Integrating the Healthcare Enterprise

# IHE Quality, Research and Public Health Technical Framework Supplement

# Clinical Research Document (CRD)

# Trial implementation


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## Foreword

This is a supplement to the IHE Quality, Research and Public Health Technical Framework V0.1. Each supplement undergoes a process of public comment and trial implementation before being incorporated into the volumes of the Technical Frameworks.

This supplement is published for Trial Implementation on September 24, 2012 and may be available for testing at subsequent IHE Connectathons. The supplement may be amended based on the results of testing. Following successful testing it will be incorporated into the Quality, Research and Public Health (QRPH) Technical Framework. Comments are invited and may be submitted at http://www.ihe.net/qrph/qrphcomments.cfm.

This supplement describes changes to the existing technical framework documents and where indicated amends text by addition (**bold underline**) or removal (~~**bold strikethrough**~~), as well as addition of new sections introduced by editor's instructions to "add new text" or similar, which for readability are not bolded or underlined.

"Boxed" instructions like the sample below indicate to the Volume Editor how to integrate the relevant section(s) into the relevant Technical Framework volume:

| *Replace Section X.X by the following:* |
|---|

General information about IHE can be found at: www.ihe.net

Information about the IHE QRPH domain can be found at: http://www.ihe.net/Domains/index.cfm

Information about the structure of IHE Technical Frameworks and Supplements can be found at: http://www.ihe.net/About/process.cfm and http://www.ihe.net/profiles/index.cfm

The current version of the IHE Technical Framework can be found at: http://www.ihe.net/Technical_Framework/index.cfm

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## Introduction to this Supplement

The Clinical Research Document Profile (CRD) specifies a standard way to generate a clinical research document from EHR data provided in the CDA standard. The CRD profile adds use-case specific constraints on the RFD profile. It is more specific about the pre-population xml requirements used when retrieving a form; a new transaction is defined which enable the archiving of the prepop and workflow data, and other actors groupings are added to enhance the security of CRD actors. Specifically, it defines the ATNA audit logs which are associated with each of the RFD transactions used in this profile, namely Retrieve Form [ITI-34], Submit Form [ITI-35] and Archive Form [ITI-36].

## Open Issues and Questions

### Comments on this new version of the CRD TF Supplement

In refactoring the CRD TF supplement (refactoring which will act as well as a global CP), we decided that we would rewrite it in what seems to us to be a more rigorous and generic way, in the hope that it would serve as a proposition and if accepted, would serve as a model of redaction for the future technical framework supplements. For this reason, we made a certain number of modifications on the profile. The two principal consequences of which are:

1. The definition of four new actors: the “CRD Form Filler”, the “CRD Form Manager”, the “CRD Form Receiver” and the “CRD Form Archiver”

These names are clearly not the most appropriate ones for the actors we created in this profile. For the moment, we just want to present our ideas. If they are accepted, then we will have to find more appropriate names for them.

2. The design of a new actor diagram for the CRD profile:

As a content profile, the CRD defines only the contents of the documents which SHALL be sent through transactions defined in other profiles. Thus, the principal actors of this profile SHALL be grouped with actors from others profiles. This is represented in the Actor/Transaction diagram as following:

- Actors defined in this profile distinguish themselves form those defined in other profiles (but used here) through their solid boxes (compared to dashed boxes).
- The solid line going from one actor to another, points to the fact that the transaction associated with the line takes place between the actors who are linked by the line. For example, in figure X.1-1 (section X.1) the Retrieve Form Transaction [ITI-34] takes place between the RFD Form Filler and the RFD Form Manager and enables the RFD Form Filler to transmit the prepop and workflow data prepared by the CRD Form Filler to the RFD Form Manager.

 

This new profile also takes into account a recent security change proposal by grouping the principal actors of this profile with actors from the security profiles: CT, ATNA, and XUA.

### Entries

Some of the sections such as "Detailed Physical Examination" do not currently require coded entries.

### Implementation issues

A practical solution has not been found yet for the implementation of the ATNA audit logs in the case of the Submit Form ([ITI-35]) and Archive Form ([ITI-36]).

## Closed Issues

None

 

# Volume 1 – Profiles

## X Clinical Research Document (CRD) Profile

The Clinical Research Document Profile (CRD) specifies a standard way to generate a clinical research document from EHR data provided in the CDA standard.

While the profile does not mandate the use of the CDASH standard, it provides guidance on how this profile could incorporate transformation of CDA content into CDASH.

The profile uses the transaction framework defined in the RFD profile. It further constrains the prepopData and workflowData data elements of the RFD Retrieve Form transaction in order to optimize the pre-population of the form used to collect the data during a patient's visit on an investigation site and an optional functionality is more tightly specified as required.

The CRD Profile additionally defines a new transaction. The use of that transaction is optional (required if the "ArchiveSourceDocuments option is selected") in this profile. This optional transaction enables the profile to meet data auditing requirements of the FDA when creating clinical research documents. It indeed enables an actor, which provides a pre-population document and some workflow data when retrieving a form, to archive the pre-population document it supplied.

Other FDA requirements which this profile meets are security requirements. This is enabled by the grouping of each of the actors defined in this profile with a CT time client actor, an ATNA secure node or application actor and an XUA X-service user actor.

In Summary, the CRD profile is just like the RFD profile except it is more specific about the pre-population xml requirements used when retrieving a form, some optional functionality is more tightly specified as required, a new transaction is created and is used to facilitate the archiving of the pre-population data, and other actors groupings are added to enhance the security of CRD actors.

## X.1 CRD Actors, Transactions, and Content Modules

Figure X.1-1 shows the actors directly involved in the CRD Profile and the relevant transactions between them. If needed for context, other actors that may be indirectly involved due to their participation in other related profiles are shown in dotted lines. Actors which have a mandatory grouping are shown in conjoined boxes.

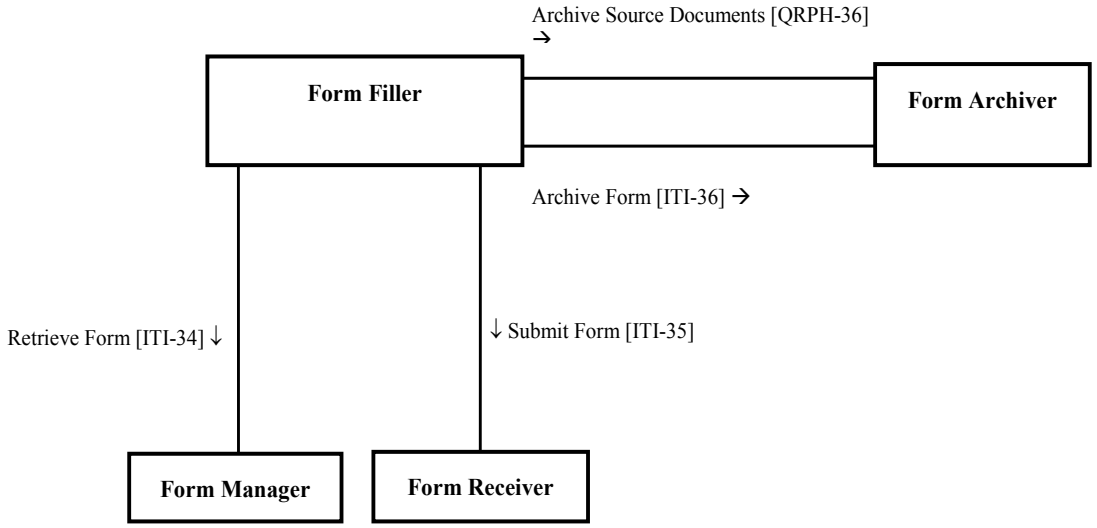


**Figure X.1-1: CRD Actor Diagram[1]**

Figure X.1-1 shows the principal actors described (bold and solid boxes) in the CRD Integration Profile. Here there are no transactions per se between these actors as this profile is a content profile, but if there were some, they would be designed in bold and solid line. The diagram also shows actors which are not defined in this profile (dashed Boxes) but which SHALL be grouped with the principal ones.

As explained in the summary and shown in table X.3-1, the CRD actors SHALL also be grouped with some ATNA, XUA and CT actors. However, for clarity's sake, it was decided not to show them in figure X.1, as this figure points out the most important features which this profile is about. An exhaustive CRD actor diagram can be found in the volume 1 appendices (Figure X.1-2).

Table X.1-1 lists the transactions for each actor directly involved in the CRD Profile. In order to claim support of this Profile, an implementation of an actor must perform the required transactions (labeled "R") and MAY support the optional transactions (labeled "O"). Actor groupings are further described in Section X.3.

[1] This is a new approach we would like to propose to the committee. See comments in the opened issues and questions section.

**Table X.1-1: CRD Profile - Actors and Transactions**

| Actors | Transactions | Optionality | Section in Vol. 2 | Note |
|---|---|---|---|---|
| Form Filler | Retrieve Form | R | ITI TF-2b: 3.34 | |
| | ArchiveSourceDocuments | O | 3.36 | |
| | Submit Form | R | ITI TF-2b: 3.35 | This transaction is further constrained in this profile. (see at the end of Vol. 3) |
| | Archive Form | O | ITI TF-2b: 3.36 | This transaction is further constrained in this profile (see at the end of Vol. 3) |
| Form Manager | Retrieve Form | R | ITI TF-2b: 3.34 | |
| Form Receiver | Submit Form | R | ITI TF-2b: 3.35 | |
| Form Archiver | ArchiveSourceDocuments | R | 3.36 | |
| | Archive Form | R | ITI TF-2b: 3.36 | |

**Table X.1-2: CRD Profile – Actors and Content Modules**

| Actors | Content Module | Optionality | Section in Vol. 3 |
|---|---|---|---|
| Form Filler | CRD Prepop data document (creator) | R | 6.3.1.D |
| | CRD Workflow data (creator) | R | 6.3.1.D1 |
| Form Manager | CRD Prepop data document (consumer) | R | 6.3.1.D |
| | CRD Workflow data (consumer) | R | 6.3.1.D1 |
| Form Archiver | CRD Prepop data document | O | 6.3.1.D |
| | CRD Workflow data | O | 6.3.1.D1 |
| Form Receiver | CRD Workflow data (creator) | R | 6.3.1.D1 |

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### X.1.1 Actor Descriptions and Actor Profile Requirements

Normative requirements are typically documented in Volume 2 (Transactions) and Volume 3 (Content Modules). Some Integration Profiles, however, contain requirements which link transactions, data, and/or behavior. Those Profile requirements are documented in this section as
245 normative requirements ("SHALL").

#### X.1.1.1 Form Filler

In addition to its role as defined in the RFD profile in ITI TF-1, the Form Filler SHALL support the generation of the pre-population data in the form of the two content modules hereafter named "CRD prepop data" and "CRD workflow data".

As described in table X.3-1, for security enhancing purposes, the Form Filler SHALL also be grouped with a CT Time Client, a XUA X-Service Provider, and an ATNA Secure Node or ATNA Secure Application.

### X.1.1.2 Form Manager

In addition to its role as defined in the RFD profile in ITI TF-1, the Form Manager MAY specify mappings between CCD and CDASH. While the profile does not mandate the use of the CDASH standard, it provides guidance on how this profile could incorporate transformation of CDA content into CDASH.

As described in table X.3-1, for security enhancing purposes, the Form Manager actor SHALL also be grouped with a CT Time Client, a XUA X-Service Provider, and an ATNA Secure Node or ATNA Secure Application.

### X.1.1.3 Form Receiver

The role of the Form Receiver in this profile is the one defined in the RFD profile in ITI TF-1.

It SHALL also be grouped with a CT Time Client, a XUA X-Service Provider, and an ATNA Secure Node or ATNA Secure Application.

### X.1.1.4 Form Archiver

The role of the Form Archiver in this section is the one defined in the RFD profile in ITI TF-1.

It SHALL also be grouped with a CT Time Client, a XUA X-Service Provider, and an ATNA Secure Node or ATNA Secure Application.

## X.2 CRD Actor Options

Options that MAY be selected for this Profile are listed in table X.2-1 along with the Actors to which they apply. Dependencies between options when applicable are specified in notes.

Specifically, in addition to the Archive Form option defined in the ITI Technical Framework supplement RFD, this profile defines a new option which is the use of the "ArchiveSourceDocuments" transaction.

**Table X.2-1: Clinical Research Document - Actors and Options**

| Actor | Options | Volume & Section |
|---|---|---|
| Form Filler | ArchiveSourceDocuments | 3.36 |
| | Archive Form | ITI TF-2b:3.36 |
| Form Manager | None | - |
| Form Receiver | None | - |

| Actor | Options | Volume & Section |
|---|---|---|
| Form Archiver | None | |

Note: Considering that we are in the CRD profile, the pre-population data is not an option anymore; it is required as the profile is precisely about defining it. The CRD Profile requires that this prepop and workflow data conforms to the xml data constrained in its volume 3. The "ArchiveSourceDocuments" option requires the Form Filler to submit the Prepop and Workflow data to the Form Archiver through the transaction of the same name defined in volume2. If this option is selected, that transaction must be completed first in order to provide the Form Manager with the context id related to the archived CRD (volume 3 of this profile provides the description of where this id will be introduced).

## X.3 CRD Required Actor Groupings

Actor(s) which are required to be grouped with another Actor(s) are listed in this section. The grouped Actor MAY be from this profile or a different domain/profile. These mandatory required groupings, plus further descriptions if necessary, are given in the table below.

