Integrating the Healthcare Enterprise

5 # IHE Quality, Research and Public Health Technical Framework Supplement

10 # Clinical Research Document
(CRD)

15 # Trial Implementation

25 **Please verify you have the most recent version of this document.** See here for Trial Implementation and Final Text versions and here for Public Comment versions.

Foreword

This is a supplement to the IHE Quality, Research and Public Health (QRPH) Technical
Framework 0.1. 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 on October 27, 2015 for trial implementation 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 Technical Framework. Comments are invited and may be submitted at
http://www.ihe.net/QRPH_Public_Comments. This supplement describes changes to the existing
technical framework documents.

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

Amend Section X.X by the following:

Where the amendment adds text, make the added text **bold underline**. Where the amendment
removes text, make the removed text **~~bold strikethrough~~**. When entire new sections are added,
introduce with editor's instructions to "add new text" or similar, which for readability are not
bolded or underlined.

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/IHE_Domains.

Information about the organization of IHE Technical Frameworks and Supplements and the
process used to create them can be found at: http://www.ihe.net/IHE_Process and
http://www.ihe.net/Profiles.

The current version of the IHE QRPH Technical Framework can be found at:
http://www.ihe.net/Technical_Frameworks.

CONTENTS

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

190   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
195   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
200   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
205   the grouping of each of the actors defined in this profile with a CT Time Client, an ATNA
Secure Node or Application Actor and an XUA X-Service User.

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
210   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
215   participation in other related profiles are shown in dotted lines. Actors which have a mandatory
grouping are shown in conjoined boxes.

Archive Source Documents [QRPH-36]
→

| Form Filler | Archive Form [ITI-36] → | Form Archiver |

Retrieve Form [ITI-34] ↓

↓ Submit Form [ITI-35]

Form Manager   Form Receiver
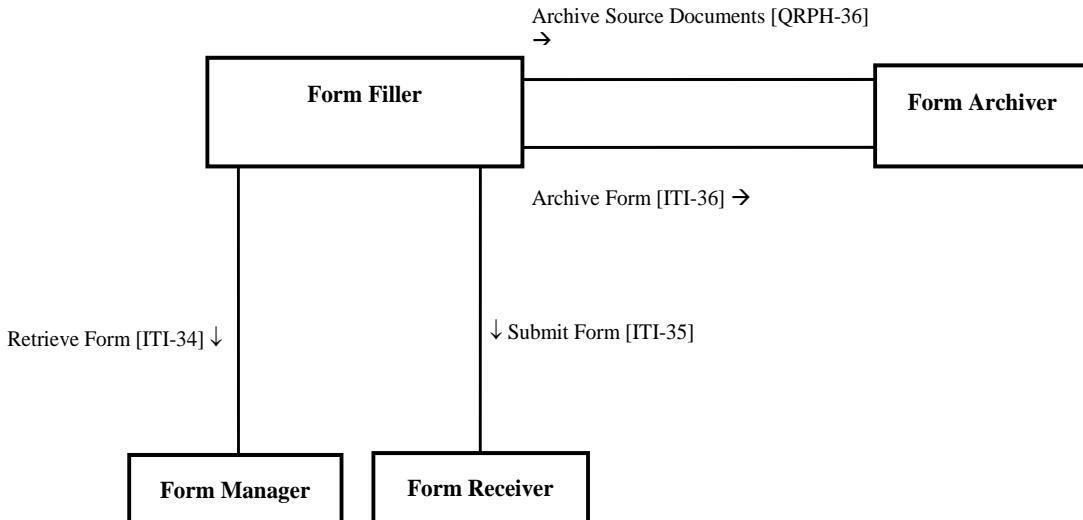
220   **Figure X.1-1: CRD Actor Diagram[1]**

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
225   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
230   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
235   groupings are further described in Section X.3.

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[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	

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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

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

245 transactions, data, and/or behavior. Those Profile requirements are documented in this section as 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

250 "CRD prepop data" and "CRD workflow data".

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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 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	QRPH TF-2: 3.36
	Archive Form	ITI TF-2b:3.36
Form Manager	None	-
Form Receiver	None	-
Form Archiver	None	

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Note: Considering that we are in the CRD Profile, the pre-population data is not an option anymore; it is required as the profile
280   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

285 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
290 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

295 ### 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

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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

305 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

310 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.

