCD will be further constrained in volume 2 of this profile.

270 **5.7.3.2 ODM/CDASH Option**

This option defines that the Form Filler can produce a valid CDASH encoded ODM as content for the prepopulation data transaction as defined in RFD.

**5.7.4 Form Manager Options**

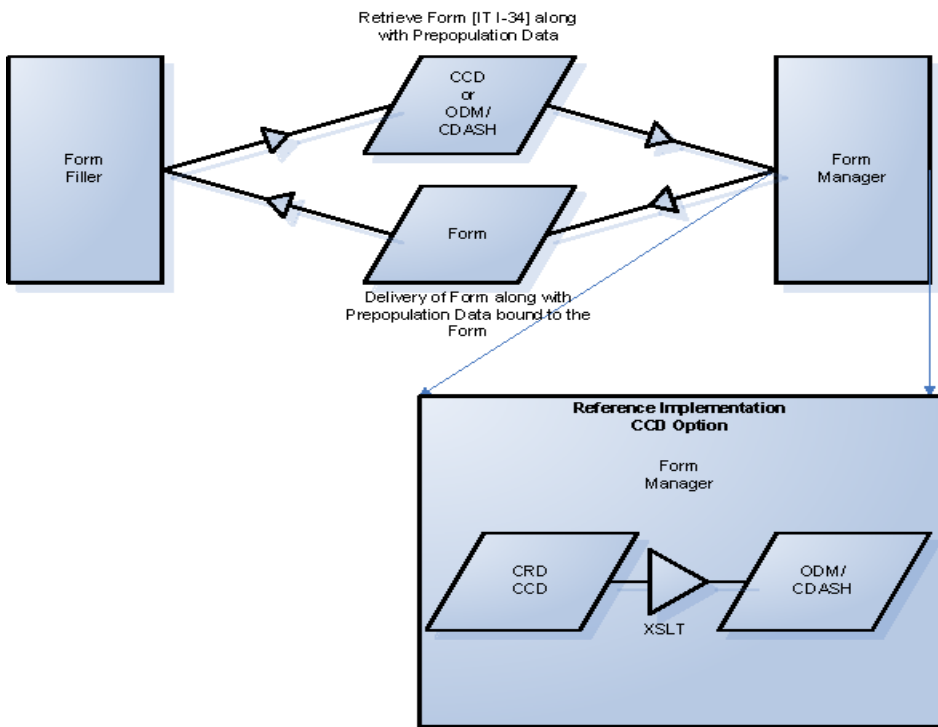
**5.7.4.1 CCD Option**

275 This option defines that the Form Manager can receive a valid CCD as content for the prepopulation data transaction as defined in RFD. This valid CCD will be further constrained in volume 2 of this profile. Note the reference implementation that then supports conversion of this CCD into ODM/CDASH.

**5.7.4.2 ODM/CDASH Option**

280 This option defines that the Form Manager can receive a valid CDASH encoded ODM as content for the prepopulation data transaction as defined in RFD. Note the reference implementation will not apply to this option as no transform is needed.

**5.7.5 Process Flow**



285 **Clinical Research Data Capture Process Flow for CCD Option**

In this Process Flow, the Form Filler knows which form it wants to retrieve from the Form Manager. In addition the Form Filler wants to send the prepopulation data for this form.

290 **CCD Option:** The CRD Profile in addition to the CCD option requires that this prepopulation data conform to the Clinical Research CCD. This CCD option requires the Form Manager to accept the Clinical Research CCD format. Inside the Form Manager there is a reference implementation (see section below) that then describes how the Form Manager could transform this Clinical Research CCD into Standard CRF.

295 **ODM/CDASH Option:** The CRD Profile in addition to the **ODM/CDASH option** requires that this prepopulation data conform to the Clinical Research ODM/CDASH. This ODM/CDASH option requires the Form Manager to accept the Clinical Research ODM/CDASH format.

The final step in this flow requires that the data that was sent to the Form Manager is then bound to the form and returned to the Form Filler.

### 5.7.6 Actor Definitions

300 The following definitions are reproduced for convenience from the RFD profile. All definitions can be found in the Information Technology Infrastructure (ITI) Domain Technical Framework, Retrieve Form for Data Capture (RFD), Trial Implementation Version, August 15, 2007.<sup>1</sup>

#### 5.7.6.1 Form Manager

The Form Manager actor provides the store of forms ready for use by a Form Filler..(17.2.1.1)

#### 5.7.6.2 Form Filler

305 The Form Filler actor retrieves forms from a Form Manager as and when required. When requesting a form, the Form Filler actor can optionally provide context information by providing pre-population xml data in the request for use by the Form Manager. The Form Filler may also specify a Form Archiver actor. The Form Archiver actor specified by the Form Filler is in addition to any Form Archiver actors specified by the Form Manager. (Section 17.2.1.2)

#### 310 5.7.6.3 Form Archiver

The Form Archiver actor receives completed or partially completed forms instance data and stores these for archival purposes. (17.2.1.4)

### 5.7.7 Transaction Definitions

#### 5.7.7.1 Retrieve Form

315 The Retrieve Form transaction carries the form identifier from a Form Filler to a Form Manager. The transaction also allows a Form Filler to optionally specify a Form Archiver actor as well as optionally containing context information in the form of xml data to be used in the selection and pre-population of the requested form prior to the form being returned to the Form Filler.

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<sup>1</sup> Retrieve Form for Data Capture Profile is available at: [ftp://ftp.ihe.net/IT\\_Infrastructure/iheitiyr5-2007-2008/Technical\\_Cmte/Profile\\_Work/RFD/IHE\\_ITI\\_TF\\_Supplement\\_RFD\\_TI\\_080207\\_noTracking.doc](ftp://ftp.ihe.net/IT_Infrastructure/iheitiyr5-2007-2008/Technical_Cmte/Profile_Work/RFD/IHE_ITI_TF_Supplement_RFD_TI_080207_noTracking.doc)

320

## Volume II - Transactions

### 5.8 Clinical Research Data Capture Content

#### 5.8.1 Standards

[CDAR2](#) – Clinical Document Architecture, Release 2, 2005 [HL7](#)

**Comment [LAS1]:** Editor: I tried this link and it appears invalid, so please check and replace with correct link

325 [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)

[ODM](#) – Operational Data Model Final Version 1.3

[CDASH](#) – Clinical Data Acquisition Standards Harmonization (Currently draft to be final September 2008. All assumptions about CDASH must be confirmed with the final version.)

#### 330 5.8.2 Data Element Index

CDASH has defined domains and elements within these domains. The Clinical Research CCD described below overlays these domains. This Data Element Index is an attempt to describe which sections are intended to cover which domains.

Clinical Research Data Capture Data Elements	
CDASH Domains	CCD Reference
Demography	CCD Header Information
Medical History	Active Problems, Past Medical History, and Procedures and Interventions
Concomitant Medication	Current Medications
Substance Use	Social History
Vital Signs	Vital Signs
Physical Exam	Physical Exam
Adverse Events	Allergies
Lab Test Results	Coded Results
ECG Test Results	Coded Results

#### 5.8.3 Document Specification (CCD Option)

335 Use this specification if the CCD Option has been chosen.

*Form Manager Actors can refer to the Reference Implementation below that outlines conversion of this CCD option into a standard case report form (Standard CRF) consisting of ODM and CDASH.*

Clinical Research Data Capture Constraints (CCD Option) <sup>2</sup>		
Data Element	Optionality	Template ID
Date of Birth	R	patientRole/patient/birthTime
Gender	R	patientRole/patient/administrativeGenderCode
Ethnicity	O	patientRole/patient/ethnicGroupCode
Race	R2	patientRole/patient/raceCode
Active Problems	R	<a href="#">1.3.6.1.4.1.19376.1.5.3.1.3.6</a>
Past Medical History	R2	<a href="#">1.3.6.1.4.1.19376.1.5.3.1.3.8</a>
Procedures and Interventions	R2	<a href="#">1.3.6.1.4.1.19376.1.5.3.1.1.13.2.11</a>
Social History	R2	<a href="#">1.3.6.1.4.1.19376.1.5.3.1.3.16</a>
Current Medications	R	<a href="#">1.3.6.1.4.1.19376.1.5.3.1.3.19</a>
Vital Signs	R2	<a href="#">1.3.6.1.4.1.19376.1.5.3.1.1.5.3.2</a>
Physical Exam	R2	<a href="#">1.3.6.1.4.1.19376.1.5.3.1.1.9.15</a>
Allergies and Other Adverse Reactions	R	<a href="#">1.3.6.1.4.1.19376.1.5.3.1.3.13</a>
Coded Results	R2	<a href="#">1.3.6.1.4.1.19376.1.5.3.1.3.28</a>

340

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

### 5.8.3.1 Header Sample

In order to ensure sufficient coverage to the Demography Domain within CDASH there are some constraints that have been applied to the Clinical Research CCD header. Specifically the Birthdate, Sex, Ethnicity, and Race are specified.