An Actor from this profile (Column 1) must implement all of the required transactions in this profile in addition to all of the required transactions for the grouped profile/actor listed (Column 2).

**Table X.3-1: Clinical Research Document - Required Actors Groupings**

| CRD Actor | Actor to be grouped with | Technical Framework Reference | Note |
|---|---|---|---|
| Form Filler | ATNA Secure Node or ATNA Secure Application | ITI TF- 1: 9.4 | Required |
| | CT Time Client | ITI TF- 1: 7.1 | Required |
| | XUA X-Service User | ITI TF- 1: 13.4 | Required |
| Form Manager | ATNA Secure Node or ATNA Secure Application | ITI TF- 1: 9.4 | Required |
| | CT Time Client | ITI TF- 1: 7.1 | Required |
| | XUA X-Service Provider | ITI TF- 1: 13.4 | Required |
| Form Receiver | ATNA Secure Node or ATNA Secure Application | ITI TF- 1: 9.4 | Required |
| | CT Time Client | ITI TF- 1: 7.1 | Required |
| | XUA X-Service Provider | ITI TF- 1: 13.4 | Required |
| Form Archiver | ATNA Secure Node or ATNA Secure Application | ITI TF- 1: 9.4 | Required |
| | CT Time Client | ITI TF- 1: 7.1 | Required |
| | XUA X-Service Provider | ITI TF- 1: 13.4 | Required |

## X.4 CRD Overview

### X.4.1 Concepts

### X.4.2 Use Case #1: Clinical Trial Visit

We are in the setting of a clinical study which implies a certain number of visits for all the patients involved. A patient enrolled in a clinical study comes to the Hospital for a visit related to that clinical study.

#### X.4.2.1 Clinical Trial Visit Use Case Description

The setting for the clinical research use case is a physician 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.

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.

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.

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 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.

#### X.4.2.1.1 Current State

Mrs. Corey Jones arrives at the clinic for a scheduled trial visit and meets with Patricia Zone (Registered Nurse) 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). 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 Thomas, the data entry person. Bob identifies the 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 the data into the correct electronic case report form (eCRF) for that trial visit. Once the source documents 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 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 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.

#### X.4.2.1.2 Desired State

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, and because Mrs. Jones informed consent indicated that it was permissible to do so, 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, the EHR checks Patricia's credentials, confirms that consent to access the EHR data has been obtained and thus 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.)

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[2] 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 archived for future regulatory auditing and 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, 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 CDASH initiative identifies data collection fields that are applicable to all clinical trials regardless of therapeutic area or phase of trial. Addition 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.

[2] These clinical trial forms or domain modules are comprised of data collection variables identified by the Clinical Data Acquisition Standards Harmonization (CDASH) Initiative. The CDASH initiative identifies data collection fields that are applicable to all clinical trials regardless of therapeutic area or phase of trial. Addition 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.

### X.4.2.2 Clinical Trial Visit Process Flow

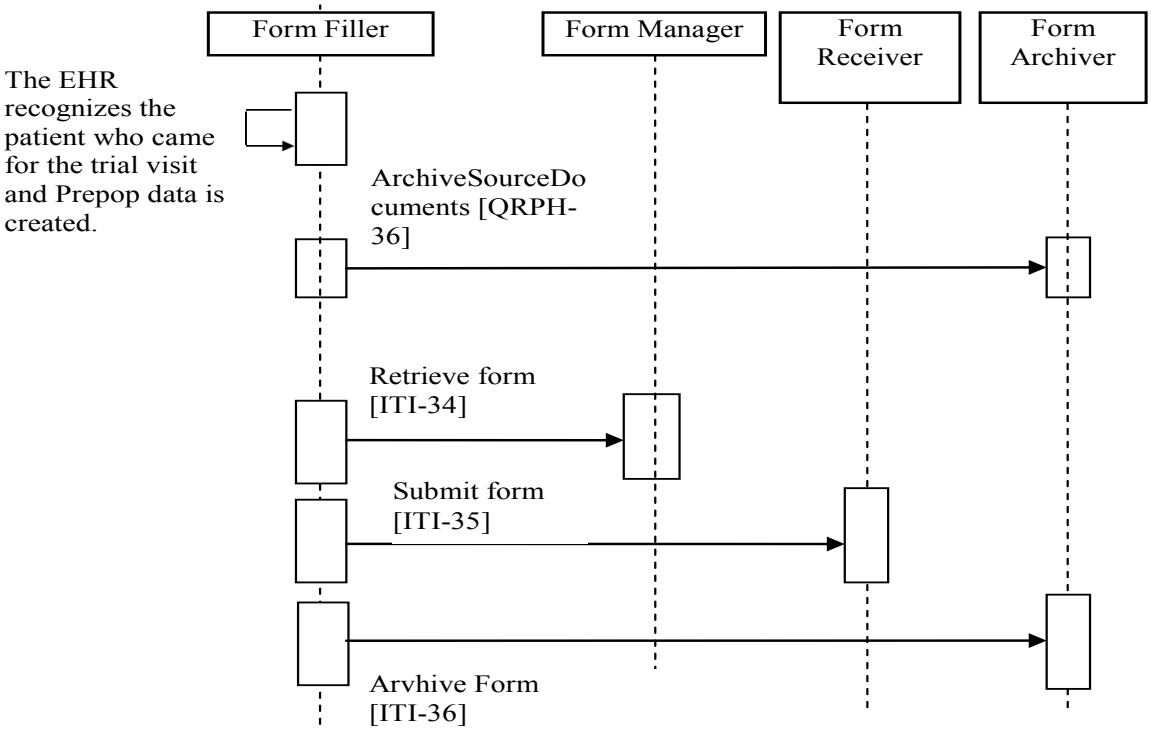



**Figure X.4.2.2-1: Basic Process Flow in CRD Profile**

In this Process Flow, the Form Filler knows which form it wants to retrieve from the Form Manager. The Form Filler wants to send prepop and workflow data for this form. In addition the Form Filler wants to archive the prepop and workflow data.

## X.5 CRD Security Considerations

### X.5.1 Consistent Time (CT)

In order to address identified security risks all actors in CRD should be grouped with Consistent Time (CT) Profile – Time Client actor. This grouping will assure that all systems have a consistent time clock to assure a consistent timestamp for audit logging.

### X.5.2 Audit Trail and Node Authentication (ATNA)

In order to address identified security risks all actors in CRD should be grouped with Audit Trail and Node Authentication (ATNA) profile – Secure Node actor or ATNA Secure Application actor. This grouping will assure that only highly trusted systems can communicate and that all changes are recorded in the audit log.

### X.5.3 Cross Enterprise User Authentication (XUA)

In order to address identified security risks all actors in CRD should be grouped with Cross Enterprise User Authentication (XUA) profile actors as appropriate. This grouping will assure that only highly trusted persons can communicate.

## X.6 CRD Cross Profile Considerations

Not applicable

# Appendices

## Actor Summary Definitions

*Add the following terms to the IHE TF General Introduction Namespace list of Actors:*

1. **Form Filler**– a system or a module in a CRD framework, the purpose of which is to retrieve a form from the Form Manager and provide pre-population data.
2. **Form Manager** – a system or a module in a CRD framework, the purpose of which is to provide a form to the Form Filler, to apply pre-population data.
3. **Form Receiver** – a system or a module in a CRD framework, the purpose of which is to receive completed forms from the Form Filler. **Form Archiver** - a system or a module in a CRD framework, the purpose of which is to receive the raw CCD and the completed form from the Form Filler.

## Transaction Summary Definitions

Add the following terms to the IHE TF General Introduction Namespace list of Transactions:

**ArchiveSourceDocuments [QRPH–36]** - This transaction allows the Form Filler to send the pre-population document to the Form Archiver.

## Glossary

*Add the following terms to the IHE Technical Frameworks General Introduction Glossary:*

None

# Volume 2 – Transactions

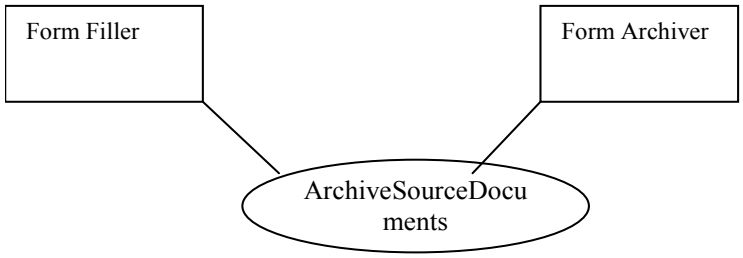
## 3.36 ArchiveSourceDocuments

This section corresponds to Transaction QRPH-36 of the IHE QRPH echnical Framework. Transaction QRPH-36 is used by the Form Filler and Form Archiver actors.

### 3.36.1 Scope

This transaction involves a Form Filler archiving content to a Form Archiver, before issuing a **Retrieve Form request to a Form Manager. The content of this transaction is similar to that of** Retrieve Form, ITI-34.

### 3.36.2 Use Case Roles




**Actor:** Form Filler

**Role:** A forms display and editing system capable of allowing form fields to be completed.

**Actor:** Form Archiver

**Role:** A system that receives submitted content for archival purposes.

### 3.36.3 Referenced Standards

Implementors of this transaction shall comply with all requirements described in ITI TF-2x: Appendix V: Web Services for IHE Transactions.

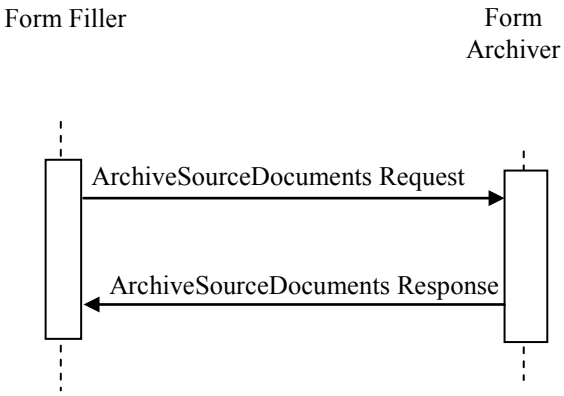
IETF RFC1738, Uniform Resource Locators (URL), December 1994, http://www.faqs.org/rfcs/rfc1738.html

IETF RFC2616 HyperText Transfer Protocol HTTP/1.1

Extensible Markup Language (XML) 1.0 (Second Edition). W3C Recommendation 6 October 2000. http://www.w3.org/TR/REC-xml.

ITI TF-2x: Appendix V Web Services for IHE Transactions

### 3.36.4 Interaction Diagram




#### 3.36.4.1 ArchiveSourceDocuments Request

ArchiveSourceDocuments involves a Form Filler archiving some content to a Form Archiver.

##### 3.36.4.1.1 Trigger Events

The Form Filler possesses some documents which it wants to archive.

##### 3.36.4.1.2 Message Semantics

The content to be archived includes both the prepopData and the workflowData as defined in section 6.3.1.

Implementors of this transaction shall comply with all requirements described in ITI TF-2x: Appendix V: Web Services for IHE Transactions.

The following parameters are specified for this transaction.

| Parameter Name | REQ | Description | Value |
|---|---|---|---|
| archiveContent | R | The xml for pre-population | Any XML further defined by a content profile. |

##### 3.36.4.1.3 Expected Actions

Upon receipt of the ArchiveSourceDocuments request, the Form Archiver shall parse the request and shall return either a responseCode value of "OK" to indicate success, or a SOAP Fault.

See the Protocol Requirements and the support materials.

The Form Archiver shall use the SOAP Faults defined in Table 3.36.4.1.3-1 when appropriate. Form Fillers shall be capable of accepting other values beyond the ones specified here.

**Table 3.36.4.1.3-1: SOAP Faults**

| Description of error | Code | Reason Text |
|---|---|---|
| There is missing information, such as no formID | Sender | Required Information Missing |

An example of a SOAP Fault is:

```
<env:Envelope xmlns:env="http://www.w3.org/2003/05/soap-envelope"
              xmlns:xml="http://www.w3.org/XML/1998/namespace">
  <env:Body>
    <env:Fault>
      <env:Code>
        <env:Value>env:Sender</env:Value>
      </env:Code>
      <env:Reason>
        <env:Text xml:lang="en">Required Information Missing</env:Text>
      </env:Reason>
    </env:Fault>
  </env:Body>
</env:Envelope>
```

### 3.36.4.1.4 Security Considerations

**T**he ArchiveSourceDocuments is a PHI-Export event, as defined in ITI TF-2a: Table 3.20.6-1. The Actors involved in the transaction SHALL create audit 480 data in conformance with DICOM (Supp 95) “Data Export”/”Data Import”. See 5.Z3.4

### 3.36.4.2.1 Trigger Events

This message is triggered by a Form Archiver actor responding to an ArchiveSourceDocuments request.

### 3.36.4.2.2 Message Semantics

A value of responseCode of OK is used to indicate that all required data are present; otherwise, a SOAP Fault shall be used.

### 3.36.4.2.3 Expected Actions

The Form Filler should be capable of stopping the workflow upon receipt of a SOAP Fault indicating missing data from this transaction.

## 3.36.5 Protocol Requirements

The ArchiveSourceDocuments request and response shall be transmitted using Synchronous Web Services Exchange, according to the requirements specified in ITI TF-2x: Appendix V.