315 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

320 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.

325 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.

330 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

335 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

340 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
345 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
350 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
355 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
360 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
365 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
370 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
375 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.)

380   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.

385   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.

X.4.2.2 Clinical Trial Visit Process Flow

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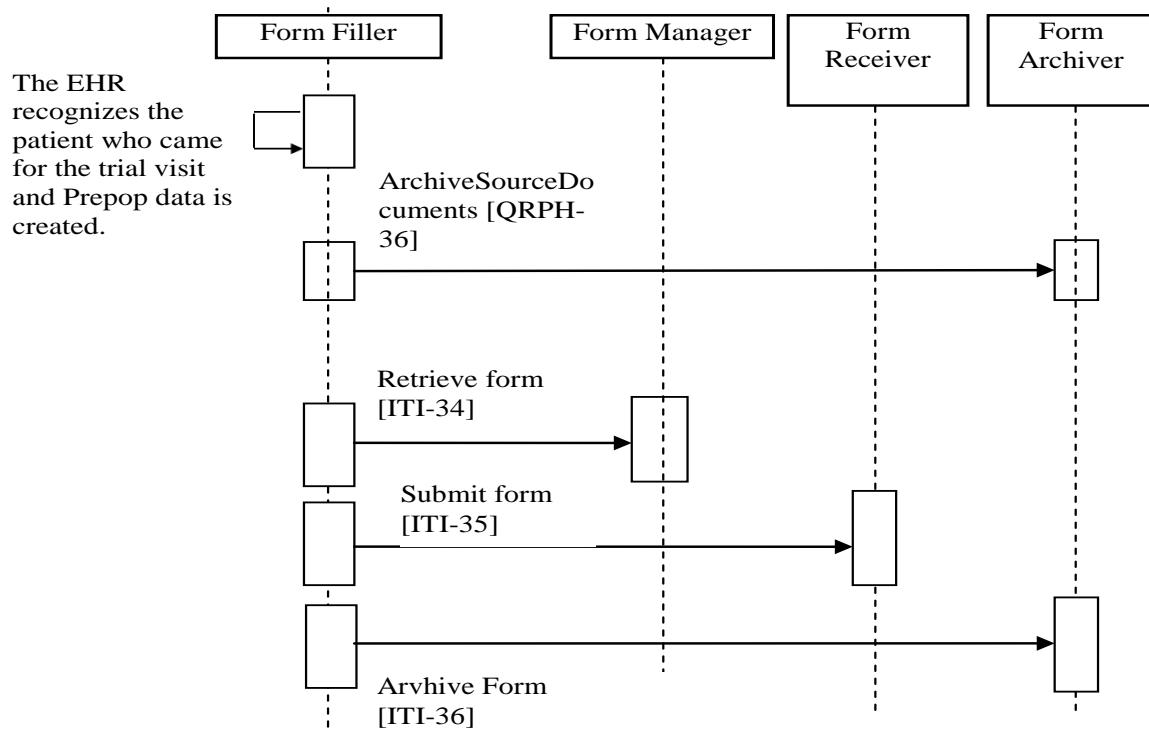
Figure X.4.2.2-1: Basic Process Flow in CRD Profile

In this Process Flow, the Form Filler knows which form it wants to retrieve from the Form
395 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
400 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 or ATNA Secure Application . This
405 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

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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.

420 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
425 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
430 pre-population document to the Form Archiver.

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Glossary

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

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None

Volume 2 – Transactions

3.36 ArchiveSourceDocuments

This section corresponds to Transaction QRPH-36 of the IHE QRPH Technical Framework.
450   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.

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3.36.2 Use Case Roles
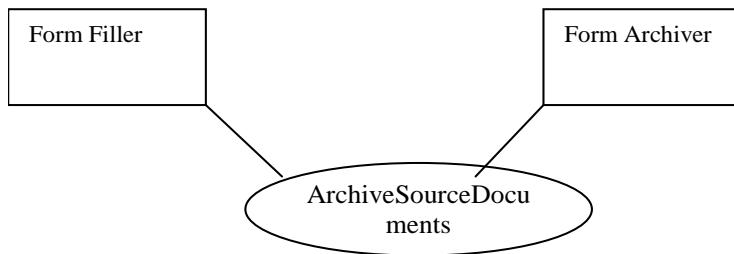
Actor: Form Filler

460   **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:
465   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
470   2000. http://www.w3.org/TR/REC-xml.