345 <recordTarget>  
 <patientRole classCode="PAT">  
 <id root="27143B24-E580-4F47-9405-3D0DC2BF1223" extension="1022"/>  
 <addr>

<sup>2</sup> PCC Template Identifiers, Integrating the Healthcare Enterprise (IHE) Patient Care Coordination (PCC) Domain Vocabulary Registry and Data Dictionary, available at [http://wiki.ihe.net/index.php?title=PCC\\_Vocabulary\\_Registry\\_and\\_Data\\_Dictionary](http://wiki.ihe.net/index.php?title=PCC_Vocabulary_Registry_and_Data_Dictionary)

```

350     <streetAddressLine/>
        <city/>
        <state>FM</state>
        <postalCode/>
        <country>Canada</country>
    </addr>
355 <telecom nullFlavor="UNK" use="HP" />
    <patient classCode="PSN" determinerCode="INSTANCE">
        <name>
            <prefix/>
            <given>Christine</given>
360     <family>Smith</family>
            <suffix/>
        </name>
        <ethnicGroupCode code="364699009" displayName="ethnic group"
            codeSystem="2.16.840.1.113883.6.96" codeSystemName="SNOMED CT" />
365     <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>
370 <providerOrganization classCode="ORG" determinerCode="INSTANCE">
    <id root="2.16.840.1.113883.19.5" />
    </providerOrganization>
</patientRole>
</recordTarget>
375 5.8.3.2 Active Problems Sample (1.3.6.1.4.1.19376.1.5.3.1.3.6)
<component>
    <section>
        <templateId root='2.16.840.1.113883.10.20.1.11' />
        <templateId root='1.3.6.1.4.1.19376.1.5.3.1.3.6' />
380     <id root=' ' extension=' ' />
        <code code='11450-4' displayName='PROBLEM LIST'
            codeSystem='2.16.840.1.113883.6.1' codeSystemName='LOINC' />
        <text>
            Text as described above
385     </text>

```

```

390     <entry>
        :
        <!-- Required Problem Concern Entry element -->
        <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.5.2' />
        :
    </entry>

</section>
</component>
395 5.8.3.3 Past Medical History Sample (1.3.6.1.4.1.19376.1.5.3.1.3.8)
<component>
    <section>
        <templateId root='1.3.6.1.4.1.19376.1.5.3.1.3.8' />
        <id root=' ' extension=' ' />
400     <code code='11348-0' displayName='HISTORY OF PAST ILLNESS'
        codeSystem='2.16.840.1.113883.6.1' codeSystemName='LOINC' />
        <text>
            Text as described above
        </text>
405     <entry>
        :
        <!-- Required Problem Concern Entry element -->
        <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.5.2' />
        :
410     </entry>

    </section>
</component>
5.8.3.4 Procedures and Interventions Sample (1.3.6.1.4.1.19376.1.5.3.1.1.13.2.11)
415 <component>
    <section>
        <templateId root='1.3.6.1.4.1.19376.1.5.3.1.1.13.2.11' />
        <id root=' ' extension=' ' />
        <code code='X-PROC' displayName='PROCEDURES PERFORMED'
420         codeSystem='2.16.840.1.113883.6.1' codeSystemName='LOINC' />
        <text>

```

```

    Text as described above
  </text>
  <entry>
425   Required and optional entries as described above
    </entry>

  </section>
</component>

430 5.8.3.5 Social History Sample (1.3.6.1.4.1.19376.1.5.3.1.3.16)
<component>
  <section>
    <templateId root='2.16.840.1.113883.10.20.1.15' />
    <templateId root='1.3.6.1.4.1.19376.1.5.3.1.3.16' />
435   <id root=' ' extension=' ' />
    <code code='29762-2' displayName='SOCIAL HISTORY'
      codeSystem='2.16.840.1.113883.6.1' codeSystemName='LOINC' />
    <text>
      Text as described above
440   </text>

  </section>
</component>

5.8.3.6 Current Medications Sample (1.3.6.1.4.1.19376.1.5.3.1.3.19)
445 <component>
  <section>   <templateId root='2.16.840.1.113883.10.20.1.8' />
    <templateId root='1.3.6.1.4.1.19376.1.5.3.1.3.19' />
    <id root=' ' extension=' ' />
    <code code='10160-0' displayName='HISTORY OF MEDICATION USE'
450     codeSystem='2.16.840.1.113883.6.1' codeSystemName='LOINC' />
    <text>
      Text as described above
    </text>
    <entry>
455     :
      <!-- Required Medications element -->
      <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.7' />

```

```

        :
    </entry>
460
    </section>
</component>

5.8.3.7 Vital Signs Sample (1.3.6.1.4.1.19376.1.5.3.1.1.5.3.2)
<component>
465   <section>
       <templateId root='1.3.6.1.4.1.19376.1.5.3.1.3.25' />
       <templateId root='1.3.6.1.4.1.19376.1.5.3.1.1.5.3.2' />
       <id root=' ' extension=' ' />
       <code code='8716-3' displayName='VITAL SIGNS'
470         codeSystem='2.16.840.1.113883.6.1' codeSystemName='LOINC' />
       <text>
         Text as described above
       </text>
       <entry>
475         :
         <!-- Required Vital Signs Organizer element -->
         <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.13.1' />
         :
       </entry>
480
     </section>
  </component>

```

**5.8.3.8 Physical Exam Sample ([1.3.6.1.4.1.19376.1.5.3.1.1.9.15](#))**

```

<component>
485   <section>
       <templateId root='1.3.6.1.4.1.19376.1.5.3.1.3.24' />
       <templateId root='1.3.6.1.4.1.19376.1.5.3.1.1.9.15' />
       <id root=' ' extension=' ' />
       <code code='29545-1' displayName='PHYSICAL EXAMINATION'
490         codeSystem='2.16.840.1.113883.6.1' codeSystemName='LOINC' />
       <text>
         Text as described above
       </text>

```

```
495 <component>
    <section>
      <templateId root='1.3.6.1.4.1.19376.1.5.3.1.3.25' />
      <!-- Optional Vital Signs Section content -->
    </section>
  </component>
500 <component>
    <section>
      <templateId root='1.3.6.1.4.1.19376.1.5.3.1.1.9.16' />
      <!-- Optional General Appearance Section content -->
    </section>
505 </component>
    <component>
      <section>
        <templateId root='1.3.6.1.4.1.19376.1.5.3.1.1.9.48' />
        <!-- Optional Visible Implanted Medical Devices Section content -->
510 </section>
      </component>
      <component>
        <section>
          <templateId root='1.3.6.1.4.1.19376.1.5.3.1.1.9.17' />
515 <!-- Optional Integumentary System Section content -->
        </section>
      </component>
      <component>
        <section>
          <templateId root='1.3.6.1.4.1.19376.1.5.3.1.1.9.18' />
520 <!-- Optional Head Section content -->
        </section>
      </component>
      <component>
525 <section>
        <templateId root='1.3.6.1.4.1.19376.1.5.3.1.1.9.19' />
        <!-- Optional Eyes Section content -->
      </section>
    </component>
530 </component>
```

```

    <section>
      <templateId root='1.3.6.1.4.1.19376.1.5.3.1.1.9.20' />
      <!-- Optional Ears, Nose, Mouth and Throat Section content -->
    </section>
535 </component>
    <component>
      <section>
        <templateId root='1.3.6.1.4.1.19376.1.5.3.1.1.9.21' />
        <!-- Optional Ears Section content -->
540 </section>
      </component>
    <component>
      <section>
        <templateId root='1.3.6.1.4.1.19376.1.5.3.1.1.9.22' />
545 <!-- Optional Nose Section content -->
      </section>
    </component>
    <component>
      <section>
550 <templateId root='1.3.6.1.4.1.19376.1.5.3.1.1.9.23' />
        <!-- Optional Mouth, Throat, and Teeth Section content -->
      </section>
    </component>
    <component>
555 <section>
      <templateId root='1.3.6.1.4.1.19376.1.5.3.1.1.9.24' />
      <!-- Optional Neck Section content -->
    </section>
  </component>
560 <component>
    <section>
      <templateId root='1.3.6.1.4.1.19376.1.5.3.1.1.9.25' />
      <!-- Optional Endocrine System Section content -->
    </section>
565 </component>
  </component>
  <component>
    <section>

```

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```
570     <templateId root='1.3.6.1.4.1.19376.1.5.3.1.1.9.26' />
        <!-- Optional Thorax and Lungs Section content -->
    </section>
</component>
<component>
    <section>
        <templateId root='1.3.6.1.4.1.19376.1.5.3.1.1.9.27' />
575     <!-- Optional Chest Wall Section content -->
    </section>
</component>
<component>
    <section>
580     <templateId root='1.3.6.1.4.1.19376.1.5.3.1.1.9.28' />
        <!-- Optional Breasts Section content -->
    </section>
</component>
<component>
585     <section>
        <templateId root='1.3.6.1.4.1.19376.1.5.3.1.1.9.29' />
        <!-- Optional Heart Section content -->
    </section>
</component>
590 <component>
    <section>
        <templateId root='1.3.6.1.4.1.19376.1.5.3.1.1.9.30' />
        <!-- Optional Respiratory System Section content -->
    </section>
595 </component>
<component>
    <section>
        <templateId root='1.3.6.1.4.1.19376.1.5.3.1.1.9.31' />
        <!-- Optional Abdomen Section content -->
600 </section>
</component>
<component>
    <section>
        <templateId root='1.3.6.1.4.1.19376.1.5.3.1.1.9.32' />
```

```

605     <!-- Optional Lymphatic System Section content -->
        </section>
    </component>
    <component>
        <section>
610         <templateId root='1.3.6.1.4.1.19376.1.5.3.1.1.9.34' />
            <!-- Optional Musculoskeletal System Section content -->
        </section>
    </component>
    <component>
615     <section>
        <templateId root='1.3.6.1.4.1.19376.1.5.3.1.1.9.35' />
        <!-- Optional Neurologic System Section content -->
    </section>
</component>
620 <component>
    <section>
        <templateId root='1.3.6.1.4.1.19376.1.5.3.1.1.9.36' />
        <!-- Optional Genitalia Section content -->
    </section>
625 </component>
    <component>
        <section>
            <templateId root='1.3.6.1.4.1.19376.1.5.3.1.1.9.37' />
            <!-- Optional Rectum Section content -->
630 </section>
        </component>

```

```

</section>
</component>

```

635 **5.8.3.9 Allergies and Other Adverse Reactions Sample**  
[\(1.3.6.1.4.1.19376.1.5.3.1.3.13\)](#)

```

<component>
    <section>
        <templateId root='2.16.840.1.113883.10.20.1.2' />
640 <templateId root='1.3.6.1.4.1.19376.1.5.3.1.3.13' />
    </section>
</component>

```