The ArchiveSourceDocuments transaction shall use SOAP 12.

**WSDL Namespace Definitions**

| | |
|---|---|
| ihei | urn:ihe:qrph:crd:2012 |
| soap12 | http://schemas.xmlsoap.org/wsdl/soap12/ |
| wsaw | http://www.w3.org/2005/08/addressing |
| xsd | http://www.w3.org/2001/XMLSchema |

These are the requirements for the ArchiveSourceDocuments transaction presented in the order in which they would appear in the WSDL definition:

- The following types shall be imported (xds:import) in the /definitions/types section:
  - Namespace=”urn:ihe:qrph:crd:2012”, schema=”CRD.xsd”
- The /definitions/message/part/@element attribute of the ArchiveSourceDocuments Request message shall be defined as: “ihe:ArchiveSourceDocumentsRequest”
- The /definitions/message/part/@element attribute of the ArchiveSourceDocuments Response message shall be defined as: “ihe:ArchiveSourceDocumentsResponse”
- The /definitions/portType/operation/input/@wsaw:Action attribute for the ArchiveSourceDocuments Request message shall be defined as “urn:ihe:qrph:2012:ArchiveSourceDocuments”
- The /definitions/portType/operation/output/@wsaw:Action attribute for the ArchiveSourceDocuments Response message shall be defined as: “urn:ihe:qrph:2012:ArchiveSourceDocumentsResponse”
- The /definitions/binding/operation/soap12:operation/@soapAction attribute shall be defined as “urn:ihe:qrph:2012:ArchiveSourceDocuments”

These are the requirements that affect the wire format of the SOAP message. The other WSDL properties are only used within the WSDL definition and do not affect interoperability. Full sample request and response messages are in ITI TF-2b: 3.36.5.1 Sample SOAP Messages.

For informative WSDL for the Form Archiver see ITI TF-2x: Appendix W. A full XML Schema Document for the RFD types is available online on the IHE FTP site (ftp://ftp.ihe.net/TF_Implementation_Material/ITI/).

### 3.36.5.1 Sample SOAP Messages

The samples in the following two sections show a typical SOAP request and its relative SOAP response. The sample messages also show the WS-Addressing headers <Action/>,

<MessageID/>, .; these WS-Addressing headers are populated according to the

ITI TF-2x: Appendix V: Web Services for IHE Transactions. Some of the body of the SOAP message is omitted for brevity.

#### 3.36.5.1.1 Sample ArchiveSourceDocuments SOAP Request

```
<soap:Envelope xmlns:soap="http://www.w3.org/2003/05/soap-envelope"
xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
xmlns:xsd="http://www.w3.org/2001/XMLSchema">
  <soap:Header>
     <wsa:To>http://localhost:4040/axis2/services/someservice</wsa:To>
      <wsa:MessageID>urn:uuid:76A2C3D9BCD3AECFF31217932910053</wsa:MessageID>
      <wsa:Action soap:mustUnderstand="1">urn:ihe:qrphi:
2012:RetrieveForm</wsa:Action>
  </soap:Header>
  <soap:Body>
    <ArchiveSourceDocumentsRequest xmlns="urn:ihe:qrph:crd:2012">
       <archiveContent>
    </ArchiveSourceDocumentsRequest >
  </soap:Body>
</soap:Envelope>
```

#### 3.36.5.1.2 Sample ArchiveSourceDocuments SOAP Response

```
<soap:Envelope xmlns:soap="http://www.w3.org/2003/05/soap-envelope"
xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
xmlns:xsd="http://www.w3.org/2001/XMLSchema">
  <soap:Header>
            <wsa:To>http://localhost:4040/axis2/services/someservice</wsa:To>

<wsa:MessageID>urn:uuid:76A2C3D9BCD3AECFF31217932910053</wsa:MessageID>
          <wsa:Action soap:mustUnderstand="1">urn:ihe:qrph:
2012:ArchiveSourceDocumentsResponse</wsa:Action>
  </soap:Header>
  <soap:Body>
    <ArchiveSourceDocumentsResponse xmlns="urn:ihe:qrph:crd:2012">
      <responseCode>OK</responseCode>
    </ArchiveSourceDocumentsResponse>
  </soap:Body>
</soap:Envelope>
```

## Audit Security Messages

## 5.Z3 Audit Record Considerations

### 5.Z3.1 Retrieve Form ([ITI-34]) audit messages

The Retrieve Form Transaction is PHI-Export event, as defined in ITI TF-2a: Table 3.20.6-1. The Actors involved in the transaction SHALL create audit data in conformance with DICOM (Supp 95) “Data Export”/”Data Import”, with the following exceptions.

### 5.Z3.1.1 Form Filler audit message:

| | Field Name | Opt | Value Constraints |
|---|---|---|---|
| **Event** AuditMessage/ EventIdentification | EventID | M | EV(110106, DCM, "Export") |
| | EventActionCode | M | "R" (Read) |
| | *EventDateTime* | *M* | *not specialized* |
| | *EventOutcomeIndicator* | *M* | *not specialized* |
| | EventTypeCode | M | EV("ITI-34", "IHE Transactions", "Retrieve Form") |
| Source (Document Source) (1) | | | |
| Human Requestor (0..n) | | | |
| Destination (Document Repository) (1) | | | |
| Audit Source (Document Source) (1) | | | |
| Subject (1) | | | |
| prepopData (1) | | | |

Where:

| | | | |
|---|---|---|---|
| **Source** AuditMessage/ ActiveParticipant | UserID | M | Host system name |
| | AlternativeUserID | M | The process ID as used within the local operating system in the local system logs. |
| | *UserName* | *U* | *not specialized* |
| | UserIsRequestor | M | "true" |
| | RoleIDCode | M | EV(110153, DCM, "Source") |
| | NetworkAccessPointTypeCode | M | "1" for machine (DNS) name, "2" for IP address |
| | NetworkAccessPointID | M | The machine name or IP address, as specified in RFC 3881. |
| **Human Requestor (if known)** AuditMessage/ ActiveParticipant | UserID | M | Identity of the human that initiated the transaction. |
| | *AlternativeUserID* | *U* | *not specialized* |
| | *UserName* | *U* | *not specialized* |
| | UserIsRequestor | M | "true" |
| | RoleIDCode | U | Access Control role(s) the user holds that allows this transaction. |
| | *NetworkAccessPointTypeCode* | *NA* | |
| | *NetworkAccessPointID* | *NA* | |

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| | | | |
|---|---|---|---|
| **Destination** AuditMessage/ ActiveParticipant | UserID | M | SOAP endpoint URI. |
| | *AlternativeUserID* | *U* | *not specialized* |
| | *UserName* | *U* | *not specialized* |
| | UserIsRequestor | M | "false" |
| | RoleIDCode | M | EV(110152, DCM, "Destination") |
| | NetworkAccessPointTypeCode | M | "1" for machine (DNS) name, "2" for IP address |
| | NetworkAccessPointID | M | The machine name or IP address, as specified in RFC 3881. |

 

| | | | |
|---|---|---|---|
| **Audit Source**<br>AuditMessage/ AuditSourceIdentification | *AuditSourceID* | *U* | *Not specialized.* |
| | *AuditEnterpriseSiteID* | *U* | *not specialized* |
| | *AuditSourceTypeCode* | *U* | *not specialized* |

| | | | |
|---|---|---|---|
| **Subject**<br>(AuditMessage/ ParticipantObjectIdentification) | ParticipantObjectTypeCode | M | "1" (Person) |
| | ParticipantObjectTypeCodeRole | M | "1" (Patient) |
| | *ParticipantObjectDataLifeCycle* | *U* | *not specialized* |
| | ParticipantObjectIDTypeCode | M | EV(2, RFC-3881, "Subject Number") |
| | *ParticipantObjectSensitivity* | *U* | *not specialized* |
| | **PARTICIPANTOBJECTID** | M | The subject ID in HL7 CX format. |
| | *ParticipantObjectName* | *U* | *not specialized* |
| | ***PARTICIPANTOBJECTQUERY*** | *U* | *not specialized* |
| | *ParticipantObjectDetail* | *U* | *not specialized* |
| **prepopData**<br>(AuditMessage/ ParticipantObjectIdentification) | ParticipantObjectTypeCode | M | "2" (System) |
| | ParticipantObjectTypeCodeRole | M | "20" (job) |
| | *ParticipantObjectDataLifeCycle* | *U* | *not specialized* |
| | ParticipantObjectIDTypeCode | M | EV(2, RFC-3881, "Document ID") |
| | *ParticipantObjectSensitivity* | *U* | *not specialized* |
| | **PARTICIPANTOBJECTID** | M | The prepopData Document unique ID |
| | *ParticipantObjectName* | *U* | *not specialized* |
| | ***PARTICIPANTOBJECTQUERY*** | *U* | *not specialized* |
| | *ParticipantObjectDetail* | *U* | *not specialized* |

### 5.Z3.1.2 Form Manager audit message:

| | Field Name | Opt | Value Constraints |
|---|---|---|---|
| **Event**<br>**AuditMessage/ EventIdentification** | EventID | M | EV(110107, DCM, "Import") |
| | EventActionCode | M | "C" (Create) |
| | *EventDateTime* | *M* | *not specialized* |
| | *EventOutcomeIndicator* | *M* | *not specialized* |
| | EventTypeCode | M | EV("ITI-34", "IHE Transactions", "Retrieve Form") |
| Source (Document Source) (1) | | | |
| Destination (Document Repository or Document Recipient) (1) | | | |
| Audit Source (Document Repository or Document Recipient) (1) | | | |
| Subject (1) | | | |
| prepopData (1) | | | |

Where:

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| | | | |
|---|---|---|---|
| **Source**<br>AuditMessage/ ActiveParticipant | UserID | M | Host system name |
| | AlternativeUserID | *U* | *not specialized* |
| | *UserName* | *U* | *not specialized* |
| | UserIsRequestor | M | "false" |
| | RoleIDCode | M | EV(110153, DCM, "Source") |
| | NetworkAccessPointTypeCode | M | "1" for machine (DNS) name, "2" for IP address |
| | NetworkAccessPointID | M | The machine name or IP address, as specified in RFC 3881. |

| | | | |
|---|---|---|---|
| **Destination**<br>AuditMessage/ ActiveParticipant | UserID | M | SOAP endpoint URI |
| | *AlternativeUserID* | M | The process ID as used within the local operating system in the local system logs. |
| | *UserName* | *U* | *not specialized* |
| | UserIsRequestor | M | "false" |
| | RoleIDCode | M | EV(110152, DCM, "Destination") |
| | NetworkAccessPointTypeCode | M | "1" for machine (DNS) name, "2" for IP address |
| | NetworkAccessPointID | M | The machine name or IP address, as specified in RFC 3881. |

| | | | |
|---|---|---|---|
| **Audit Source**<br>AuditMessage/ AuditSourceIdentification | *AuditSourceID* | *U* | *Not specialized.* |
| | *AuditEnterpriseSiteID* | *U* | *not specialized* |
| | *AuditSourceTypeCode* | *U* | *not specialized* |

| | | | |
|---|---|---|---|
| **Subject**<br>(AuditMessage/ ParticipantObjectIdentification) | ParticipantObjectTypeCode | M | "1" (Person) |
| | ParticipantObjectTypeCodeRole | M | "1" (Patient) |
| | *ParticipantObjectDataLifeCycle* | *U* | *not specialized* |
| | ParticipantObjectIDTypeCode | M | EV(2, RFC-3881, "Subject Number") |
| | *ParticipantObjectSensitivity* | *U* | *not specialized* |
| | **PARTICIPANTOBJECTID** | M | The subject ID in HL7 CX format. |
| | *ParticipantObjectName* | *U* | *not specialized* |
| | ***PARTICIPANTOBJECTQUERY*** | *U* | *not specialized* |
| | *ParticipantObjectDetail* | *U* | *not specialized* |
| **prepopData**<br>(AuditMessage/ ParticipantObjectIdentification) | ParticipantObjectTypeCode | M | "2" (System) |
| | ParticipantObjectTypeCodeRole | M | "20" (job) |
| | *ParticipantObjectDataLifeCycle* | *U* | *not specialized* |
| | ParticipantObjectIDTypeCode | M | EV2, RFC-3881, "Document ID") |
| | *ParticipantObjectSensitivity* | *U* | *not specialized* |
| | **PARTICIPANTOBJECTID** | M | The prepopData Document unique ID |

| | | | |
|---|---|---|---|
| | *ParticipantObjectName* | *U* | *not specialized* |
| | ***PARTICIPANTOBJECTQUERY*** | *U* | *not specialized* |
| | *ParticipantObjectDetail* | *U* | *not specialized* |

## 5.Z3.2 Submit Form ([ITI-35]) audit messages

The Submit Form Transaction MAY be a PHI-Export event, as defined in ITI TF-2a: Table 3.20.6-1. The Actors involved in the transaction SHALL create audit data in conformance with DICOM (Supp 95) "Data Export"/"Data Import", with the following exceptions.