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

3.36.4 Interaction Diagram
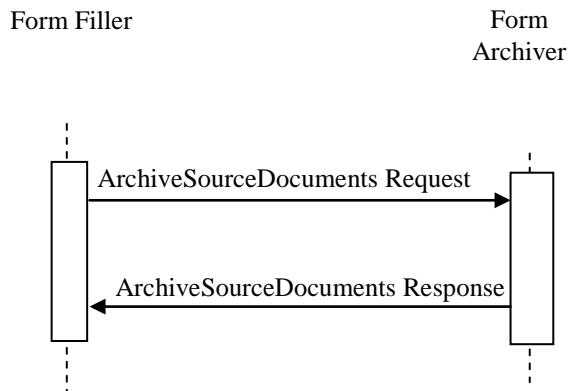
475

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.

480 **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.

485 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
490 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.

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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>
```

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3.36.4.1.4 Security Considerations

The 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
515 DICOM® (Supp 95) "Data Export"/"Data Import". See QRPH TF-2: 5.Z3.4

3.36.4.2.1 Trigger Events

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

3.36.4.2.2 Message Semantics

520 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.

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525 **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.

530 **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:

535
  - 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"

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- 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:
545   "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
550 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

555 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.

560 ### 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

600   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")

Form Filler) (1)
Human Requestor (0..n)
ion (Form Manager or Form Processor) (1)
urce (Form Filler) (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.

605

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.
AuditMessage/ ActiveParticipant	*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	*AuditSourceID*	*U*	*not specialized*
AuditMessage/ AuditSourceIdentific ation	*AuditEnterpriseSiteID*	*U*	*not specialized*
	AuditSourceTypeCode	*U*	*not specialized*

Subject	ParticipantObjectTypeCode	M	"1" (Person)
(AuditMessage/ ParticipantObjectI dentification)	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*
	PARTICIPANTOBJECTQUER Y	*U*	*not specialized*
	ParticipantObjectDetail	*U*	*not specialized*

610

prepopData	ParticipantObjectTypeCode	M	"2" (System)
(AuditMessage/ ParticipantObjectI dentification)	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*
	PARTICIPANTOBJECTQUER Y	*U*	*not specialized*
	ParticipantObjectDetail	*U*	*not specialized*

_____

5.Z3.1.2 Form Manager audit message:

	Field Name	Opt	Value Constraints
Event **AuditMessage/** **EventIdentification** **tion**	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")
Form Filler) (1)			
Requestor (0..n)			
ion (Form Manager) (1)			
Audit Source (Form Manager) (1)			
Subject (1)			
prepopData (1)			

615   Where:

	Field Name	Opt	Value Constraints
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.

_____

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 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 AuditMessage/ AuditSourceIdentific ation	*AuditSourceID*	*U*	*not specialized*
	AuditEnterpriseSiteID	*U*	*not specialized*
	AuditSourceTypeCode	*U*	*not specialized*

Subject (AuditMessage/ ParticipantObjectI dentification)	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*

620

prepopData (AuditMessage/ ParticipantObjectI dentification)	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.Z3.1.2 Form Processor 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-34", "IHE Transactions", "Retrieve Form")
Source (Form Filler) (1)			
Human Requestor (0..n)			
Destination (Form Processor) (1)			
Audit Source (Form Processor) (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.

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*	

625

Destination	UserID	M	SOAP endpoint URI
AuditMessage/ ActiveParticipant	*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.

630

Audit Source	*AuditSourceID*	*U*	*not specialized*
AuditMessage/ AuditSourceIdentific ation	*AuditEnterpriseSiteID*	*U*	*not specialized*
	AuditSourceTypeCode	*U*	*not specialized*

Subject	ParticipantObjectTypeCode	M	"1" (Person)
(AuditMessage/ ParticipantObjectI dentification)	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*