```

        <id root=' ' extension=' '/>
        <code code='48765-2' displayName='Allergies, adverse reactions, alerts'
          codeSystem='2.16.840.1.113883.6.1' codeSystemName='LOINC' />
        <text>
645     Text as described above
        </text>
        <entry>
          :
          <!-- Required Allergies and Intolerances Concern element -->
650     <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.5.3' />
          :
        </entry>

      </section>
655 </component>

```

**5.8.3.10 Coded Results Sample ([1.3.6.1.4.1.19376.1.5.3.1.3.28](#))**

```

<component>
  <section>
    <templateId root='1.3.6.1.4.1.19376.1.5.3.1.3.28' />
660 <id root=' ' extension=' '/>
    <code code='30954-2' displayName='STUDIES SUMMARY'
      codeSystem='2.16.840.1.113883.6.1' codeSystemName='LOINC' />
    <text>
665     Text as described above
    </text>
    <entry>
      :
      <!-- Required Procedure Entry element -->
670     <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.16' />
      :
    </entry>
    <entry>
      :
      <!-- Required if known References Entry element -->
675     <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.4' />
      :

```

&lt;/entry&gt;

&lt;/section&gt;

680 &lt;/component&gt;

#### 5.8.4 Document Specification (ODM/CDASH Option)

Use this specification if the ODM/CDASH Option has been chosen.

Clinical Research Data Capture Constraints (CDASH Option)			
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.
Demography	BRTHYR	R	Year of subject's birth.
	BRTHMO	R	Month of subject's birth.
	BRTHDY	R2	Day of subject's birth.
	BRHTM	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.
	DMDTC	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.
Subject Characteristics	SCDTC	R2	Date of collection.
	SCTM (Note: If collected, will be derived into SCDTC.)	O	Time of collection.

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Clinical Research Data Capture Constraints (CDASH Option)			
CDASH Domain	Clinical Database Variable Name	Optionality	Definition
		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.
Medical History	MHTERM	R	Verbatim or preprinted CRF term for the medical condition or event.
	MHONG	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.
Concomitant Medication	CMYN	O	General prompt question to aid in monitoring and data cleaning.
	CMSPID	O	A sponsor-defined reference number.
	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

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Clinical Research Data Capture Constraints (CDASH Option)			
CDASH Domain	Clinical Database Variable Name	Optionality	Definition
			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.
	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.
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	O	Time substance use started.

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Clinical Research Data Capture Constraints (CDASH Option)			
CDASH Domain	Clinical Database Variable Name	Optionality	Definition
	derived into SUSTDTC.)		
	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	VSDTC	R2	Date of measurements
	VSSPID	O	Sponsor defined reference number
	VISITDY	O	Study day of measurements, measured as integer days
	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 - 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.

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Clinical Research Data Capture Constraints (CDASH Option)			
CDASH Domain	Clinical Database Variable Name	Optionality	Definition
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.
	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.
	AESEV And/or AETOXGR	R2	Description of the severity of the adverse event.
	AEREL	R2	Indication of whether the investigational product had a

IHE QRPH Technical Framework Supplement – Clinical Research Data Capture (CRD)

Clinical Research Data Capture Constraints (CDASH Option)			
CDASH Domain	Clinical Database Variable Name	Optionality	Definition
			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)
	AEOU	R2	Description of the subject's status associated with an event.
Lab Test Results - Scenario 1: Central processing	LBDMC	R	Date of sample collection.
	LBDM (Note: If collected, will be derived into LBDMC.)	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.
	LBTP	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	LBDMC	R	Date of sample collection.
	LBDM (Note: If collected, will be derived into LBDMC.)	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.
	LBTP	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.

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Clinical Research Data Capture Constraints (CDASH Option)			
CDASH Domain	Clinical Database Variable Name	Optionality	Definition
	LBORRESU	R	Original units in which the data were collected.
	LBORNRL0 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...	LBDMC	R	Date of sample collection.
	LBDM (Note: If collected, will be derived into LBDMC.)	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.
	LBTP	R2	Relative time for use when multiple sequential assessments are done,
	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.
ECG Test Results - Scenario 1: Central reading...	LBDMC	R	Date of sample collection.
	LBDM (Note: If collected, will be	O	Time of collection.

IHE QRPH Technical Framework Supplement – Clinical Research Data Capture (CRD)

Clinical Research Data Capture Constraints (CDASH Option)			
CDASH Domain	Clinical Database Variable Name	Optionality	Definition
	derived into LBDTC.)		
	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.
	LBTPPT	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.
	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 (as in Scenario 1): But...	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).

Clinical Research Data Capture Constraints (CDASH Option)			
CDASH Domain	Clinical Database Variable Name	Optionality	Definition
	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.
	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

5.8.4.1 ODM Version 1.1 Sample <http://cdisc.org/models/odm/v1.1/odm1-1-0-example.xml>

Comment [LAS2]: Editor: This link is broken

```
<?xml version="1.0" encoding="ISO-8859-1"?>
<!DOCTYPE ODM SYSTEM "odm1-1-0.dtd" >
<!--
    This XML Example is intended to provide a very small, valid example of
    a CDISC study using CDISC ODM V1.1
-->
<!--
    In this small example study, a pharmaceutical company is conducting a
    Phase II initial efficacy study. This pharmaceutical company
    ("The Pharm") has hired a contract research organization (CRO) to
    collect, clean and complete data for this study. The Pharm and the CRO
    use completely different clinical data management systems, so the 2
    companies have agreed to use CDISC'S ODM V1.1 for their data exchange.

    The data are coming in slowly and only the CRF pages from the first two
    visits for two patients have been returned from the investigational site
    to the CRO so far. During the first visit, both demographic and vital
    statistics data are collected. During the second visit, only vital
    statistics are collected. The data from the first patient's first visit
    included an incorrect systolic blood pressure. The incorrect value was
    changed to the correct value in a separate data entry session, and this
    change was captured in the audit trail of the clinical data management
    system.
-->
```

## IHE QRPH Technical Framework Supplement – Clinical Research Data Capture (CRD)

```
<ODM FileType="Transactional" FileOID="987-654-321" CreationDateTime="2001-11-15T16:37:21-05:00"
AsOfDateTime="2001-11-15T16:37:21-05:00" Description="Two visits for patients P001 and P027, plus updates
of data for P001" Granularity="All">
```

```
<Study OID="123-456-789">
  <GlobalVariables>
    <StudyName>HarrisonA</StudyName>
    <StudyDescription>Phase II initial efficacy</StudyDescription>
    <ProtocolName>B00-2136</ProtocolName>
  </GlobalVariables>
  <BasicDefinitions/>
  <!-- Beginning of metadata definitions . . . -->
  <MetaDataVersion OID="MetaDataVersion.001" Name="Release 1">
    <Protocol>
      <!--There are 2 study events defined, corresponding to Visit 1 and Visit 2. On "Demog and
Vitals:", signing unit is used, while on Visit 2, the "Vitals Only" is used
-->
      <StudyEventRef StudyEventOID="VISIT_1" Mandatory="Yes"/>
      <StudyEventRef StudyEventOID="VISIT_2" Mandatory="Yes"/>
    </Protocol>
    <StudyEventDef OID="VISIT_1" Name="Visit1" Repeating="No" Type="Scheduled">
      <FormRef FormOID="PAGE_1" Mandatory="No"/>
    </StudyEventDef>
    <StudyEventDef OID="VISIT_2" Name="Visit2" Repeating="No" Type="Scheduled">
      <FormRef FormOID="PAGE_2" Mandatory="No"/>
    </StudyEventDef>
    <!--There are 2 signing units defined: one to collect demographics AND vitals and one to collect just
vitals.
-->
```

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```
<FormDef OID="PAGE_1" Name="Demog and Vitals" Repeating="No">
  <ItemGroupRef ItemGroupOID="DEMOG" Mandatory="No"/>
  <ItemGroupRef ItemGroupOID="VITALS" Mandatory="No"/>
</FormDef>
<FormDef OID="PAGE_2" Name="Vitals Only" Repeating="No">
  <ItemGroupRef ItemGroupOID="VITALS" Mandatory="No"/>
</FormDef>
<!--There are 2 item groups (ItemGroups): Demographics and Vitals
-->
<!--The demographics item group contains 7 item references (ItemRef) corresponding to Patient ID,
Patient Initials, Sex, Date of Birth, Sponsor Patient ID, Weight (lb) and Weight (kg)-->
<ItemGroupDef OID="DEMOG" Name="Demographics" Repeating="Yes" IsReferenceData="No"
SASDatasetName="DEMOG">
  <ItemRef ItemOID="PT" Mandatory="No"/>
  <ItemRef ItemOID="INITIALS" Mandatory="No"/>
  <ItemRef ItemOID="SEX" Mandatory="No"/>
  <ItemRef ItemOID="DOB" Mandatory="No"/>
  <ItemRef ItemOID="SPONSOR_PTID" Mandatory="No"/>
  <ItemRef ItemOID="WEIGHT_LB" Mandatory="No"/>
  <ItemRef ItemOID="WEIGHT_KG" Mandatory="No"/>
</ItemGroupDef>
<!--The Vitals item group contains 6 item references (ItemRef) corresponding to the Patient ID, Visit
Name, Systolic Blood Pressure, Diastolic Blood Pressure, Sponsor Patient ID, and Occurrence Number (of
repeat measurement).-->
<ItemGroupDef OID="VITALS" Name="Vital Signs" Repeating="Yes" IsReferenceData="No"
SASDatasetName="VITALS">
  <ItemRef ItemOID="PT" Mandatory="No"/>
  <ItemRef ItemOID="VISITNAME" Mandatory="No"/>
```