### 5.Z3.2.1 Form Filler audit message:

| | Field Name | Opt | Value Constraints |
|---|---|---|---|
| **Event** AuditMessage/ EventIdentification | EventID | M | EV(110106, DCM, "Export") |
| | EventActionCode | M | "R" (Read) |
| | *EventDateTime* | *M* | *not specialized* |
| | *EventOutcomeIndicator* | *M* | *not specialized* |
| | EventTypeCode | M | EV("ITI-35", "IHE Transactions", "Submit Form") |
| Source (Document Source) (1) | | | |
| Human Requestor (0..n) | | | |
| Destination (Document Repository) (1) | | | |
| Audit Source (Document Source) (1) | | | |
| Subject (1) | | | |
| FormData (1) | | | |

Where:

| | | | |
|---|---|---|---|
| **Source** AuditMessage/ ActiveParticipant | UserID | M | Host system name |
| | AlternativeUserID | M | The process ID as used within the local operating system in the local system logs. |
| | *UserName* | *U* | *not specialized* |
| | UserIsRequestor | M | "true" |
| | RoleIDCode | M | EV(110153, DCM, "Source") |
| | NetworkAccessPointTypeCode | M | "1" for machine (DNS) name, "2" for IP address |
| | NetworkAccessPointID | M | The machine name or IP address, as specified in RFC 3881. |
| **Human Requestor (if known)** AuditMessage/ ActiveParticipant | UserID | M | Identity of the human that initiated the transaction. |
| | *AlternativeUserID* | *U* | *not specialized* |
| | *UserName* | *U* | *not specialized* |
| | UserIsRequestor | M | "true" |
| | RoleIDCode | U | Access Control role(s) the user holds that allows this transaction. |
| | *NetworkAccessPointTypeCode* | *NA* | |
| | *NetworkAccessPointID* | *NA* | |

| | | | |
|---|---|---|---|
| **Destination** | UserID | M | SOAP endpoint URI. |

 

| | | | |
|---|---|---|---|
| | *AlternativeUserID* | *U* | *not specialized* |
| | *UserName* | *U* | *not specialized* |
| | UserIsRequestor | M | "false" |
| | RoleIDCode | M | EV(110152, DCM, "Destination") |
| | NetworkAccessPointTypeCode | M | "1" for machine (DNS) name, "2" for IP address |
| | NetworkAccessPointID | M | The machine name or IP address, as specified in RFC 3881. |

| | | | |
|---|---|---|---|
| **Audit Source** AuditMessage/ AuditSourceIdentification | *AuditSourceID* | *U* | *Not specialized.* |
| | *AuditEnterpriseSiteID* | *U* | *not specialized* |
| | *AuditSourceTypeCode* | *U* | *not specialized* |

| | | | |
|---|---|---|---|
| **Subject** (AuditMessage/ ParticipantObjectIdentification) | ParticipantObjectTypeCode | M | "1" (Person) |
| | ParticipantObjectTypeCodeRole | M | "1" (Patient) |
| | *ParticipantObjectDataLifeCycle* | *U* | *not specialized* |
| | ParticipantObjectIDTypeCode | M | EV(2, RFC-3881, "Subject Number") |
| | *ParticipantObjectSensitivity* | *U* | *not specialized* |
| | **PARTICIPANTOBJECTID** | M | The subject ID in HL7 CX format. |
| | *ParticipantObjectName* | *U* | *not specialized* |
| | ***PARTICIPANTOBJECTQUERY*** | *U* | *not specialized* |
| | *ParticipantObjectDetail* | *U* | *not specialized* |
| **FormData** (AuditMessage/ ParticipantObjectIdentification) | ParticipantObjectTypeCode | M | "2" (System) |
| | ParticipantObjectTypeCodeRole | M | "20" (job) |
| | *ParticipantObjectDataLifeCycle* | *U* | *not specialized* |
| | ParticipantObjectIDTypeCode | M | EV(2, RFC-3881, "Form ID") |
| | *ParticipantObjectSensitivity* | *U* | *not specialized* |
| | **PARTICIPANTOBJECTID** | M | A form identifier |
| | *ParticipantObjectName* | *U* | *not specialized* |
| | ***PARTICIPANTOBJECTQUERY*** | *U* | *not specialized* |
| | *ParticipantObjectDetail* | *U* | *not specialized* |

### 5.Z3.2.2 Form Receiver audit message:

| | Field Name | Opt | Value Constraints |
|---|---|---|---|
| **Event** AuditMessage/ EventIdentification | EventID | M | EV(110107, DCM, "Import") |
| | EventActionCode | M | "C" (Create) |
| | *EventDateTime* | *M* | *not specialized* |
| | *EventOutcomeIndicator* | *M* | *not specialized* |
| | EventTypeCode | M | EV("ITI-35", "IHE Transactions", "Submit Form") |
| Source (Document Source) (1) | | | |
| Destination (Document Repository or Document Recipient) (1) | | | |

 

| |
|---|
| Audit Source (Document Repository or Document Recipient) (1) |
| Subject (1) |
| FormData (1) |

630 Where:

| | | | |
|---|---|---|---|
| **Source**<br>AuditMessage/ ActiveParticipant | UserID | M | Host system name |
| | AlternativeUserID | *U* | *not specialized* |
| | *UserName* | *U* | *not specialized* |
| | UserIsRequestor | M | "false" |
| | RoleIDCode | M | EV(110153, DCM, "Source") |
| | NetworkAccessPointTypeCode | M | "1" for machine (DNS) name, "2" for IP address |
| | NetworkAccessPointID | M | The machine name or IP address, as specified in RFC 3881. |

| | | | |
|---|---|---|---|
| **Destination**<br>AuditMessage/ ActiveParticipant | UserID | M | SOAP endpoint URI |
| | *AlternativeUserID* | M | The process ID as used within the local operating system in the local system logs. |
| | *UserName* | *U* | *not specialized* |
| | UserIsRequestor | M | "false" |
| | RoleIDCode | M | EV(110152, DCM, "Destination") |
| | NetworkAccessPointTypeCode | M | "1" for machine (DNS) name, "2" for IP address |
| | NetworkAccessPointID | M | The machine name or IP address, as specified in RFC 3881. |

| | | | |
|---|---|---|---|
| **Audit Source**<br>AuditMessage/ AuditSourceIdentification | *AuditSourceID* | *U* | *Not specialized.* |
| | *AuditEnterpriseSiteID* | *U* | *not specialized* |
| | *AuditSourceTypeCode* | *U* | *not specialized* |

| | | | |
|---|---|---|---|
| **Subject**<br>(AuditMessage/ ParticipantObjectIdentification) | ParticipantObjectTypeCode | M | "1" (Person) |
| | ParticipantObjectTypeCodeRole | M | "1" (Patient) |
| | *ParticipantObjectDataLifeCycle* | *U* | *not specialized* |
| | ParticipantObjectIDTypeCode | M | EV(2, RFC-3881, "Subject Number") |
| | *ParticipantObjectSensitivity* | *U* | *not specialized* |
| | **PARTICIPANTOBJECTID** | M | The subject ID in HL7 CX format. |
| | *ParticipantObjectName* | *U* | *not specialized* |
| | ***PARTICIPANTOBJECTQUERY*** | *U* | *not specialized* |
| | *ParticipantObjectDetail* | *U* | *not specialized* |
| **Form Data** | ParticipantObjectTypeCode | M | "2" (System) |

| | | | |
|---|---|---|---|
| | ParticipantObjectTypeCodeRole | M | "20" (job) |
| | *ParticipantObjectDataLifeCycle* | *U* | *not specialized* |
| | ParticipantObjectIDTypeCode | M | EV2, RFC-3881, "Form ID") |
| | *ParticipantObjectSensitivity* | *U* | *not specialized* |
| | **PARTICIPANTOBJECTID** | M | An identifier for the form |
| | *ParticipantObjectName* | *U* | *not specialized* |
| | ***PARTICIPANTOBJECTQUERY*** | *U* | *not specialized* |
| | *ParticipantObjectDetail* | *U* | *not specialized* |

### 5.Z3.3 Archive Form ([ITI-36]) audit messages

The Archive Form Transaction MAY be a PHI-Export event, as defined in ITI TF-2a: Table 3.20.6-1. The Actors involved in the transaction SHALL create audit data in conformance with DICOM (Supp 95) "Data Export"/"Data Import", with the following exceptions.

#### 5.Z3.3.1 Form Filler audit message:

The requirements are the same as in section 5.Z3.2.1, Submit Form from Form Filler, except the eventType SHALL be EV("ITI-36", "IHE Transactions", "Archive Form").

#### 5.Z3.3.2 Form Archiver audit message:

The requirements are the same as in section 5.Z3.2.2, except the eventType SHALL be EV("ITI-36", "IHE Transactions", "Archive Form").

### 5.Z3.4 ArchiveSourceDocuments ([QRPH-36]) audit messages

The Retrieve Form Transaction is PHI-Export event, as defined in ITI TF-2a: Table 3.20.6-1. The Actors involved in the transaction SHALL create audit data in conformance with DICOM (Supp 95) "Data Export"/"Data Import", with the following exceptions.

#### 5.Z3.4.1 Form Filler audit message:

| | Field Name | Opt | Value Constraints |
|---|---|---|---|
| **Event** AuditMessage/ EventIdentification | EventID | M | EV(110106, DCM, "Export") |
| | EventActionCode | M | "R" (Read) |
| | *EventDateTime* | *M* | *not specialized* |
| | *EventOutcomeIndicator* | *M* | *not specialized* |
| | EventTypeCode | M | EV("QRPH-36", "IHE Transactions", "ArchiveSourceDocuments") |
| Source (Document Source) (1) | | | |
| Human Requestor (0..n) | | | |
| Destination (Document Repository) (1) | | | |
| Audit Source (Document Source) (1) | | | |

| Subject (1) |
|---|
| prepopData (1) |

Where:

| | | | |
|---|---|---|---|
| **Source**<br>AuditMessage/ ActiveParticipant | UserID | M | Host system name |
| | AlternativeUserID | M | The process ID as used within the local operating system in the local system logs. |
| | *UserName* | *U* | *not specialized* |
| | UserIsRequestor | M | "true" |
| | RoleIDCode | M | EV(110153, DCM, "Source") |
| | NetworkAccessPointTypeCode | M | "1" for machine (DNS) name, "2" for IP address |
| | NetworkAccessPointID | M | The machine name or IP address, as specified in RFC 3881. |
| **Human Requestor (if known)**<br>AuditMessage/ ActiveParticipant | UserID | M | Identity of the human that initiated the transaction. |
| | *AlternativeUserID* | *U* | *not specialized* |
| | *UserName* | *U* | *not specialized* |
| | UserIsRequestor | M | "true" |
| | RoleIDCode | U | Access Control role(s) the user holds that allows this transaction. |
| | *NetworkAccessPointTypeCode* | *NA* | |
| | *NetworkAccessPointID* | *NA* | |

| | | | |
|---|---|---|---|
| **Destination**<br>AuditMessage/ ActiveParticipant | UserID | M | SOAP endpoint URI. |
| | *AlternativeUserID* | *U* | *not specialized* |
| | *UserName* | *U* | *not specialized* |
| | UserIsRequestor | M | "false" |
| | RoleIDCode | M | EV(110152, DCM, "Destination") |
| | NetworkAccessPointTypeCode | M | "1" for machine (DNS) name, "2" for IP address |
| | NetworkAccessPointID | M | The machine name or IP address, as specified in RFC 3881. |

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| | | | |
|---|---|---|---|
| **Audit Source**<br>AuditMessage/ AuditSourceIdentification | *AuditSourceID* | *U* | *Not specialized.* |
| | *AuditEnterpriseSiteID* | *U* | *not specialized* |
| | *AuditSourceTypeCode* | *U* | *not specialized* |

| | | | |
|---|---|---|---|
| **Subject** | ParticipantObjectTypeCode | M | "1" (Person) |

| | | | |
|---|---|---|---|
| | ParticipantObjectTypeCodeRole | M | "1" (Patient) |
| | *ParticipantObjectDataLifeCycle* | *U* | *not specialized* |
| | ParticipantObjectIDTypeCode | M | EV(2, RFC-3881, "Subject Number") |
| | *ParticipantObjectSensitivity* | *U* | *not specialized* |
| | **PARTICIPANTOBJECTID** | M | The subject ID in HL7 CX format. |
| | *ParticipantObjectName* | *U* | *not specialized* |
| | ***PARTICIPANTOBJECTQUERY*** | *U* | *not specialized* |
| | *ParticipantObjectDetail* | *U* | *not specialized* |
| **prepopData** (AuditMessage/ ParticipantObjectIdentification) | ParticipantObjectTypeCode | M | "2" (System) |
| | ParticipantObjectTypeCodeRole | M | "20" (job) |
| | *ParticipantObjectDataLifeCycle* | *U* | *not specialized* |
| | ParticipantObjectIDTypeCode | M | EV(2, RFC-3881, "Document ID") |
| | *ParticipantObjectSensitivity* | *U* | *not specialized* |
| | **PARTICIPANTOBJECTID** | M | The prepopData Document unique ID |
| | *ParticipantObjectName* | *U* | *not specialized* |
| | ***PARTICIPANTOBJECTQUERY*** | *U* | *not specialized* |
| | *ParticipantObjectDetail* | *U* | *not specialized* |