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```
<ItemRef ItemOID="SBP" Mandatory="No"/>
<ItemRef ItemOID="DBP" Mandatory="No"/>
<ItemRef ItemOID="SPONSOR_PTID" Mandatory="No"/>
<ItemRef ItemOID="OCCUR_NUM" Mandatory="No"/>
</ItemGroupDef>
<!--There are 12 items defined: Patient ID, Initials, Date of Birth, Sex, Systolic Blood Pressure,
Diastolic Blood Pressure, Visit Name, Sponsor Patient ID, Visit Number (not currently used), Occurrence
Number, Weight (lb) and Weight (kg).-->
<ItemDef OID="PT" Name="PT" DataType="text" Length="4" SASFieldName="PT"/>
<ItemDef OID="INITIALS" Name="Initials" DataType="text" Length="5" SASFieldName="INITIALS"/>
<ItemDef OID="DOB" Name="Date of Birth" DataType="date" SASFieldName="DOB"/>
<ItemDef OID="SEX" Name="Sex" DataType="text" Length="1" SASFieldName="SEX">
  <CodeListRef CodeListOID="CodeList.001"/>
</ItemDef>
<ItemDef OID="SBP" Name="Systolic Blood Pressure" DataType="integer" SASFieldName="SBP" Length="3"/>
<ItemDef OID="DBP" Name="Diastolic Blood Pressure" DataType="integer" SASFieldName="DBP" Length="3"/>
<ItemDef OID="VISITNAME" Name="Visit" DataType="text" Length="20" SASFieldName="VISNAME"/>
<ItemDef OID="SPONSOR_PTID" Name="Sponsor Patient ID" DataType="text" Length="12"
SASFieldName="SPONPTID"/>
<ItemDef OID="VISITNUM" Name="Numeric Version of Visit" DataType="integer" SASFieldName="VISITNUM"
Length="2"/>
<ItemDef OID="OCCUR_NUM" Name="Occurence Number" DataType="integer" SASFieldName="OCCURNUM"
Length="2"/>
<ItemDef OID="WEIGHT_LB" Name="Weight in pounds" DataType="float" SASFieldName="WEIGHTLB" Length="4"
SignificantDigits="1"/>
<ItemDef OID="WEIGHT_KG" Name="Weight in kilograms " DataType="float" SASFieldName="WEIGHTKG"
Length="4" SignificantDigits="1"/>
<!--There is a single codelist for Sex with entries for "m" and "f".-->
<CodeList OID="CodeList.001" Name="Sex" DataType="text" SASFormatName="CLSEX">
```

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```
<CodeListItem CodedValue="m">
  <Decode>
    <TranslatedText xml:lang="en">Male</TranslatedText>
  </Decode>
</CodeListItem>
<CodeListItem CodedValue="f">
  <Decode>
    <TranslatedText xml:lang="en">Female</TranslatedText>
  </Decode>
</CodeListItem>
</CodeList>
<!--Since structure and content of Presentation have not yet been defined, we have inserted an empty
Presentation element.-->
  <Presentation OID="" />
</MetaDataVersion>
</Study>
<!--Beginning of Administrative Data-->
<AdminData>
  <!--There are 2 users: John Doe (the investigator) and Mary Brown (the data entry person)-->
  <User OID="User.001">
    <FirstName>John</FirstName>
    <LastName>Doe</LastName>
  </User>
  <User OID="User.002">
    <FirstName>Mary</FirstName>
    <LastName>Brown</LastName>
  </User>
```

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```
<!--There is 1 location: General Hospital (a site).-->
<Location OID="Location.001" Name="General Hospital" LocationType="Site">
  <MetaDataVersionRef StudyOID="123-456-789" MetaDataVersionOID="MetaDataVersion.001"
EffectiveDate="2001-10-19T10:45:57-05:00"/>
</Location>
<!--There is one signature definition (electronic signature for data entry)
-->
<SignatureDef OID="SignatureDef.001" Methodology="Electronic">
  <Meaning>Entry</Meaning>
  <LegalReason>Signer accepts responsibility for initial data entry</LegalReason>
</SignatureDef>
</AdminData>
<!--Beginning of Clinical Data-->
<ClinicalData StudyOID="123-456-789" MetaDataVersionOID="MetaDataVersion.001">
  <!-- SubjectData element for the first of 2 patients in this example -->
  <SubjectData SubjectKey="P001" TransactionType="Insert">
    <!-- EventData element for Visit 1 for this patient -->
    <StudyEventData StudyEventOID="VISIT_1">
      <!-- FormData element for the DEMOG and Vitals form collected on Visit 1 (Original) -->
      <FormData FormOID="PAGE_1">
        <AuditRecord>
          <UserRef UserOID="User.002"/>
          <LocationRef LocationOID="Location.001"/>
          <DateTimeStamp>2001-05-31-T10:08:40-05:00</DateTimeStamp>
        </AuditRecord>
        <!-- Electronic signature for this form -->
        <Signature>
```

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```
<UserRef UserOID="User.001"/>
<LocationRef LocationOID="Location.001"/>
<SignatureRef SignatureOID="SignatureDef.001"/>
<DateTimeStamp>2001-05-30T10:06:32-05:00</DateTimeStamp>
</Signature>
<!-- ItemGroupData element for the Demographics part of the form -->
<ItemGroupData ItemGroupOID="DEMOG" ItemGroupRepeatKey="1">
  <ItemData ItemOID="PT" Value="P001"/>
  <ItemData ItemOID="INITIALS" Value="AMH"/>
  <ItemData ItemOID="SEX" Value="f"/>
  <ItemData ItemOID="DOB" Value="1947-07-16"/>
  <ItemData ItemOID="SPONSOR_PTID" Value="B00-2136-001"/>
  <ItemData ItemOID="WEIGHT_LB" Value="150"/>
  <ItemData ItemOID="WEIGHT_KG" Value="68.18"/>
  <!-- ItemGroupData element for the Vitals part of the form -->
</ItemGroupData>
<ItemGroupData ItemGroupOID="VITALS" ItemGroupRepeatKey="">
  <ItemData ItemOID="PT" Value="P001"/>
  <ItemData ItemOID="VISITNAME" Value="Visit1"/>
  <ItemData ItemOID="SBP" Value="120"/>
  <ItemData ItemOID="DBP" Value="80"/>
  <ItemData ItemOID="SPONSOR_PTID" Value="B00-2136-001"/>
  <ItemData ItemOID="OCCUR_NUM" Value="1"/>
</ItemGroupData>
</FormData>
<!-- FormData element for the Vitals form collected on Visit 1 (Modified) -->
```

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```
</StudyEventData>
<!-- StudyEventData element for Visit 2 for the patient -->
<StudyEventData StudyEventOID="VISIT_2">
  <!-- FormData element for the Vitals only form collected on Visit 2 -->
  <FormData FormOID="PAGE_2">
    <AuditRecord>
      <UserRef UserOID="User.002"/>
      <LocationRef LocationOID="Location.001"/>
      <DateTimeStamp>2001-05-31T9:06:45-05:00</DateTimeStamp>
    </AuditRecord>
    <!-- Electronic signature for this form -->
    <Signature>
      <UserRef UserOID="User.001"/>
      <LocationRef LocationOID="Location.001"/>
      <SignatureRef SignatureOID="SignatureDef.001"/>
      <DateTimeStamp>2001-05-30T10:06:32-05:00</DateTimeStamp>
    </Signature>
    <!-- Data for 3 repeats of Vitals item group on this form -->
    <ItemGroupData ItemGroupOID="VITALS" ItemGroupRepeatKey="1">
      <ItemData ItemOID="PT" Value="P001"/>
      <ItemData ItemOID="VISITNAME" Value="Visit2"/>
      <ItemData ItemOID="SBP" Value="130"/>
      <ItemData ItemOID="DBP" Value="90"/>
      <ItemData ItemOID="SPONSOR_PTID" Value="B00-2136-001"/>
      <ItemData ItemOID="OCCUR_NUM" Value="1"/>
    </ItemGroupData>
```

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```
<ItemGroupData ItemGroupOID="VITALS" ItemGroupRepeatKey="2">
  <ItemData ItemOID="PT" Value="P001"/>
  <ItemData ItemOID="VISITNAME" Value="Visit2"/>
  <ItemData ItemOID="SBP" Value="125"/>
  <ItemData ItemOID="DBP" Value="86"/>
  <ItemData ItemOID="SPONSOR_PTID" Value="B00-2136-001"/>
  <ItemData ItemOID="OCCUR_NUM" Value="2"/>
</ItemGroupData>
<ItemGroupData ItemGroupOID="VITALS" ItemGroupRepeatKey="3">
  <ItemData ItemOID="PT" Value="P001"/>
  <ItemData ItemOID="VISITNAME" Value="Visit2"/>
  <ItemData ItemOID="SBP" Value="122"/>
  <ItemData ItemOID="DBP" Value="84"/>
  <ItemData ItemOID="SPONSOR_PTID" Value="B00-2136-001"/>
  <ItemData ItemOID="OCCUR_NUM" Value="3"/>
</ItemGroupData>
</FormData>
</StudyEventData>
</SubjectData>
<SubjectData SubjectKey="P001" TransactionType="Update">
  <StudyEventData StudyEventOID="VISIT_1">
    <FormData FormOID="Page 1">
      <AuditRecord>
        <UserRef UserOID="User.002"/>
        <LocationRef LocationOID="Location.001"/>
        <DateTimeStamp>2001-05-31T08:47:07-05:00</DateTimeStamp>
      </AuditRecord>
    </FormData>
  </StudyEventData>
</SubjectData>
```

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```
<ReasonForChange>Error in initial data entry</ReasonForChange>
</AuditRecord>
<Signature>
  <UserRef UserOID="User.001" />
  <LocationRef LocationOID="Location.001" />
  <SignatureRef SignatureOID="SignatureDef.001" />
  <DateTimeStamp>2001-05-30T10:06:32-05:00</DateTimeStamp>
</Signature>
<ItemGroupData ItemGroupOID="VITALS" ItemGroupRepeatKey="1">
  <ItemData ItemOID="SBP" Value="130" />
</ItemGroupData>
</FormData>
</StudyEventData>
</SubjectData>
<SubjectData SubjectKey="P027" TransactionType="Insert">
  <!-- EventData element for Visit 1 for this patient -->
  <StudyEventData StudyEventOID="VISIT_1">
    <!-- FormData element for the DEMOG and Vitals form collected on Visit 1 (Original) -->
    <FormData FormOID="PAGE_1">
      <AuditRecord>
        <UserRef UserOID="User.002" />
        <LocationRef LocationOID="Location.001" />
        <DateTimeStamp>2001-05-31-T10:08:40-05:00</DateTimeStamp>
      </AuditRecord>
      <!-- Electronic signature for this form -->
      <Signature>
```

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```
<UserRef UserOID="User.001"/>
<LocationRef LocationOID="Location.001"/>
<SignatureRef SignatureOID="SignatureDef.001"/>
<DateTimeStamp>2001-05-30T10:06:32-05:00</DateTimeStamp>
</Signature>
<!-- ItemGroupData element for the Demographics part of the form -->
<ItemGroupData ItemGroupOID="DEMOG" ItemGroupRepeatKey="1">
  <ItemData ItemOID="PT" Value="P027"/>
  <ItemData ItemOID="INITIALS" Value="VLP"/>
  <ItemData ItemOID="SEX" Value="f"/>
  <ItemData ItemOID="DOB" Value="1944-12-20"/>
  <ItemData ItemOID="SPONSOR_PTID" Value="B00-2136-027"/>
  <ItemData ItemOID="WEIGHT_LB" Value="139"/>
  <ItemData ItemOID="WEIGHT_KG" Value="63.04"/>
  <!-- ItemGroupData element for the Vitals part of the form -->
</ItemGroupData>
<ItemGroupData ItemGroupOID="VITALS" ItemGroupRepeatKey="">
  <ItemData ItemOID="PT" Value="P027"/>
  <ItemData ItemOID="VISITNAME" Value="Visit1"/>
  <ItemData ItemOID="SBP" Value="115"/>
  <ItemData ItemOID="DBP" Value="75"/>
  <ItemData ItemOID="SPONSOR_PTID" Value="B00-2136-027"/>
  <ItemData ItemOID="OCCUR_NUM" Value="1"/>
</ItemGroupData>
</FormData>
<!-- FormData element for the Vitals form collected on Visit 1 (Modified) -->
```

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```
</StudyEventData>
<!-- StudyEventData element for Visit 2 for the patient -->
<StudyEventData StudyEventOID="VISIT_2">
  <!-- FormData element for the Vitals only form collected on Visit 2 -->
  <FormData FormOID="PAGE_2">
    <AuditRecord>
      <UserRef UserOID="User.002"/>
      <LocationRef LocationOID="Location.001"/>
      <DateTimeStamp>2001-05-31T9:06:45-05:00</DateTimeStamp>
    </AuditRecord>
    <!-- Electronic signature for this form -->
    <Signature>
      <UserRef UserOID="User.001"/>
      <LocationRef LocationOID="Location.001"/>
      <SignatureRef SignatureOID="SignatureDef.001"/>
      <DateTimeStamp>2001-05-30T10:06:32-05:00</DateTimeStamp>
    </Signature>
    <!-- Data for 3 repeats of Vitals item group on this form -->
    <ItemGroupData ItemGroupOID="VITALS" ItemGroupRepeatKey="1">
      <ItemData ItemOID="PT" Value="P027"/>
      <ItemData ItemOID="VISITNAME" Value="Visit2"/>
      <ItemData ItemOID="SBP" Value="120"/>
      <ItemData ItemOID="DBP" Value="90"/>
      <ItemData ItemOID="SPONSOR_PTID" Value="B00-2136-027"/>
      <ItemData ItemOID="OCCUR_NUM" Value="1"/>
    </ItemGroupData>
```

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```
<ItemGroupData ItemGroupOID="VITALS" ItemGroupRepeatKey="2">
  <ItemData ItemOID="PT" Value="P027"/>
  <ItemData ItemOID="VISITNAME" Value="Visit2"/>
  <ItemData ItemOID="SBP" Value="120"/>
  <ItemData ItemOID="DBP" Value="80"/>
  <ItemData ItemOID="SPONSOR_PTID" Value="B00-2136-027"/>
  <ItemData ItemOID="OCCUR_NUM" Value="2"/>
</ItemGroupData>
<ItemGroupData ItemGroupOID="VITALS" ItemGroupRepeatKey="3">
  <ItemData ItemOID="PT" Value="P027"/>
  <ItemData ItemOID="VISITNAME" Value="Visit2"/>
  <ItemData ItemOID="SBP" Value="125"/>
  <ItemData ItemOID="DBP" Value="80"/>
  <ItemData ItemOID="SPONSOR_PTID" Value="B00-2136-027"/>
  <ItemData ItemOID="OCCUR_NUM" Value="3"/>
</ItemGroupData>
</FormData>
</StudyEventData>
</SubjectData>
</ClinicalData>
</ODM>
```

### 5.8.5 Reference Implementation

#### 5.8.5.1 Clinical Research CCD to Standard CRF (ODM/CDASH) Crosswalk

This section is intended to be a guide as to how a Form Manager would crosswalk a Clinical Research CCD 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. IHE is developing processes which aren't ready at time of this publication to help maintain source control and facilitate sharing and updating of this as well as other reference transformations. When the IHE process and procedures are determined this section will refer to those documents.

### 5.8.5.2 XSLT Sample

```
<?xml version="1.0" encoding="UTF-8"?>
<!-- mapping CCD to ODM/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" exclude-result-prefixes="cda">
<xsl:output method="xml" version="1.0" encoding="UTF-8" indent="yes" omit-xml-declaration="no"/>

<xsl:template match="cda:ClinicalDocument">
  <ODM xmlns:cd="http://www.cdisc.org/ns/odm/v1.3" xmlns:ds="http://www.w3.org/2000/09/xmlsig#"
    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">
    <ClinicalData>
      <SubjectData>
        <SiteRef>
          <StudyEventData>
            <!-- ODM/CDASH.CommonIdentifiers -->
            <xsl:call-template name="demography"/>
            <!-- ODM/CDASH.SubjectCharacteristics -->
            <xsl:call-template name="medicalHistory"/>
            <xsl:call-template name="conMeds"/>
            <xsl:call-template name="substanceAbuse"/>
            <xsl:call-template name="vitalSigns"/>
            <!-- ODM/CDASH.Physical Exam -->
          
```

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```

        <xsl:call-template name="adverseEvents" />
        <xsl:call-template name="labResults" />
        <!-- ODM/CDASH.ECG results -->
    </StudyEventData>
</SiteRef>
</SubjectData>
</ClinicalData>
</ODM>
</xsl:template>

<!-- Demography -->
<xsl:template name="demography">
    <xsl:variable name="patientNode" select="cda:recordTarget/cda:patientRole/cda:patient" />
    <FormData>
        <xsl:attribute name="FormOID">DemographicsForm</xsl:attribute>
        <ItemGroupData ItemGroupOID='DM'>
            <ItemData ItemOID='SEX'>
                <xsl:attribute name="value">
                    <xsl:value-of
select="$patientNode/cda:administrativeGenderCode/@code" />
                </xsl:attribute>
            </ItemData>
            <ItemData ItemOID='BRTHDTC'>
                <xsl:choose>
                    <xsl:when test="$patientNode/cda:birthTime/@value">
                        <xsl:attribute name="value">

```

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```

                                <xsl:value-of
select="$patientNode/cda:birthTime/@value"/>
                                </xsl:attribute>
                                </xsl:when>
                                <xsl:otherwise>
                                <xsl:attribute name="nullFlavor">UNK</xsl:attribute>
                                </xsl:otherwise>
                                </xsl:choose>
</ItemData>
<ItemData ItemOID='ETHNIC'>
    <xsl:attribute name="value">
        <xsl:value-of select="$patientNode/cda:ethnicityCode/@displayName"/>
    </xsl:attribute>
</ItemData>
<ItemData ItemOID='RACE'>
    <xsl:attribute name="value">
        <xsl:value-of select="$patientNode/cda:raceCode/@displayName"/>
    </xsl:attribute>
</ItemData>
</ItemGroupData>
</FormData>
</xsl:template>

```

```

<!-- Medical History - looking for entries in any of the following CDA sections: Conditions, Past
Medical History, Procedures -->
<xsl:template name="medicalHistory">

```

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```
<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)"/>

<xsl:if test="($conditionsCount+$pmhCount+$proceduresCount)>0">
  <FormData FormOID='MedicalHistory'>
    <xsl:for-each select="$ccdConditions/cda:entry">
      <ItemGroupData ItemGroupOID='CONDITION'>
        <xsl:call-template name="problemItemData">
          <xsl:with-param name="theNode" select="."/>
        </xsl:call-template>
      </ItemGroupData>
    </xsl:for-each>
    <xsl:for-each select="$ccdPMH/cda:entry">
      <ItemGroupData ItemGroupOID='PASTCONDITION'>
        <xsl:call-template name="problemItemData">
          <xsl:with-param name="theNode" select="."/>
        </xsl:call-template>
      </ItemGroupData>
    </xsl:for-each>
    <xsl:for-each select="$ccdProcedures/cda:entry">
```

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```
        <ItemGroupData ItemGroupOID='PROCEDURE'>
            <xsl:call-template name="procedureItemData">
                <xsl:with-param name="theNode" select="."/>
            </xsl:call-template>
        </ItemGroupData>
    </xsl:for-each>
</FormData>
</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:for-each select="$ccdMedication/cda:entry">
                <xsl:variable name="originalTextRef"
select="cda:substanceAdministration/cda:consumable/cda:manufacturedProduct/cda:manufacturedMaterial/cda:code/cda:originalText/cda:reference/@value"/>
                <xsl:variable name="originalText"
select="cda:substanceAdministration/cda:consumable/cda:manufacturedProduct/cda:manufacturedMaterial/cda:code/cda:originalText"/>
                <ItemGroupData ItemGroupOID='CM'>
                    <ItemData ItemDataOID='CMTRT'>
                        <xsl:attribute name="value">
```