### 5.Z3.4.2 Form Archiver audit message:

| | Field Name | Opt | Value Constraints |
|---|---|---|---|
| **Event** AuditMessage/ EventIdentification | EventID | M | EV(110107, DCM, "Import") |
| | EventActionCode | M | "C" (Create) |
| | *EventDateTime* | *M* | *not specialized* |
| | *EventOutcomeIndicator* | *M* | *not specialized* |
| | EventTypeCode | M | EV("QRPH-36", "IHE Transactions", "ArchiveSourceDocuments") |
| Source (Document Source) (1) | | | |
| Destination (Document Repository or Document Recipient) (1) | | | |
| Audit Source (Document Repository or Document Recipient) (1) | | | |
| Subject (1) | | | |
| prepopData (1) | | | |

Where:

| | | | |
|---|---|---|---|
| **Source** AuditMessage/ ActiveParticipant | UserID | M | Host system name |
| | AlternativeUserID | *U* | *not specialized* |
| | *UserName* | *U* | *not specialized* |
| | UserIsRequestor | M | "false" |
| | RoleIDCode | M | EV(110153, DCM, "Source") |
| | NetworkAccessPointTypeCode | M | "1" for machine (DNS) name, "2" for IP address |
| | NetworkAccessPointID | M | The machine name or IP address, as specified in RFC 3881. |

| | | | |
|---|---|---|---|
| **Destination** | UserID | M | SOAP endpoint URI |

 

| | | | |
|---|---|---|---|
| | *AlternativeUserID* | M | The process ID as used within the local operating system in the local system logs. |
| | *UserName* | *U* | *not specialized* |
| | UserIsRequestor | M | "false" |
| | RoleIDCode | M | EV(110152, DCM, "Destination") |
| | NetworkAccessPointTypeCode | M | "1" for machine (DNS) name, "2" for IP address |
| | NetworkAccessPointID | M | The machine name or IP address, as specified in RFC 3881. |

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| | | | |
|---|---|---|---|
| **Audit Source** AuditMessage/ AuditSourceIdentification | *AuditSourceID* | *U* | *Not specialized.* |
| | *AuditEnterpriseSiteID* | *U* | *not specialized* |
| | *AuditSourceTypeCode* | *U* | *not specialized* |

| | | | |
|---|---|---|---|
| **Subject** (AuditMessage/ ParticipantObjectIdentification) | ParticipantObjectTypeCode | M | "1" (Person) |
| | ParticipantObjectTypeCodeRole | M | "1" (Patient) |
| | *ParticipantObjectDataLifeCycle* | *U* | *not specialized* |
| | ParticipantObjectIDTypeCode | M | EV(2, RFC-3881, "Subject Number") |
| | *ParticipantObjectSensitivity* | *U* | *not specialized* |
| | **PARTICIPANTOBJECTID** | M | The subject ID in HL7 CX format. |
| | *ParticipantObjectName* | *U* | *not specialized* |
| | ***PARTICIPANTOBJECTQUERY*** | *U* | *not specialized* |
| | *ParticipantObjectDetail* | *U* | *not specialized* |
| **prepopData** (AuditMessage/ ParticipantObjectIdentification) | ParticipantObjectTypeCode | M | "2" (System) |
| | ParticipantObjectTypeCodeRole | M | "20" (job) |
| | *ParticipantObjectDataLifeCycle* | *U* | *not specialized* |
| | ParticipantObjectIDTypeCode | M | EV2, RFC-3881, "Document ID") |
| | *ParticipantObjectSensitivity* | *U* | *not specialized* |
| | **PARTICIPANTOBJECTID** | M | The prepopData Document unique ID |
| | *ParticipantObjectName* | *U* | *not specialized* |
| | ***PARTICIPANTOBJECTQUERY*** | *U* | *not specialized* |
| | *ParticipantObjectDetail* | *U* | *not specialized* |

 

# Volume 3 – Content Modules

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# 5 HL7 V3 CDA Content Modules

### 6.3.1 CDA Document Content Modules

*Add to section 6.3.1*

The prepopData and workflowData data elements are included in the Retrieve Form Request message sent by the RFD Form Filler to the RFD Form Manager during the Retrieve Form transaction. As indicated in table 6.3.1-1 which further constrain them, those data elements also constitute the archiveContent data element which is archived by the Form Filler to the Form Archiver during the ArchiveSourceDocuments transaction when the option "ArchiveSourceDocuments" is selected.

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

| Parameter Name | REQ | Description | Value |
|---|---|---|---|
| prepopData | R | The xml for pre-population | As defined in ITI-TF supplement RFD : 3.34 |
| **workflowData** | R | The xml representation of workflow specific values. | This value is a well-formed xml document.as defined below. |
| formID | R | The identifier of a form. | A string identifying the form |
| encodedResponse | R | Tells the Form Archiver whether or not to return an encoded response | {true,false} |
| archiveURL | R | Tells the Form Archiver whether or not the Form Filler is exercising the Archive Option | the URL of any Form Filler identified Form Archiver or the null string |
| context | R | The xml specifics of workflow context | As defined in section 6.3.1.D1 |
| instanceID | R | An id value of a previously submitted instance of data. | A string identifying an instance of previously submitted data; may be nil. |

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

**Table 6.3.1-2: Optionality Key**

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

### 6.3.1.D CRD prepopData Document Content Module

Table 6.3.1.D-1 below lists the data elements which SHALL be provided as part of the Prepop data and the constraints (expressed in terms of optionality and templates) they SHALL obey in order to claim conformance to the CRD profile. The last but one column of the table indicates the places where exhaustive information on these data elements (including their CCD parents' template IDs and names) can be found.

**Table 6.3.1.D-1: Clinical Research Document prepop Data Content**

| | | | | |
|---|---|---|---|---|
| **Template ID** | **1.3.6.1.4.1.19376.1.7.3.1.1.10** | | | |
| **Parent Template** | **CCD document: 2.16.840.1.113883.10.20.1** | | | |
| **General Description** | The CRD document content module template specifies the content structure for an XML document containing Prepop data and provided by the Form Filler to the Form Manager during the Retrieve Form Transaction [ITI-34]. | | | |
| **Document Code** | LOINC Code: 34133-9 "Summary of Episode Note" | | | |
| **Opt** | **Data Element or Section Name** | **Template ID** | **Specification Document** | **Constraint** |
| **Header Elements** | | | | |
| R | Date of Birth | patientRole/patient/birthTime | 1.3.6.1.4.1.19376.1.5.3.1.3.6 | |
| R | Gender | patientRole/patient/administrativeGenderCode | 1.3.6.1.4.1.19376.1.5.3.1.3.6 | |
| O | Ethnicity | patientRole/patient/ethnicGroupCode | 1.3.6.1.4.1.19376.1.5.3.1.3.6 | |
| R2 | Race | patientRole/patient/raceCode | 1.3.6.1.4.1.19376.1.5.3.1.3.6 | |
| **Sections** | | | | |
| R | Active Problems | 1.3.6.1.4.1.19376.1.5.3.1.3.6 | PCC TF-2: 6.3.3.2.3 | |
| R2 | History of Past Illness | 1.3.6.1.4.1.19376.1.5.3.1.3.8 | PCC TF-2: 6.3.3.2.5 | |
| R2 | Procedures | 2.16.840.1.113883.10.20.1.12 | CCD specification: 3.14 | |
| R2 | Social History | 1.3.6.1.4.1.19376.1.5.3.1.3.16 | PCC TF-2: 6.3.3.2.14 | |
| R | Medications | 1.3.6.1.4.1.19376.1.5.3.1.3.19 | PCC TF-2: 6.3.3.3.1 | |
| R2 | Coded Vital Signs | 1.3.6.1.4.1.19376.1.5.3.1.1.5.3.2 | PCC TF-2: 6.3.3.4.5 | |
| R2 | Detailed Physical Examination | 1.3.6.1.4.1.19376.1.5.3.1.1.9.15 | PCC TF-2: 6.3.3.4.2 | |

| | | | | |
|---|---|---|---|---|
| R | Allergies and Other Adverse Reactions | 1.3.6.1.4.1.19376.1.5.3.1.3.13 | PCC TF-2: 6.3.3.2.11 | |
| R2 | Coded Results | 1.3.6.1.4.1.19376.1.5.3.1.3.28 | PCC TF-2:6.3.3.5.2 | |

### 6.3.1.D1 CRD Workflow Data Content Module

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

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

Table 6.3.1.D1-1 below lists the data elements which SHALL be provided as sub elements of that "Context" data element and the constraints (expressed in terms of optionality) they SHALL obey in order to claim conformance to the CRD profile.

Most of these sub elements are defined using CDASH Common Identifier Variables. Table 6.3.1.D1-2 provides a definition of these variables as well as a mapping to the CRD Workflow Data elements to which they are linked and the specification document where they are defined.

The sub element "PrePopArchiveID" (table 6.3.1.D1-2) contains the "documentId" of the prepopulation and workflow data submitted to the Form Archiver through the transaction ArchiveSourceDocuments transaction. Recall that this archiving of the prepopulation and workflow data (when the required option is selected) takes place before the "Retrieve Form" transaction [ITI-34].

**Table 6.3.1.D1-1: "Context" data element constraints**

| Optionality | Data element | Data Location |
|---|---|---|
| R | context | workflowData/context |
| R | StudyID | workflowData/context/ StudyID |
| R | SiteID | workflowData/context/ SiteID |
| R | SubjID | workflowData/context/ SubjID |
| O | USubjID | workflowData/context/ USubjID |
| O | InvID | workflowData/context/ InvID |
| O | SpID | workflowData/context/ SpID |
| O | Visit | workflowData/context/ Visit |

 

| Optionality | Data element | Data Location |
|---|---|---|
| O | VisitNum | workflowData/context/ VisitNum |
| R | VisDatTim | workflowData/context/ VisDatTim |
| R2 | PrePopArchiveID | workflowData/context/ PrePopArchiveID |

**Table 6.3.1.D1-2: Data elements CDASH reference**

| CDASH Data Collection Field | Definition | Specification document | CRD Data Element |
|---|---|---|---|
| Protocol/Study Identifier | Unique Identifier for a study within a submission | CDASH Standard, version 1.1: section 5.1.2 | StudyID |
| Site Identifier Within a Study | Unique identifier for the study site | CDASH Standard, version 1.1: section 5.1.3 | SiteID |
| Subject Identifier | Subject identifier for the study | CDASH Standard, version 1.1: section 5.1.4 | SubjID |
| Unique Subject Identifier | Unique subject identifier within a submission | CDASH Standard, version 1.1: section 5.1.5 | USubjID |
| Investigator Identifier | Investigator identifier | CDASH Standard, version 1.1: section 5.1.6 | InvID |
| Sponsor-Defined Identifier | Sponsor-defined reference number | CDASH Standard, version 1.1: section 5.1.1 | SpID |
| Visit | Visit Name / Visit Number | CDASH Standard, version 1.1: section 5.2.1/5.2.2 | Visit/ VisitNum |
| Date of Visit | Date the visit took place | CDASH Standard, version 1.1: section 5.2.3/5.2.4<br>QRPH-TF suppl CRD: section 3.Z2.1 | VisDatTim |
| Time of Visit | Time the visit took place | CDASH Standard, version 1.1: section 5.2.5/5.2.6<br>QRPH-TF suppl CRD: section 3.Z2.1 | VisDatTim |

### 6.3.1.D1.1 Workflow Data Sample

The content of workflowData parameter SHALL *minimally* be:

```
<workflowData>
<formID>a String identifying the form</formID>
<encodedResponse> false</encodedResponse>
<archiveURL />
<instanceID/>
<context>
```

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

The content of workflowData parameter SHALL ***optimally*** be:

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

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

### Submit Form ([ITI-35]) transaction constraint

This profile further constrains the Submit Form transaction [ITI-35] as defined in the RFD profile in ITI TF-1. In order to claim support of the CRD profile, BOTH the form instance data and the information contained in the workflowData data element SHALL be transmitted during the Submit Form transaction to the Form Receiver. The submission of the workflowData data element along with the instance form is not profiled, and is under the responsibility of the Form Manager.

### Archive Form ([ITI-36]) transaction constraint

This profile further constrains the Archive Form transaction [ITI-36] as defined in the RFD profile in ITI TF-1. In order to claim support of the CRD profile, BOTH the form instance data and the information contained in the workflowData data element SHALL be transmitted during the Archive Form transaction to the Form Archiver. The submission of the workflowData data element along with the instance form is not profiled, and is under the responsibility of the Form Manager.

# Appendices

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## Appendix A: CCD-ODM/CDASH mapping and CRD constraints

| | CCD-CDASH mapping and CRD constraints | | | |
|---|---|---|---|---|
| **CRD Reference** | **CDASH Domain** | **Clinical Database Variable Name** | **Optionality** | **Definition** |
| | **Common Identifiers** | STUDYID | R2 | Unique Identifier for a study within a submission. |
| | | SITEID | R2 | Unique identifier for the site. |
| | | SUBJID | R2 | Subject identifier. |
| | | INVID | O | Investigator identifier. |
| | | VISIT | O | Visit Name. |
| **Header Information** | **Demography** | BRTHYR | R | Year of subject's birth. |
| | | BRTHMO | R | Month of subject's birth. |
| | | BRTHDY | R2 | Day of subject's birth. |
| | | BRTHTM | O | Time of subject's birth, |
| | | SEX | R | The assemblage of physical properties or qualities by which male is distinguished from female; the physical difference between male and female; the distinguishing peculiarity of male or female. (NCI – CDISC Definition). |
| | | AGE | O | Numeric Age of Subject. |
| | | AGEU | O | Age units. |
| | | DMDAT | R2 | Date of collection. |
| | | DMTM (Note: If collected, will be derived into DMDTC.) | O | Time of collection. |
| | | ETHNIC | O | A social group characterized by a distinctive social and cultural tradition maintained from generation to generation, a common history and origin and a sense of identification with the group; members of the group have distinctive features in their way of life, shared experiences and often a common genetic heritage; these features MAY be |

| | CCD-CDASH mapping and CRD constraints | | | |
|---|---|---|---|---|
| **CRD Reference** | **CDASH Domain** | **Clinical Database Variable Name** | **Optionality** | **Definition** |
| | | | | 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. |
| | | | O | The age (in weeks) of the newborn infant, counted from the first day of the woman's last menstrual period (LMP) or health status indicators / Clinical Estimate (CE). |
| | | SCTESTCD | O | Natural eye color |
| | | SCTESTCD | O | Subject's childbearing potential |
| | | SCTESTCD | O | Education level achieved at start of study (Reference date) |
| | | SCTESTCD | O | Sub-study participation information. |
| **Active Problems, Past Medical History, and Procedures and Interventions** | **Medical History** | MHTERM | R | Verbatim or preprinted CRF term for the medical condition or event. |
| | | MHONGO | R | Identifies the end of the event as being ONGOING or RESOLVED. |
| | | MHYN | O | Lead prompt for the Medical History (e.g., "Has the subject experienced any past and / or concomitant diseases or past surgeries?"). |
| | | MHSPID | O | O sponsor-defined reference number (e.g., Preprinted line number). |
| | | MHCAT | O | Used to define a category of related records (e.g., CARDIAC or GENERAL). |
| | | MHSCAT | O | A categorization of the condition or event pre-printed on the CRF or instructions. |
| | | MHOCCUR | O | A pre-printed prompt used to indicate whether or not a medical condition has occurred. |
| | | MHSTDTC | O | Start Date of Medical History Event. |
| | | MHENDTC | O | End Date/Time of Medical History Event. |

| | CCD-CDASH mapping and CRD constraints | | | |
|---|---|---|---|---|
| **CRD Reference** | **CDASH Domain** | **Clinical Database Variable Name** | **Optionality** | **Definition** |
| **Current Medications** | **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 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. |

| | CCD-CDASH mapping and CRD constraints | | | |
|---|---|---|---|---|
| **CRD Reference** | **CDASH Domain** | **Clinical Database Variable Name** | **Optionality** | **Definition** |
| | | 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. |
| **Social History** | **Substance Use** | SUTRT | R | The type of substance (e.g., TOBACCO, ALCOHOL, CAFFEINE, etc. Or CIGARETTES, CIGARS, COFFEE, etc.). |
| | | SUNCF | R2 | Substance Use Occurrence. |
| | | SUCAT | O | Used to define a category of related records (e.g., TOBACCO, ALCOHOL, CAFFEINE, etc.). |
| | | SUDOSTXT | O | Substance use consumption amounts or a range of consumption information collected in text form [e.g., 1-2 (packs), 8 (ounces), etc.]. |
| | | SUDOSU | O | Units for SUDOSTXT (e.g., PACKS, OUNCES, etc.). |
| | | SUDOSFRQ | O | Usually expressed as the number of uses consumed per a specific interval (e.g., PER DAY, PER WEEK, OCCASIONAL). |
| | | SUSTDTC | O | Date substance use started. |
| | | SUSTTM (Note: If collected, will be derived into SUSTDTC.) | O | Time substance use started. |
| | | SUENDTC | O | Date substance use ended. |
| | | SUENTM (Note: If collected, will be derived into SUENDTC.) | O | Time substance use ended. |
| | | SUDUR | O | The duration of the substance use. |

| | CCD-CDASH mapping and CRD constraints | | | |
|---|---|---|---|---|
| **CRD Reference** | **CDASH Domain** | **Clinical Database Variable Name** | **Optionality** | **Definition** |
| **Vital Signs** | **Vital Signs** | VSDTC | R2 | Date of measurements |
| | | VSSPID | O | Sponsor defined reference number |
| | | VISITDY | O | Study day of measurements, measured as integer days |
| | | VSTPT | O | Text description of time when measurement SHOULD be taken |
| | | VSTM (Note: If collected, will be derived into VSDTC.) | O | Time of measurements. |
| | | VSTEST | R2 | Verbatim name of the test or examination used to obtain the measurement or finding. |
| | | VSSTAT | R2 | Used to indicate that a vital signs measurement was not done. |
| | | VSORRES | R | Result of the vital signs measurement as originally received or collected. |
| | | VSORRESU | R | Original units in which the data were collected. |
| | | VSLOC | R2 | Location on body where measurement was performed. |
| | | VSPOS | R2 | Position of the subject during a measurement or examination. |
| **Physical Exam** | **Physical Exam - Best Practice Approach** | PESTAT | O | Used to indicate if exam was not done as scheduled. |
| | | PEDTC | O | Date of examination. |
| | | PETM (Note: If collected, will be derived into PEDTC.) | O | Time of examination. |
| | **Physical Exam - Traditional Approach** | PEDONE | O | Used to indicate if exam was not done as scheduled. |
| | | PEDTC | R2 | Date of examination. |
| | | PETM (Note: If collected, will be derived into PEDTC.) | O | Time of examination. |
| | | PESPID | O | Sponsor defined reference number. |
| | | AEYN | O | General prompt question to aid in monitoring and data cleaning. |
| | | AESPID | O | A sponsor-defined reference number. |

| | CCD-CDASH mapping and CRD constraints | | | |
|---|---|---|---|---|
| **CRD Reference** | **CDASH Domain** | **Clinical Database Variable Name** | **Optionality** | **Definition** |
| **Allergies and Other Adverse Reactions** | **Adverse Events** | 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 |

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

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

| | CCD-CDASH mapping and CRD constraints | | | |
|---|---|---|---|---|
| **CRD Reference** | **CDASH Domain** | **Clinical Database Variable Name** | **Optionality** | **Definition** |
| | | LBCAT LBSCAT | R2 | Type of draw / category / panel name. Used to define a category of related records. |
| | | LBTPT | R2 | Relative time for use when multiple sequential assessments are done, |
| | | LBFAST (for example) | R2 | Conditions for sampling defined in the protocol. |
| | | 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…** | LBDTC | R | Date of sample collection. |
| | | LBTM (Note: If collected, will be derived into LBDTC.) | O | Time of collection. |
| | | SBSTAT | R2 | Status of whether or not lab was done. |

| | CCD-CDASH mapping and CRD constraints | | | |
|---|---|---|---|---|
| **CRD Reference** | **CDASH Domain** | **Clinical Database Variable Name** | **Optionality** | **Definition** |
| **Coded Results** | | LBCAT LBSCAT | R2 | Type of draw / category / panel name. Used to define a category of related records. |
| | | LBTPT | R2 | Relative time for use when multiple sequential assessments are done. |
| | | LBFAST (for example) | O | Conditions for sampling defined in the protocol. |
| | | LBREFID | O | Internal or external specimen identifier. |
| | **ECG Test Results - Scenario 2: Local reading: ECGs…** | EGSTAT | R2 | Status of whether or not ECG was done. |
| | | EGREASND | O | Describes why the ECG was not done (e.g., BROKEN EQUIPMENT, SUBJECT REFUSED). |
| | | EGDTC | R2 | Date of ECG. |
| | | EGTM (Note: If collected, will be derived into EGDTC.) | R2 | Time of ECG. |
| | | 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, |

| | CCD-CDASH mapping and CRD constraints | | | |
|---|---|---|---|---|
| **CRD Reference** | **CDASH Domain** | **Clinical Database Variable Name** | **Optionality** | **Definition** |
| | | | | 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). |
| | | 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 |

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

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

## B.1 XSLT Sample

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

<!-- kick off the transformation with this default template -->
<xsl:template match="cda:ClinicalDocument">
  <!--odm:ODM xmlns:ds="http://www.w3.org/2000/09/xmldsig#"
xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance" ODMVersion="1.3"
FileOID="CLL.003" PriorFileOID="CRF_CLL_v1.6" FileType="SnapShot"
Description="IHE CDASH from CCD"-->
   <!-- TODO: add attributes for the following
     AsOfDateTime="2008-04-28T14:03:56"
     CreationDateTime="2008-04-28T14:03:56"
   -->
  <xsl:element name="ODM" namespace="http://www.cdisc.org/ns/odm/v1.3">
    <xsl:attribute name="AsOfDateTime"><xsl:value-of select="current-
dateTime()"/></xsl:attribute>
    <xsl:attribute name="ODMVersion">1.3</xsl:attribute>
    <xsl:attribute name="FileType">Transactional</xsl:attribute>
    <xsl:attribute name="FileOID">TEST</xsl:attribute>
    <xsl:attribute name="CreationDateTime"><xsl:value-of select="current-
dateTime()"/></xsl:attribute>
    <!-- ClinicalData element -->
    <xsl:element name="ClinicalData"
namespace="http://www.cdisc.org/ns/odm/v1.3">
     <xsl:attribute name="StudyOID">CLL.001</xsl:attribute>
     <xsl:attribute name="MetaDataVersionOID">001</xsl:attribute>
     <!-- SubjectData element -->
```

```
    <xsl:element name="SubjectData"
namespace="http://www.cdisc.org/ns/odm/v1.3">
      <xsl:attribute name="SubjectKey">1038</xsl:attribute>
      <!-- SiteRef element -->
      <xsl:element name="SiteRef"
namespace="http://www.cdisc.org/ns/odm/v1.3">
       <xsl:attribute name="LocationOID">100</xsl:attribute>
      </xsl:element>
      <!-- StudyEventData element -->
      <xsl:element name="StudyEventData"
namespace="http://www.cdisc.org/ns/odm/v1.3">
       <xsl:attribute name="StudyEventOID">CLL_CRF</xsl:attribute>
      <!-- multiple FormData Elements, representing CDASH Domains -->
      <!-- demography -->
      <xsl:call-template name="demography"/>
      <!-- medical history -->
      <xsl:call-template name="medicalHistory"/>
      <!-- conMeds -->
      <xsl:call-template name="conMeds"/>
      <!-- substance use -->
      <xsl:call-template name="substanceAbuse"/>
      <!-- vitals -->
      <xsl:call-template name="vitalSigns"/>
      <!-- physical exam -->
      <!-- AE -->
      <xsl:call-template name="adverseEvents"/>
      <!-- lab results -->
      <!-- ECG results -->
      </xsl:element>
   </xsl:element>
  </xsl:element>
  </xsl:element>
</xsl:template>

  <!-- ODM Templates -->
  <!-- demography -->
  <xsl:template name="demography">
  <!-- get the patient node, from which we can get the sex and date of birth -
->
   <xsl:variable name="patientNode"
select="cda:recordTarget/cda:patientRole/cda:patient"/>
   <xsl:element name="FormData" namespace="http://www.cdisc.org/ns/odm/v1.3">
    <xsl:attribute name="FormOID">DemographicsForm</xsl:attribute>
    <xsl:comment>check on whether or not we can get Ethnicity and
Race</xsl:comment>
    <xsl:element name="ItemGroupData"
namespace="http://www.cdisc.org/ns/odm/v1.3">
      <xsl:attribute name="ItemGroupOID">DM</xsl:attribute>
      <!-- SEX -->
      <xsl:element name="ItemData"
namespace="http://www.cdisc.org/ns/odm/v1.3">
       <xsl:attribute name="ItemOID">SEX</xsl:attribute>
```

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


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

  <!-- if we have any of the above then we output this section, i.e., FormData
element -->
  <xsl:if test="($conditionsCount+$pmhCount+$proceduresCount)>0">
    <xsl:element name="FormData" namespace="http://www.cdisc.org/ns/odm/v1.3">
      <xsl:attribute name="FormOID">MedicalHistory</xsl:attribute>
      <!-- just loop thru the entry elements in each of the sections -->
```