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```

                <xsl:choose>
                    <xsl:when test="$originalTextRef"><xsl:value-of
select="//*[@ID=substring-after($originalTextRef,'#')]" /></xsl:when>
                    <xsl:otherwise><xsl:value-of
select="$originalText" /></xsl:otherwise>
                </xsl:choose>
            </xsl:attribute>
        </ItemData>
        <!-- Need table to translate HL7 frequency, e.g., 6h to BID -->
        <xsl:variable name="routeCode"
select="cda:substanceAdministration/cda:routeCode/@displayName" />
        <xsl:if test="$routeCode">
            <ItemData ItemDataOID='CMROUTE'>
                <xsl:attribute name="value"><xsl:value-of
select="$routeCode" /></xsl:attribute>
            </ItemData>
        </xsl:if>
        <xsl:variable name="medStartDate"
select="cda:substanceAdministration/cda:effectiveTime[@xsi:type='IVL_TS']/cda:low/@value" />
        <xsl:if test="$medStartDate">
            <ItemData ItemDataOID='CMSTDTC'>
                <xsl:attribute name="value"><xsl:value-of
select="$medStartDate" /></xsl:attribute>
            </ItemData>
        </xsl:if>
        <xsl:variable name="medEndDate"
select="cda:substanceAdministration/cda:effectiveTime[@xsi:type='IVL_TS']/cda:high/@value" />
        <xsl:if test="$medEndDate">
            <ItemData ItemDataOID='CMENDDTC'>

```

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```

                                <xsl:attribute name="value"><xsl:value-of
select="$medEndDate"/></xsl:attribute>
                                </ItemData>
                                </xsl:if>
                                <xsl:variable name="medIndicationValueNode"
select="cda:substanceAdministration/cda:precondition/cda:criterion/cda:value"/>
                                <xsl:if test="$medIndicationValueNode/@displayName">
                                    <ItemData ItemDataOID='CMINDC'>
                                        <xsl:attribute name="value">
                                            <xsl:value-of
select="$medIndicationValueNode/@displayName"/>
                                        </xsl:attribute>
                                        <xsl:attribute name="xsi:type">
                                            <xsl:value-of
select="$medIndicationValueNode/@xsi:type"/>
                                        </xsl:attribute>
                                        <xsl:attribute name="code">
                                            <xsl:value-of select="$medIndicationValueNode/@code"/>
                                        </xsl:attribute>
                                        <xsl:attribute name="codeSystem">
                                            <xsl:value-of
select="$medIndicationValueNode/@codeSystem"/>
                                        </xsl:attribute>
                                    </ItemData>
                                </xsl:if>
                                <xsl:variable name="medDoseQuantity"
select="cda:substanceAdministration/cda:doseQuantity/@value"/>
                                <xsl:if test="$medDoseQuantity">
```

## IHE QRPH Technical Framework Supplement – Clinical Research Data Capture (CRD)

```
        <ItemData ItemDataOID='CMDSTXT'>
            <xsl:attribute name="value">
                <xsl:value-of select="$medDoseQuantity"/>
            </xsl:attribute>
        </ItemData>
    </xsl:if>
</ItemGroupData>
</xsl:for-each>
</FormData>
</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">
    <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">
```

IHE QRPH Technical Framework Supplement – Clinical Research Data Capture (CRD)

```
<FormData FormDataOID='VSForm'>
  <xsl:for-each select="$vitalsSection/cda:entry/cda:organizer/cda:component">
    <xsl:variable name="vitalsDateTime"
select="cda:observation/cda:effectiveTime/@value"/>
    <ItemGroupData ItemGroupDataOID='VS'>
      <ItemData ItemDataOID='VSDTC'>
        <xsl:attribute name="value">
          <xsl:value-of select="$vitalsDateTime"/>
        </xsl:attribute>
      </ItemData>
      <xsl:variable name="vitalsResultNode"
select="cda:observation/cda:value"/>
      <ItemData ItemDataOID='VSTEST'>
        <xsl:attribute name="value">
          <xsl:value-of
select="cda:observation/cda:code/@displayName"/>
        </xsl:attribute>
      </ItemData>
      <xsl:choose>
        <xsl:when test="$vitalsResultNode/@xsi:type='PQ'">
          <ItemData ItemDataOID='VSORRES'>
            <xsl:attribute name="value"><xsl:value-of
select="$vitalsResultNode/@value"/></xsl:attribute>
          </ItemData>
          <ItemData ItemDataOID='VSORRESU'>
            <xsl:attribute name="value"><xsl:value-of
select="$vitalsResultNode/@unit"/></xsl:attribute>
          </ItemData>
        </xsl:choose>
    </ItemGroupData>
  </xsl:for-each>
</FormData>
```

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```

                </xsl:when>
                <xsl:otherwise>
                    <ItemData ItemDataOID='VSORRES'><xsl:attribute
name="value"><xsl:value-of select="$vitalsResultNode"/></xsl:attribute></ItemData>
                </xsl:otherwise>
            </xsl:choose>
        </ItemGroupData>
    </xsl:for-each>
</FormData>
</xsl:if>
</xsl:template>

```

```

<!-- LB -->
<xsl:template name="labResults">
    <xsl:variable name="LRSection"
select="cda:component/cda:structuredBody/cda:component/cda:section[cda:code/@code='30954-2']"/>
    <xsl:if test="$LRSection/cda:entry/cda:organizer">
        <FormData FormDataOID='LBForm'>
            <xsl:for-each
select="$LRSection/cda:entry/cda:organizer/cda:component/cda:observation">
                <ItemGroupData ItemGroupDataOID='LB'>
                    <ItemData ItemDataOID='LBDC'>
                        <xsl:attribute name="value">
                            <xsl:value-of select="cda:effectiveTime/@value"/>
                        </xsl:attribute>
                    </ItemData>
                </ItemGroupData>
            </xsl:for-each>
        </FormData>
    </xsl:if>
</xsl:template>

```

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```
<ItemData ItemDataOID='LBSTAT'>
  <xsl:attribute name="value">
    <xsl:value-of select="cda:statusCode/@code"/>
  </xsl:attribute>
</ItemData>
<ItemData ItemDataOID='LBREFID'>
  <xsl:attribute name="value">
    <xsl:value-of select="cda:id/@root"/>
  </xsl:attribute>
  <xsl:attribute name="code">
    <xsl:value-of select="cda:code/@code"/>
  </xsl:attribute>
  <xsl:attribute name="codeSystem">
    <xsl:value-of select="cda:code/@codeSystem"/>
  </xsl:attribute>
</ItemData>
<ItemData ItemDataOID='LBTEST'>
  <xsl:attribute name="value">
    <xsl:value-of select="cda:code/@displayName"/>
  </xsl:attribute>
</ItemData>
<ItemData ItemDataOID='LBORRES'>
  <xsl:attribute name="value">
    <xsl:value-of select="cda:value/@value"/>
  </xsl:attribute>
  <xsl:attribute name="xsi:type">
```

IHE QRPH Technical Framework Supplement – Clinical Research Data Capture (CRD)

```
                <xsl:value-of select="cda:value/@xsi:type" />
            </xsl:attribute>
        </ItemData>
        <ItemData ItemDataOID='LBORRESU'>
            <xsl:attribute name="value">
                <xsl:value-of select="cda:value/@unit" />
            </xsl:attribute>
        </ItemData>
        <xsl:choose>
            <xsl:when
test="cda:referenceRange/cda:observationRange/cda:value/cda:low/@value">
                <ItemData ItemDataOID='LBORNRL0'>
                    <xsl:attribute name="value">
                        <xsl:value-of
select="cda:referenceRange/cda:observationRange/cda:value/cda:low/@value" />
                    </xsl:attribute>
                </ItemData>
            </xsl:when>
            <!--<xsl:otherwise>
                <ItemData ItemDataOID='LBORNRL0'>
                    <xsl:attribute name="text">
                        <xsl:value-of
select="cda:referenceRange/cda:observationRange/cda:text" />
                    </xsl:attribute>
                </ItemData>
            </xsl:otherwise-->
        </xsl:choose>
```

IHE QRPH Technical Framework Supplement – Clinical Research Data Capture (CRD)

```
<xsl:choose>
  <xsl:when
test="cda:referenceRange/cda:observationRange/cda:value/cda:high/@value">
    <ItemData ItemDataOID='LBORNRHI'>
      <xsl:attribute name="value">
        <xsl:value-of
select="cda:referenceRange/cda:observationRange/cda:value/cda:high/@value"/>
      </xsl:attribute>
    </ItemData>
  </xsl:when>
  <!--<xsl:otherwise>
    <ItemData ItemDataOID='LBORNRHI'>
      <xsl:attribute name="text">
        <xsl:value-of
select="cda:referenceRange/cda:observationRange/cda:text"/>
      </xsl:attribute>
    </ItemData>
  </xsl:otherwise-->
</xsl:choose>
<ItemData ItemDataOID='LBNRIND'>
  <xsl:attribute name="value">
    <xsl:value-of select="cda:interpretationCode/@code"/>
  </xsl:attribute>
  <xsl:attribute name="codeSystem">
    <xsl:value-of
select="cda:interpretationCode/@codeSystem"/>
  </xsl:attribute>
</ItemData>
```

IHE QRPH Technical Framework Supplement – Clinical Research Data Capture (CRD)

```
                </ItemGroupData>
            </xsl:for-each>
        </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="$aeSection/cda:entry/cda:act">
        <FormData FormDataOID='AEForm'>
            <xsl:for-each select="$aeSection/cda:entry">
                <ItemDataGroup ItemDataGroupOID='AE'>
                    <xsl:variable name="originalTextRef"
select="cda:act/cda:entryRelationship/cda:observation/cda:participant/cda:participantRole/cda:playingEntity
/cda:code/cda:originalText/cda:reference/@value" />
                    <xsl:variable name="codedDisplayName"
select="cda:act/cda:entryRelationship/cda:observation/cda:participant/cda:participantRole/cda:playingEntity
/cda:code/@displayName" />
                    <ItemData ItemDataOID='AETERM'>
                        <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>
                    </ItemData>
                </xsl:for-each>
            </FormData>
        </xsl:if>
    </xsl:template>
```

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```

        </xsl:attribute>
    </ItemData>
    <xsl:variable name="aeStartDateTime"
select="cda:act/cda:entryRelationship/cda:observation/cda:effectiveTime/@value"/>
    <xsl:if test="$aeStartDateTime">
        <ItemData ItemDataOID='AESTDTC'>
            <xsl:attribute name="value">
                <xsl:value-of select="$aeStartDateTime"/>
            </xsl:attribute>
        </ItemData>
    </xsl:if>
</ItemDataGroup>
</xsl:for-each>
</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="$theNode/cda:act/cda:entryRelationship/cda:observation/cda:text/cda:reference/@value"/>
    <xsl:variable name="codedValue"
select="$theNode/cda:act/cda:entryRelationship/cda:observation/cda:value/@displayName"/>

```

IHE QRPH Technical Framework Supplement – Clinical Research Data Capture (CRD)

```
<xsl:variable name="valueNode"
select="$theNode/cda:act/cda:entryRelationship/cda:observation/cda:value"/>
<!-- problem status translates into the CDASH MHONG -->
<xsl:variable name="problemStatusNode"
select="$theNode/cda:act/cda:entryRelationship/cda:observation/cda:entryRelationship/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:effectiveTime/cda:low/@value"/>
<xsl:variable name="problemResolved"
select="$theNode/cda:act/cda:entryRelationship/cda:observation/cda:effectiveTime/cda:high/@value"/>
<ItemData ItemOID='MHTERM'>
  <xsl:choose>
    <xsl:when test="string-length($codedValue)>0">
      <xsl:attribute name="value">
        <xsl:value-of select="$codedValue"/>
      </xsl:attribute>
      <xsl:attribute name="xsi:type">
        <xsl:value-of select="$valueNode/@xsi:type"/>
      </xsl:attribute>
      <xsl:attribute name="code">
        <xsl:value-of select="$valueNode/@code"/>
      </xsl:attribute>
      <xsl:attribute name="codeSystem">
        <xsl:value-of select="$valueNode/@codeSystem"/>
      </xsl:attribute>
    </xsl:when>
  </xsl:choose>
</ItemData>
```

IHE QRPH Technical Framework Supplement – Clinical Research Data Capture (CRD)

```
</xsl:when>
<xsl:when test="string-length($originalTextRef)>0">
    <xsl:attribute name="value">
        <xsl:value-of select="//*[@ID=substring-
after($originalTextRef,'#')]" />
    </xsl:attribute>
</xsl:when>
<xsl:otherwise>
    <xsl:attribute name="value">
        ???
    </xsl:attribute>
</xsl:otherwise>
</xsl:choose>
</ItemData>
<ItemData ItemOID='MHONG'>
    <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>
</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 -->
```

IHE QRPH Technical Framework Supplement – Clinical Research Data Capture (CRD)

```
<xsl:if test="$problemOnset">
  <ItemData ItemDataOID='MHSTDTC'>
    <xsl:attribute name="value">
      <xsl:value-of select="$problemOnset" />
    </xsl:attribute>
  </ItemData>
</xsl:if>
<xsl:if test="$problemResolved">
  <ItemData ItemDataOID='MHENDDTTC'>
    <xsl:attribute name="value">
      <xsl:value-of select="$problemResolved" />
    </xsl:attribute>
  </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" />
  <ItemData ItemOID='MHTERM'>
    <xsl:attribute name="value">
      <xsl:choose>
        <xsl:when test="string-length($originalTextRef)>0"><xsl:value-of
select="//*[@ID=substring-after($originalTextRef, '#')]" /></xsl:when>
```

## IHE QRPH Technical Framework Supplement – Clinical Research Data Capture (CRD)

```
                <xsl:when test="string-length($codedValue)>0"><xsl:value-of
select="$codedValue"/></xsl:when>
                <xsl:otherwise>???
```

### 5.8.5.3 Sample Standard CRF output from the Sample XSLT

```
<?xml version="1.0"?>
<ODM ODMVersion="1.3" FileOID="CLL.003" PriorFileOID="CRF_CLL_v1.6" FileType="SnapShot" Description="IHE
CDASH from CCD" xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
xmlns:cd="http://www.cdisc.org/ns/odm/v1.3" xmlns:ds="http://www.w3.org/2000/09/xmldsig#">
  <ClinicalData>
    <SubjectData>
      <SiteRef>
        <StudyEventData>
          <FormData FormOID="DemographicsForm">
            <ItemGroupData ItemGroupOID="DM">
              <ItemData ItemOID="SEX" value="M"/>
              <ItemData ItemOID="BRTHDTC" value="19320924"/>
              <ItemData ItemOID="ETHNIC" value=""/>
              <ItemData ItemOID="RACE" value=""/>
            </ItemGroupData>
```

## IHE QRPH Technical Framework Supplement – Clinical Research Data Capture (CRD)

```
</FormData>
<FormData FormOID="MedicalHistory">
  <ItemGroupData ItemGroupOID="CONDITION">
    <ItemData ItemOID="MHTERM" value="Asthma"
xsi:type="CD" code="195967001" codeSystem="2.16.840.1.113883.6.96"/>
    <ItemData ItemOID="MHONG" value="ONGOING"/>
    <ItemData ItemDataOID="MHSTDTC" value="1950"/>
  </ItemGroupData>
  <ItemGroupData ItemGroupOID="CONDITION">
    <ItemData ItemOID="MHTERM" value="Pneumonia"
xsi:type="CD" code="233604007" codeSystem="2.16.840.1.113883.6.96"/>
    <ItemData ItemOID="MHONG" value="RESOLVED"/>
    <ItemData ItemDataOID="MHSTDTC" value="199701"/>
  </ItemGroupData>
  <ItemGroupData ItemGroupOID="CONDITION">
    <ItemData ItemOID="MHTERM" value="Pneumonia"
xsi:type="CD" code="233604007" codeSystem="2.16.840.1.113883.6.96"/>
    <ItemData ItemOID="MHONG" value="RESOLVED"/>
    <ItemData ItemDataOID="MHSTDTC" value="199903"/>
  </ItemGroupData>
  <ItemGroupData ItemGroupOID="CONDITION">
    <ItemData ItemOID="MHTERM" value="Myocardial
infarction" xsi:type="CD" code="22298006" codeSystem="2.16.840.1.113883.6.96"/>
    <ItemData ItemOID="MHONG" value="RESOLVED"/>
    <ItemData ItemDataOID="MHSTDTC" value="199701"/>
  </ItemGroupData>
  <ItemGroupData ItemGroupOID="PROCEDURE">
```

IHE QRPH Technical Framework Supplement – Clinical Research Data Capture (CRD)

```
replacement, left"/>
                                <ItemData ItemOID="MHTERM" value="Total hip
                                <ItemData ItemDataOID="MHONG" value="RESOLVED"/>
                                </ItemGroupData>
                                </FormData>
                                <FormData FormDataOID="ConMedForm">
                                <ItemGroupData ItemGroupOID="CM">
                                <ItemData ItemDataOID="CMTRT" value="Albuterol
inhalant"/>
                                <ItemData ItemDataOID="CMROUTE" value="Inhalation,
oral"/>
                                <ItemData ItemDataOID="CMINDC" value="Wheezing"
xsi:type="CE" code="56018004" codeSystem="2.16.840.1.113883.6.96"/>
                                <ItemData ItemDataOID="CMDSTXT" value="2"/>
                                </ItemGroupData>
                                <ItemGroupData ItemGroupOID="CM">
                                <ItemData ItemDataOID="CMTRT" value="Clopidogrel"/>
                                <ItemData ItemDataOID="CMDSTXT" value="1"/>
                                </ItemGroupData>
                                <ItemGroupData ItemGroupOID="CM">
                                <ItemData ItemDataOID="CMTRT" value="Metoprolol"/>
                                <ItemData ItemDataOID="CMDSTXT" value="1"/>
                                </ItemGroupData>
                                <ItemGroupData ItemGroupOID="CM">
                                <ItemData ItemDataOID="CMTRT" value="Prednisone"/>
                                <ItemData ItemDataOID="CMSTDTC" value="20000328"/>
                                <ItemData ItemDataOID="CMDSTXT" value="1"/>
                                </ItemGroupData>
```

## IHE QRPH Technical Framework Supplement – Clinical Research Data Capture (CRD)

```
<ItemGroupData ItemGroupOID="CM">
  <ItemData ItemDataOID="CMTRT" value="Cephalexin"/>
  <ItemData ItemDataOID="CMSTDTC" value="20000328"/>
  <ItemData ItemDataOID="CMENDDTC" value="20000404"/>
  <ItemData ItemDataOID="CMDSTXT" value="1"/>
</ItemGroupData>
</FormData>
<FormData FormDataOID="VSForm">
  <ItemGroupData ItemGroupDataOID="VS">
    <ItemData ItemDataOID="VSDTC" value="19991114"/>
    <ItemData ItemDataOID="VSTEST" value="Body height"/>
    <ItemData ItemDataOID="VSORRES" value="177"/>
    <ItemData ItemDataOID="VSORRESU" value="cm"/>
  </ItemGroupData>
  <ItemGroupData ItemGroupDataOID="VS">
    <ItemData ItemDataOID="VSDTC" value="19991114"/>
    <ItemData ItemDataOID="VSTEST" value="Body weight"/>
    <ItemData ItemDataOID="VSORRES" value="86"/>
    <ItemData ItemDataOID="VSORRESU" value="kg"/>
  </ItemGroupData>
  <ItemGroupData ItemGroupDataOID="VS">
    <ItemData ItemDataOID="VSDTC" value="19991114"/>
    <ItemData ItemDataOID="VSTEST" value="Systolic BP"/>
    <ItemData ItemDataOID="VSORRES" value="132"/>
    <ItemData ItemDataOID="VSORRESU" value="mm[Hg]"/>
  </ItemGroupData>
</FormData>
```

IHE QRPH Technical Framework Supplement – Clinical Research Data Capture (CRD)