 

```
    <!-- NOTE:  we're making up the ItemGroupOID's....these SHOULD be
standardized; it also might be that all med history items SHOULD be in one
ItemGroup -->
    <xsl:for-each select="$ccdConditions/cda:entry">
      <xsl:element name="ItemGroupData"
namespace="http://www.cdisc.org/ns/odm/v1.3">
        <xsl:attribute name="ItemGroupOID">CONDITION</xsl:attribute>
        <xsl:call-template name="problemItemData"><xsl:with-param
name="theNode" select="."/></xsl:call-template>
      </xsl:element>
    </xsl:for-each>
    <xsl:for-each select="$ccdPMH/cda:entry">
      <xsl:element name="ItemGroupData"
namespace="http://www.cdisc.org/ns/odm/v1.3">
        <xsl:attribute name="ItemGroupOID">PASTCONDITION</xsl:attribute>
        <xsl:call-template name="problemItemData"><xsl:with-param
name="theNode" select="."/></xsl:call-template>
      </xsl:element>
    </xsl:for-each>
    <xsl:for-each select="$ccdProcedures/cda:entry">
      <xsl:element name="ItemGroupData"
namespace="http://www.cdisc.org/ns/odm/v1.3">
        <xsl:attribute name="ItemGroupOID">PROCEDURE</xsl:attribute>
        <xsl:call-template name="procedureItemData"><xsl:with-param
name="theNode" select="."/></xsl:call-template>
      </xsl:element>
    </xsl:for-each>
   </xsl:element>
  </xsl:if>
</xsl:template>


<!-- CON MEDS -->
<xsl:template name="conMeds">
  <xsl:variable name="ccdMedication"
select="cda:component/cda:structuredBody/cda:component/cda:section[cda:code/@
code='10160-0']"/>
  <xsl:variable name="conMedCount" select="count($ccdMedication/cda:entry)"/>
  <xsl:if test="$conMedCount>0">
    <!--FormData FormDataOID='ConMedForm'-->
    <xsl:element name="FormData" namespace="http://www.cdisc.org/ns/odm/v1.3">
      <xsl:attribute name="FormOID">ConMedForm</xsl:attribute>
      <xsl:for-each select="$ccdMedication/cda:entry">
      <!-- we MAY be pointed to the text of the med, or we MAY just have the
text-->
      <xsl:variable name="originalTextRef"
select="cda:substanceAdministration/cda:consumable/cda:manufacturedProduct/cd
a:manufacturedMaterial/cda:code/cda:originalText/cda:reference/@value"/>
      <xsl:variable name="originalText"
select="cda:substanceAdministration/cda:consumable/cda:manufacturedProduct/cd
a:manufacturedMaterial/cda:code/cda:originalText"/>
      <!--ItemGroupData ItemGroupOID='CM'-->
```

```
    <xsl:element name="ItemGroupData"
namespace="http://www.cdisc.org/ns/odm/v1.3">
      <xsl:attribute name="ItemGroupOID">CM</xsl:attribute>
      <!-- CMTRT -->
      <!--ItemData ItemDataOID='CMTRT'-->
      <xsl:element name="ItemData"
namespace="http://www.cdisc.org/ns/odm/v1.3">
        <xsl:attribute name="ItemOID">CMTRT</xsl:attribute>
        <xsl:attribute name="Value">
          <xsl:choose>
            <xsl:when test="$originalTextRef"><xsl:value-of
select="//*[@ID=substring-after($originalTextRef,'#')]"/></xsl:when>
            <xsl:otherwise><xsl:value-of
select="$originalText"/></xsl:otherwise>
          </xsl:choose>
        </xsl:attribute>
      </xsl:element>
      <!-- CMDOSFREQ -->
      <xsl:comment>need table to translate HL7 frequency, e.g., 6h to
BID</xsl:comment>
      <!-- CMROUTE -->
      <xsl:variable name="routeCode"
select="cda:substanceAdministration/cda:routeCode/@displayName"/>
      <xsl:if test="$routeCode">
        <!--ItemData ItemDataOID='CMROUTE'-->
        <xsl:element name="ItemData"
namespace="http://www.cdisc.org/ns/odm/v1.3">
          <xsl:attribute name="ItemOID">CMROUTE</xsl:attribute>
          <xsl:attribute name="Value"><xsl:value-of
select="$routeCode"/></xsl:attribute>
        </xsl:element><!--/ItemData-->
      </xsl:if>
      <!-- CMSTDTC -->
      <xsl:variable name="medStartDate"
select="cda:substanceAdministration/cda:effectiveTime[@xsi:type='IVL_TS']/cda
:low/@value"/>
      <xsl:if test="$medStartDate">
        <!--ItemData ItemDataOID='CMSTDTC'-->
        <xsl:element name="ItemData"
namespace="http://www.cdisc.org/ns/odm/v1.3">
          <!-- transform stupid non-ISO8601-XML date to ISO8601 date -->
          <xsl:variable name="ISODATE">
            <xsl:call-template name="HL7DateToISO8601">
              <xsl:with-param name="HL7Date" select="$medStartDate"/>
            </xsl:call-template>
          </xsl:variable>
          <xsl:attribute name="ItemOID">CMSTDTC</xsl:attribute>
          <!--xsl:attribute name="Value"><xsl:value-of
select="$medStartDate"/></xsl:attribute-->
          <xsl:attribute name="Value"><xsl:value-of
select="$ISODATE"/></xsl:attribute>
        </xsl:element><!--/ItemData-->
```

```
      </xsl:if>
      <!-- CMENDTC -->
      <xsl:variable name="medEndDate"
select="cda:substanceAdministration/cda:effectiveTime[@xsi:type='IVL_TS']/cda
:high/@value"/>
      <xsl:if test="$medEndDate">
        <!--ItemData ItemDataOID='CMENDDTC'-->
        <xsl:element name="ItemData"
namespace="http://www.cdisc.org/ns/odm/v1.3">
          <xsl:attribute name="ItemOID">CMENDDTC</xsl:attribute>
          <!-- transform stupid non-ISO8601-XML date to ISO8601 date -->
          <xsl:variable name="ISODATE">
            <xsl:call-template name="HL7DateToISO8601">
              <xsl:with-param name="HL7Date" select="$medEndDate"/>
            </xsl:call-template>
          </xsl:variable>
          <!--xsl:attribute name="Value"><xsl:value-of
select="$medEndDate"/></xsl:attribute-->
          <xsl:attribute name="Value"><xsl:value-of
select="$ISODATE"/></xsl:attribute>
        </xsl:element><!--/ItemData-->
      </xsl:if>
    </xsl:element>
    <!--/ItemGroupData-->
   </xsl:for-each>
   </xsl:element>
  </xsl:if>
</xsl:template>

<!-- SUBSTANCE ABUSE -->
<xsl:template name="substanceAbuse">
  <!-- we could look into the social history for any of a specific list of
substance abuse entries...if any are present then we emit the section -->
  <!-- however, there are probably too many codes to consider....just quickly
looking we see several SNOMED codes for smoking, cigarette smoking, .... -->
</xsl:template>


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

 

```
    <xsl:variable name="vitalsDateTime" select="cda:effectiveTime/@value"/>
    <!--ItemGroupData ItemGroupDataOID='VS'-->
    <xsl:element name="ItemGroupData"
namespace="http://www.cdisc.org/ns/odm/v1.3">
      <xsl:attribute name="ItemGroupOID">VS</xsl:attribute>
      <!-- VSDTC -->
      <!--ItemData ItemDataOID='VSDTC'-->
      <xsl:element name="ItemData"
namespace="http://www.cdisc.org/ns/odm/v1.3">
        <!-- transform stupid non-ISO8601-XML date to ISO8601 date -->
        <xsl:variable name="ISODATE">
          <xsl:call-template name="HL7DateToISO8601">
            <xsl:with-param name="HL7Date" select="$vitalsDateTime"/>
          </xsl:call-template>
        </xsl:variable>
        <xsl:attribute name="ItemOID">VSDTC</xsl:attribute>
        <!--xsl:attribute name="Value"><xsl:value-of
select="$vitalsDateTime"/></xsl:attribute-->
        <xsl:attribute name="Value"><xsl:value-of
select="$ISODATE"/></xsl:attribute>
      </xsl:element><!--/ItemData-->
    <!-- now go get all of the components from this recording -->
    <xsl:for-each select="cda:component">
      <xsl:variable name="vitalsResultNode"
select="cda:observation/cda:value"/>
      <!-- VSTEST -->
      <!--ItemData ItemDataOID='VSTEST'-->
      <xsl:element name="ItemData"
namespace="http://www.cdisc.org/ns/odm/v1.3">
        <xsl:attribute name="ItemOID">VSTEST</xsl:attribute>
        <xsl:attribute name="Value"><xsl:value-of
select="cda:observation/cda:code/@displayName"/></xsl:attribute>
      </xsl:element>
        <xsl:choose>
          <xsl:when test="$vitalsResultNode/@xsi:type='PQ'">
          <!-- VSORRES -->
            <!--ItemData ItemDataOID='VSORRES'-->
            <xsl:element name="ItemData"
namespace="http://www.cdisc.org/ns/odm/v1.3">
              <xsl:attribute name="ItemOID">VSORRES</xsl:attribute>
              <xsl:attribute name="Value"><xsl:value-of
select="$vitalsResultNode/@value"/></xsl:attribute>
            </xsl:element><!--/ItemData-->
            <!-- VSORRESU -->
            <!--ItemData ItemDataOID='VSORRESU'-->
            <xsl:element name="ItemData"
namespace="http://www.cdisc.org/ns/odm/v1.3">
              <xsl:attribute name="ItemOID">VSORRESU</xsl:attribute>
              <xsl:attribute name="Value"><xsl:value-of
select="$vitalsResultNode/@unit"/></xsl:attribute>
            </xsl:element><!--/ItemData-->
          </xsl:when>
```

```
          <xsl:otherwise>
            <!-- VSORRES ...no units -->
            <!--ItemData ItemDataOID='VSORRES'-->
            <xsl:element name="ItemData"
namespace="http://www.cdisc.org/ns/odm/v1.3">
              <xsl:attribute name="ItemOID">VSORRES</xsl:attribute>
              <xsl:attribute name="Value"><xsl:value-of
select="$vitalsResultNode"/></xsl:attribute>
            </xsl:element><!--/ItemData-->
          </xsl:otherwise>
        </xsl:choose>
      </xsl:for-each>
      </xsl:element><!--/ItemGroupData-->
    </xsl:for-each>
  </xsl:element><!--/FormData-->
</xsl:if>
</xsl:template>

<!-- AE -->
<xsl:template name="adverseEvents">
<xsl:variable name="aeSection"
select="cda:component/cda:structuredBody/cda:component/cda:section[cda:code/@
code='48765-2']"/>
<xsl:if test="$aeSection/cda:entry/cda:act">
  <!--FormData FormDataOID='AEForm'-->
  <xsl:element name="FormData" namespace="http://www.cdisc.org/ns/odm/v1.3">
    <xsl:attribute name="FormOID">AEForm</xsl:attribute>
    <xsl:for-each select="$aeSection/cda:entry">
      <!--ItemDataGroup ItemDataGroupOID='AE'-->
      <xsl:element name="ItemGroupData"
namespace="http://www.cdisc.org/ns/odm/v1.3">
        <xsl:attribute name="ItemGroupOID">AE</xsl:attribute>
        <!-- AETERM -->
        <xsl:variable name="originalTextRef"
select="cda:act/cda:entryRelationship/cda:observation/cda:participant/cda:par
ticipantRole/cda:playingEntity/cda:code/cda:originalText/cda:reference/@value
"/>
        <xsl:variable name="codedDisplayName"
select="cda:act/cda:entryRelationship/cda:observation/cda:participant/cda:par
ticipantRole/cda:playingEntity/cda:code/@displayName"/>
        <!--ItemData ItemDataOID='AETERM'-->
        <xsl:element name="ItemData"
namespace="http://www.cdisc.org/ns/odm/v1.3">
          <xsl:attribute name="ItemOID">AETERM</xsl:attribute>
          <xsl:attribute name="Value">
            <xsl:choose>
              <xsl:when test="$originalTextRef"><xsl:value-of
select="//*[@ID=substring-after($originalTextRef,'#')]"/></xsl:when>
              <xsl:otherwise><xsl:value-of
select="$codedDisplayName"/></xsl:otherwise>
            </xsl:choose>
          </xsl:attribute>
```

 

```
      </xsl:element><!--/ItemData-->
      <!-- AESTDTC -->
      <xsl:variable name="aeStartDateTime"
select="cda:act/cda:entryRelationship/cda:observation/cda:effectiveTime/@valu
e"/>
      <xsl:if test="$aeStartDateTime">
        <!--ItemData ItemDataOID='AESTDTC'-->
        <xsl:element name="ItemData"
namespace="http://www.cdisc.org/ns/odm/v1.3">
          <xsl:attribute name="ItemOID">AESTDTC</xsl:attribute>
          <xsl:attribute name="value"><xsl:value-of
select="$aeStartDateTime"/></xsl:attribute>
        </xsl:element><!--/ItemData-->
      </xsl:if>
    </xsl:element><!--/ItemDataGroup-->
  </xsl:for-each>
 </xsl:element><!--/FormData-->
</xsl:if>

</xsl:template>

<!-- helper templates -->

<!-- CDASH a med history item -->
<xsl:template name="problemItemData">
<xsl:param name="theNode"/>
 <!-- we MAY be pointed to the text of the condition, or we MAY just have a
coded value display name -->
 <xsl:variable name="originalTextRef"
select="$theNode/cda:act/cda:entryRelationship/cda:observation/cda:text/cda:r
eference/@value"/>
 <xsl:variable name="codedValue"
select="$theNode/cda:act/cda:entryRelationship/cda:observation/cda:value/@dis
playName"/>
 <!-- problem status translates into the CDASH MHONG -->
 <xsl:variable name="problemStatusNode"
select="$theNode/cda:act/cda:entryRelationship/cda:observation/cda:entryRelat
ionship/cda:observation[cda:code/@code='33999-4']"/>
 <!-- can have status coded or by reference -->
 <xsl:variable name="problemStatusRef"
select="$problemStatusNode/cda:text/cda:reference/@value"/>
 <!-- onset and end dates for problems -->
 <xsl:variable name="problemOnset"
select="$theNode/cda:act/cda:entryRelationship/cda:observation/cda:effectiveT
ime/cda:low/@value"/>
 <xsl:variable name="problemResolved"
select="$theNode/cda:act/cda:entryRelationship/cda:observation/cda:effectiveT
ime/cda:high/@value"/>
 <!-- MHTERM -->
 <!--ItemData ItemOID='MHTERM'-->
 <xsl:element name="ItemData" namespace="http://www.cdisc.org/ns/odm/v1.3">
  <xsl:attribute name="ItemOID">MHTERM</xsl:attribute>
```

 

```
    <xsl:attribute name="Value">
      <xsl:choose>
        <xsl:when test="string-length($originalTextRef)>0"><xsl:value-of
select="//*[@ID=substring-after($originalTextRef,'#')]"/></xsl:when>
        <xsl:when test="string-length($codedValue)>0"><xsl:value-of
select="$codedValue"/></xsl:when>
        <xsl:otherwise>???</xsl:otherwise>
      </xsl:choose>
    </xsl:attribute>
  </xsl:element><!--/ItemData-->
  <!-- MHONG -->
  <!--ItemData ItemOID='MHONG'-->
  <xsl:element name="ItemData" namespace="http://www.cdisc.org/ns/odm/v1.3">
    <xsl:attribute name="ItemOID">MHONG</xsl:attribute>
    <xsl:attribute name="Value">
      <xsl:choose>
        <xsl:when
test="$problemStatusNode/cda:value/@displayName='Active'">ONGOING</xsl:when>
        <xsl:when test="//*[@ID=substring-
after($problemStatusRef,'#')]='Active'">ONGOING</xsl:when>
        <xsl:otherwise>RESOLVED</xsl:otherwise>
      </xsl:choose>
    </xsl:attribute>
  </xsl:element><!--/ItemData-->

  <xsl:comment>research adding type and category (MHCAT, MHSCAT)</xsl:comment>
  <!-- NOTE:  might need a more generic template to handle the multiple ways
that time can be reported in ccd -->
  <!-- MSSTDTC -->
  <xsl:if test="$problemOnset">
    <!--ItemData ItemDataOID='MHSTDTC'-->
    <xsl:element name="ItemData" namespace="http://www.cdisc.org/ns/odm/v1.3">
      <!-- transform stupid non-ISO8601-XML date to ISO8601 date -->
      <xsl:variable name="ISODATE">
          <xsl:call-template name="HL7DateToISO8601">
            <xsl:with-param name="HL7Date" select="$problemOnset"/>
          </xsl:call-template>
        </xsl:variable>
      <xsl:attribute name="ItemOID">MHSTDTC</xsl:attribute>
      <!--xsl:attribute name="Value"><xsl:value-of
select="$problemOnset"/></xsl:attribute-->
      <xsl:attribute name="Value"><xsl:value-of
select="$ISODATE"/></xsl:attribute>
    </xsl:element><!--/ItemData-->
  </xsl:if>
  <!-- MHENDDTC -->
  <xsl:if test="$problemResolved">
    <!--ItemData ItemDataOID='MHENDDTC'-->
    <xsl:element name="ItemData" namespace="http://www.cdisc.org/ns/odm/v1.3">
      <xsl:attribute name="ItemOID">MHENDDTC</xsl:attribute>
      <xsl:attribute name="Value"><xsl:value-of
select="$problemResolved"/></xsl:attribute>
```

 

```
    </xsl:element><!--/ItemData-->
  </xsl:if>
</xsl:template>

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

<xsl:template name="HL7DateToISO8601">
  <xsl:param name="HL7Date"></xsl:param>
  <xsl:choose>
    <xsl:when test="string-length($HL7Date) = 4">
      <xsl:value-of select="$HL7Date"/>
    </xsl:when>
    <xsl:when test="string-length($HL7Date) = 6">
      <xsl:variable name="YEAR" select="substring($HL7Date,1,4)"/>
      <xsl:variable name="MONTH" select="substring($HL7Date,5,2)"/>
      <xsl:value-of select="concat($YEAR,'-',$MONTH)"/>
    </xsl:when>
    <xsl:when test="string-length($HL7Date) = 8">
      <xsl:variable name="YEAR" select="substring($HL7Date,1,4)"/>
      <xsl:variable name="MONTH" select="substring($HL7Date,5,2)"/>
      <xsl:variable name="DAY" select="substring($HL7Date,7,2)"/>
      <xsl:value-of select="concat($YEAR,'-',$MONTH,'-',$DAY)"/>
```

```
    </xsl:when>
    <xsl:when test="string-length($HL7Date) = 10">
      <xsl:variable name="YEAR" select="substring($HL7Date,1,4)"/>
      <xsl:variable name="MONTH" select="substring($HL7Date,5,2)"/>
      <xsl:variable name="DAY" select="substring($HL7Date,7,2)"/>
      <xsl:variable name="HOUR" select="substring($HL7Date,9,2)"/>
      <xsl:value-of select="concat($YEAR,'-',$MONTH,'-',$DAY,'T',$HOUR)"/>
    </xsl:when>
    <xsl:when test="string-length($HL7Date) = 12">
      <xsl:variable name="YEAR" select="substring($HL7Date,1,4)"/>
      <xsl:variable name="MONTH" select="substring($HL7Date,5,2)"/>
      <xsl:variable name="DAY" select="substring($HL7Date,7,2)"/>
      <xsl:variable name="HOUR" select="substring($HL7Date,9,2)"/>
      <xsl:variable name="MINUTE" select="substring($HL7Date,11,2)"/>
      <xsl:value-of select="concat($YEAR,'-',$MONTH,'-
',$DAY,'T',$HOUR,':',$MINUTE)"/>
    </xsl:when>
    <xsl:when test="string-length($HL7Date) = 14">
      <xsl:variable name="YEAR" select="substring($HL7Date,1,4)"/>
      <xsl:variable name="MONTH" select="substring($HL7Date,5,2)"/>
      <xsl:variable name="DAY" select="substring($HL7Date,7,2)"/>
      <xsl:variable name="HOUR" select="substring($HL7Date,9,2)"/>
      <xsl:variable name="MINUTE" select="substring($HL7Date,11,2)"/>
      <xsl:variable name="SECOND" select="substring($HL7Date,13,2)"/>
      <xsl:value-of select="concat($YEAR,'-',$MONTH,'-
',$DAY,'T',$HOUR,':',$MINUTE,':',$SECOND)"/>
    </xsl:when>
    <!-- can still be extended for the case milliseconds are given -->
    <!-- CASE NOT FOUND -->
    <xsl:otherwise><xsl:value-of select="$HL7Date"/></xsl:otherwise>
  </xsl:choose>

</xsl:template>


</xsl:stylesheet>
```

## B.2 Sample Standard CRF output from the Sample XSLT

```
<?xml version="1.0" encoding="UTF-8"?>
<ODM xmlns="http://www.cdisc.org/ns/odm/v1.3" AsOfDateTime="2008-09-
23T22:28:40.739+02:00" ODMVersion="1.3" FileType="Transactional"
FileOID="TEST" CreationDateTime="2008-09-23T22:28:40.739+02:00">
  <ClinicalData StudyOID="CLL.001" MetaDataVersionOID="001">
    <SubjectData SubjectKey="1038">
      <SiteRef LocationOID="100"/>
      <StudyEventData StudyEventOID="CLL_CRF">
        <FormData FormOID="DemographicsForm">
          <!--check on whether or not we can get Ethnicity and Race-->
          <ItemGroupData ItemGroupOID="DM">
            <ItemData ItemOID="SEX" Value="M"/>
```

```
        <ItemData ItemOID="BRTHDTC" Value="1932-09-24"/>
      </ItemGroupData>
    </FormData>
    <FormData FormOID="MedicalHistory">
      <ItemGroupData ItemGroupOID="CONDITION">
        <ItemData ItemOID="MHTERM" Value="Asthma"/>
        <ItemData ItemOID="MHONG" Value="ONGOING"/>
        <!--research adding type and category (MHCAT, MHSCAT)-->
        <ItemData ItemOID="MHSTDTC" Value="1950"/>
      </ItemGroupData>
      <ItemGroupData ItemGroupOID="CONDITION">
        <ItemData ItemOID="MHTERM" Value="Pneumonia"/>
        <ItemData ItemOID="MHONG" Value="RESOLVED"/>
        <!--research adding type and category (MHCAT, MHSCAT)-->
        <ItemData ItemOID="MHSTDTC" Value="1997-01"/>
      </ItemGroupData>
      <ItemGroupData ItemGroupOID="CONDITION">
        <ItemData ItemOID="MHTERM" Value="Pneumonia"/>
        <ItemData ItemOID="MHONG" Value="RESOLVED"/>
        <!--research adding type and category (MHCAT, MHSCAT)-->
        <ItemData ItemOID="MHSTDTC" Value="1999-03"/>
      </ItemGroupData>
      <ItemGroupData ItemGroupOID="CONDITION">
        <ItemData ItemOID="MHTERM" Value="Myocardial infarction"/>
        <ItemData ItemOID="MHONG" Value="RESOLVED"/>
        <!--research adding type and category (MHCAT, MHSCAT)-->
        <ItemData ItemOID="MHSTDTC" Value="1997-01"/>
      </ItemGroupData>
      <ItemGroupData ItemGroupOID="PROCEDURE">
        <ItemData ItemOID="MHTERM" Value="Total hip replacement, left"/>
        <ItemData ItemOID="MHONG" Value="RESOLVED"/>
        <!--??? what to do about an effectiveTime of center ???-->
      </ItemGroupData>
    </FormData>
    <FormData FormOID="ConMedForm">
      <ItemGroupData ItemGroupOID="CM">
        <ItemData ItemOID="CMTRT" Value="Albuterol inhalant"/>
        <!--need table to translate HL7 frequency, e.g., 6h to BID-->
        <ItemData ItemOID="CMROUTE" Value="Inhalation, oral"/>
      </ItemGroupData>
      <ItemGroupData ItemGroupOID="CM">
        <ItemData ItemOID="CMTRT" Value="Clopidogrel"/>
        <!--need table to translate HL7 frequency, e.g., 6h to BID-->
      </ItemGroupData>
      <ItemGroupData ItemGroupOID="CM">
        <ItemData ItemOID="CMTRT" Value="Metoprolol"/>
        <!--need table to translate HL7 frequency, e.g., 6h to BID-->
      </ItemGroupData>
      <ItemGroupData ItemGroupOID="CM">
        <ItemData ItemOID="CMTRT" Value="Prednisone"/>
        <!--need table to translate HL7 frequency, e.g., 6h to BID-->
        <ItemData ItemOID="CMSTDTC" Value="2000-03-28"/>
```

```
        </ItemGroupData>
        <ItemGroupData ItemGroupOID="CM">
          <ItemData ItemOID="CMTRT" Value="Cephalexin"/>
          <!--need table to translate HL7 frequency, e.g., 6h to BID-->
          <ItemData ItemOID="CMSTDTC" Value="2000-03-28"/>
          <ItemData ItemOID="CMENDDTC" Value="2000-04-04"/>
        </ItemGroupData>
      </FormData>
      <FormData FormOID="VSFORM">
        <ItemGroupData ItemGroupOID="VS">
          <ItemData ItemOID="VSDTC" Value="1999-11-14"/>
          <ItemData ItemOID="VSTEST" Value="Body height"/>
          <ItemData ItemOID="VSORRES" Value="177"/>
          <ItemData ItemOID="VSORRESU" Value="cm"/>
          <ItemData ItemOID="VSTEST" Value="Body weight"/>
          <ItemData ItemOID="VSORRES" Value="86"/>
          <ItemData ItemOID="VSORRESU" Value="kg"/>
          <ItemData ItemOID="VSTEST" Value="Systolic BP"/>
          <ItemData ItemOID="VSORRES" Value="132"/>
          <ItemData ItemOID="VSORRESU" Value="mm[Hg]"/>
          <ItemData ItemOID="VSTEST" Value="Diastolic BP"/>
          <ItemData ItemOID="VSORRES" Value="86"/>
          <ItemData ItemOID="VSORRESU" Value="mm[Hg]"/>
        </ItemGroupData>
        <ItemGroupData ItemGroupOID="VS">
          <ItemData ItemOID="VSDTC" Value="2000-04-07"/>
          <ItemData ItemOID="VSTEST" Value="Body height"/>
          <ItemData ItemOID="VSORRES" Value="177"/>
          <ItemData ItemOID="VSORRESU" Value="cm"/>
          <ItemData ItemOID="VSTEST" Value="Body weight"/>
          <ItemData ItemOID="VSORRES" Value="88"/>
          <ItemData ItemOID="VSORRESU" Value="kg"/>
          <ItemData ItemOID="VSTEST" Value="Systolic BP"/>
          <ItemData ItemOID="VSORRES" Value="145"/>
          <ItemData ItemOID="VSORRESU" Value="mm[Hg]"/>
          <ItemData ItemOID="VSTEST" Value="Diastolic BP"/>
          <ItemData ItemOID="VSORRES" Value="88"/>
          <ItemData ItemOID="VSORRESU" Value="mm[Hg]"/>
        </ItemGroupData>
      </FormData>
      <FormData FormOID="AEForm">
        <ItemGroupData ItemGroupOID="AE">
          <ItemData ItemOID="AETERM" Value="Penicillin"/>
        </ItemGroupData>
        <ItemGroupData ItemGroupOID="AE">
          <ItemData ItemOID="AETERM" Value="Aspirin"/>
        </ItemGroupData>
        <ItemGroupData ItemGroupOID="AE">
          <ItemData ItemOID="AETERM" Value="Codeine"/>
        </ItemGroupData>
      </FormData>
    </StudyEventData>
```

```
    </SubjectData>
  </ClinicalData>
</ODM>
```

 

# Volume 4 – National Extensions

*Add appropriate Country section*

Not applicable