```
<ItemGroupData ItemGroupDataOID="VS">
  <ItemData ItemDataOID="VSDTC" value="19991114"/>
  <ItemData ItemDataOID="VSTEST" value="Diastolic BP"/>
  <ItemData ItemDataOID="VSORRES" value="86"/>
  <ItemData ItemDataOID="VSORRESU" value="mm[Hg]"/>
</ItemGroupData>
<ItemGroupData ItemGroupDataOID="VS">
  <ItemData ItemDataOID="VSDTC" value="20000407"/>
  <ItemData ItemDataOID="VSTEST" value="Body height"/>
  <ItemData ItemDataOID="VSORRES" value="177"/>
  <ItemData ItemDataOID="VSORRESU" value="cm"/>
</ItemGroupData>
<ItemGroupData ItemGroupDataOID="VS">
  <ItemData ItemDataOID="VSDTC" value="20000407"/>
  <ItemData ItemDataOID="VSTEST" value="Body weight"/>
  <ItemData ItemDataOID="VSORRES" value="88"/>
  <ItemData ItemDataOID="VSORRESU" value="kg"/>
</ItemGroupData>
<ItemGroupData ItemGroupDataOID="VS">
  <ItemData ItemDataOID="VSDTC" value="20000407"/>
  <ItemData ItemDataOID="VSTEST" value="Systolic BP"/>
  <ItemData ItemDataOID="VSORRES" value="145"/>
  <ItemData ItemDataOID="VSORRESU" value="mm[Hg]"/>
</ItemGroupData>
<ItemGroupData ItemGroupDataOID="VS">
  <ItemData ItemDataOID="VSDTC" value="20000407"/>

```

IHE QRPH Technical Framework Supplement – Clinical Research Data Capture (CRD)

```
<ItemData ItemDataOID="VSTEST" value="Diastolic BP"/>
<ItemData ItemDataOID="VSORRES" value="88"/>
<ItemData ItemDataOID="VSORRESU" value="mm[Hg]"/>
</ItemGroupData>
</FormData>
<FormData FormDataOID="AEForm">
  <ItemDataGroup ItemDataGroupOID="AE">
    <ItemData ItemDataOID="AETERM" value="Penicillin"/>
  </ItemDataGroup>
  <ItemDataGroup ItemDataGroupOID="AE">
    <ItemData ItemDataOID="AETERM" value="Aspirin"/>
  </ItemDataGroup>
  <ItemDataGroup ItemDataGroupOID="AE">
    <ItemData ItemDataOID="AETERM" value="Codeine"/>
  </ItemDataGroup>
</FormData>
<FormData FormDataOID="LBForm">
  <ItemGroupData ItemGroupDataOID="LB">
    <ItemData ItemDataOID="LBDTC" value="200003231430"/>
    <ItemData ItemDataOID="LBSTAT" value="completed"/>
    <ItemData ItemDataOID="LBREFID" value="107c2dc0-67a5-
11db-bd13-0800200c9a66" code="30313-1" codeSystem="2.16.840.1.113883.6.1"/>
    <ItemData ItemDataOID="LBTEST" value="HGB"/>
    <ItemData ItemDataOID="LBORRES" value="13.2"
xsi:type="PQ"/>
    <ItemData ItemDataOID="LBORRESU" value="g/dl"/>
  </ItemGroupData>
</FormData>
```

IHE QRPH Technical Framework Supplement – Clinical Research Data Capture (CRD)

```
codeSystem="2.16.840.1.113883.5.83"/>
    <ItemData ItemDataOID="LBNRIND" value="N"
</ItemGroupData>
<ItemGroupData ItemGroupDataOID="LB">
    <ItemData ItemDataOID="LBDTC" value="200003231430"/>
    <ItemData ItemDataOID="LBSTAT" value="completed"/>
    <ItemData ItemDataOID="LBREFID" value="8b3fa370-67a5-
11db-bd13-0800200c9a66" code="33765-9" codeSystem="2.16.840.1.113883.6.1"/>
    <ItemData ItemDataOID="LBTEST" value="WBC"/>
    <ItemData ItemDataOID="LBORRES" value="6.7"
</ItemGroupData>
<ItemData ItemDataOID="LBORRESU" value="10+3/u1"/>
<ItemData ItemDataOID="LBORNRL0" value="4.3"/>
<ItemData ItemDataOID="LBORNRHI" value="10.8"/>
<ItemData ItemDataOID="LBNRIND" value="N"
codeSystem="2.16.840.1.113883.5.83"/>
</ItemGroupData>
<ItemGroupData ItemGroupDataOID="LB">
    <ItemData ItemDataOID="LBDTC" value="200003231430"/>
    <ItemData ItemDataOID="LBSTAT" value="completed"/>
    <ItemData ItemDataOID="LBREFID" value="80a6c740-67a5-
11db-bd13-0800200c9a66" code="26515-7" codeSystem="2.16.840.1.113883.6.1"/>
    <ItemData ItemDataOID="LBTEST" value="PLT"/>
    <ItemData ItemDataOID="LBORRES" value="123"
</ItemGroupData>
<ItemData ItemDataOID="LBORRESU" value="10+3/u1"/>
<ItemData ItemDataOID="LBORNRL0" value="150"/>
<ItemData ItemDataOID="LBORNRHI" value="350"/>
```

IHE QRPH Technical Framework Supplement – Clinical Research Data Capture (CRD)

```
codeSystem="2.16.840.1.113883.5.83"/>
    <ItemData ItemDataOID="LBNRIND" value="L"
</ItemGroupData>
<ItemGroupData ItemGroupDataOID="LB">
    <ItemData ItemDataOID="LBDTC" value="200004061300"/>
    <ItemData ItemDataOID="LBSTAT" value="completed"/>
    <ItemData ItemDataOID="LBREFID" value="a40027e1-67a5-
11db-bd13-0800200c9a66" code="2951-2" codeSystem="2.16.840.1.113883.6.1"/>
    <ItemData ItemDataOID="LBTEST" value="NA"/>
    <ItemData ItemDataOID="LBORRES" value="140"
xsi:type="PQ"/>
    <ItemData ItemDataOID="LBORRESU" value="meq/l"/>
    <ItemData ItemDataOID="LBORNRL0" value="135"/>
    <ItemData ItemDataOID="LBORNRHI" value="145"/>
    <ItemData ItemDataOID="LBNRIND" value="N"
codeSystem="2.16.840.1.113883.5.83"/>
</ItemGroupData>
<ItemGroupData ItemGroupDataOID="LB">
    <ItemData ItemDataOID="LBDTC" value="200004061300"/>
    <ItemData ItemDataOID="LBSTAT" value="completed"/>
    <ItemData ItemDataOID="LBREFID" value="a40027e2-67a5-
11db-bd13-0800200c9a66" code="2823-3" codeSystem="2.16.840.1.113883.6.1"/>
    <ItemData ItemDataOID="LBTEST" value="K"/>
    <ItemData ItemDataOID="LBORRES" value="4.0"
xsi:type="PQ"/>
    <ItemData ItemDataOID="LBORRESU" value="meq/l"/>
    <ItemData ItemDataOID="LBORNRL0" value="3.5"/>
    <ItemData ItemDataOID="LBORNRHI" value="5.0"/>
```

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```
codeSystem="2.16.840.1.113883.5.83"/>
    <ItemData ItemDataOID="LBNRIND" value="N"
</ItemGroupData>
<ItemGroupData ItemGroupDataOID="LB">
    <ItemData ItemDataOID="LBDTC" value="200004061300"/>
    <ItemData ItemDataOID="LBSTAT" value="completed"/>
    <ItemData ItemDataOID="LBREFID" value="a40027e3-67a5-
11db-bd13-0800200c9a66" code="2075-0" codeSystem="2.16.840.1.113883.6.1"/>
    <ItemData ItemDataOID="LBTEST" value="CL"/>
    <ItemData ItemDataOID="LBORRES" value="102"
</ItemGroupData>
<ItemData ItemDataOID="LBORRESU" value="meq/l"/>
<ItemData ItemDataOID="LBORNRL0" value="98"/>
<ItemData ItemDataOID="LBORNRHI" value="106"/>
<ItemData ItemDataOID="LBNRIND" value="N"
codeSystem="2.16.840.1.113883.5.83"/>
</ItemGroupData>
<ItemGroupData ItemGroupDataOID="LB">
    <ItemData ItemDataOID="LBDTC" value="200004061300"/>
    <ItemData ItemDataOID="LBSTAT" value="completed"/>
    <ItemData ItemDataOID="LBREFID" value="a40027e4-67a5-
11db-bd13-0800200c9a66" code="1963-8" codeSystem="2.16.840.1.113883.6.1"/>
    <ItemData ItemDataOID="LBTEST" value="HCO3"/>
    <ItemData ItemDataOID="LBORRES" value="35"
</ItemGroupData>
<ItemData ItemDataOID="LBORRESU" value="meq/l"/>
<ItemData ItemDataOID="LBORNRL0" value="18"/>
<ItemData ItemDataOID="LBORNRHI" value="23"/>
```

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```
codeSystem="2.16.840.1.113883.5.83"/>
    <ItemData ItemDataOID="LBNRIND" value="H"
    </ItemGroupData>
  </FormData>
</StudyEventData>
  </SiteRef>
</SubjectData>
</ClinicalData>
</ODM>
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