	PARTICIPANTOBJECTQUER Y	*U*	*not specialized*
	ParticipantObjectDetail	*U*	*not specialized*

prepopData	ParticipantObjectTypeCode	M	"2" (System)
(AuditMessage/ ParticipantObjectI dentification)	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*
	PARTICIPANTOBJECTQUER Y	*U*	*not specialized*
	ParticipantObjectDetail	*U*	*not specialized*

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

635 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")
Form Filler) (1)			
Human Requestor (0..n)			
ion (Form Receiver or Form Processor) (1)			
urce (Form Filler) (1)			
Subject (1)			
FormData (1)			

Where:

	Field Name	Opt	Value Constraints
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.

640

	Field Name	Opt	Value Constraints
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*	

	Field Name	Opt	Value Constraints
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.

_____

645

Audit Source	AuditSourceID	U	not specialized
AuditMessage/ AuditSourceIdentific ation	AuditEnterpriseSiteID	U	not specialized
	AuditSourceTypeCode	U	not specialized

Subject	ParticipantObjectTypeCode	M	"1" (Person)
(AuditMessage/ ParticipantObjectI dentification)	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	ParticipantObjectTypeCode	M	"2" (System)
(AuditMessage/ ParticipantObjectI dentification)	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	EventID	M	EV(110107, DCM, "Import")
AuditMessage/ EventIdentificati on	EventActionCode	M	"C" (Create)
	EventDateTime	M	not specialized
	EventOutcomeIndicator	M	not specialized
	EventTypeCode	M	EV("ITI-35", "IHE Transactions", "Submit Form")
Form Filler) (1)			
Requestor (0..n)			
ion (Form Receiver) (1)			
ource (Form Receiver) (1)			
Subject (1)			
FormData (1)			

650   Where:

_____

Source	UserID	M	Host system name
AuditMessage/ ActiveParticipant	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.

Human Requestor (if known)	UserID	M	Identity of the human that initiated the transaction.
	AlternativeUserID	U	*not specialized*
AuditMessage/ ActiveParticipant	*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
AuditMessage/ ActiveParticipant	*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	*AuditSourceID*	*U*	*not specialized*
AuditMessage/ AuditSourceIdentific ation	*AuditEnterpriseSiteID*	*U*	*not specialized*
	AuditSourceTypeCode	*U*	*not specialized*

655

Subject	ParticipantObjectTypeCode	M	"1" (Person)
(AuditMessage/ ParticipantObjectI dentification)	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)
(AuditMessage/ ParticipantObjectI dentification)	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*
	PARTICIPANTOBJECTQUER Y	*U*	*not specialized*
	ParticipantObjectDetail	*U*	*not specialized*

5.Z3.2.3 Form Processor audit message:

	Field Name	**Opt**	**Value Constraints**
Event	EventID	M	EV(110107, DCM, "Import")
AuditMessage/ EventIdentificati on	EventActionCode	M	"C" (Create)
	EventDateTime	*M*	*not specialized*
	EventOutcomeIndicator	*M*	*not specialized*
	EventTypeCode	M	EV("ITI-35", "IHE Transactions", "Submit Form")

Form Filler) (1)
Requestor (0..n)
Destination (Form Processor) (1)
urce (Form Processor) (1)
Subject (1)
FormData (1)

Where:

Source	UserID	M	Host system name
AuditMessage/ ActiveParticipant	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.

660

Human Requestor (if known)	UserID	M	Identity of the human that initiated the transaction.
	AlternativeUserID	*U*	*not specialized*
	UserName	*U*	*not specialized*
AuditMessage/ ActiveParticipant	UserIsRequestor	M	"true"
	RoleIDCode	U	Access Control role(s) the user holds that allows this transaction.
	NetworkAccessPointTypeCode	*NA*	
	NetworkAccessPointID	*NA*	

Destination 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 AuditMessage/ AuditSourceIdentific ation	*AuditSourceID*	*U*	*not specialized*
	AuditEnterpriseSiteID	*U*	*not specialized*
	AuditSourceTypeCode	*U*	*not specialized*

Subject (AuditMessage/ ParticipantObjectI dentification)	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 (AuditMessage/ ParticipantObjectI dentification)	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*

665

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: No
670 Exceptions.

5.Z3.3.1 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	-36", "IHE Transactions", "Archive Form")
Form Filler) (1)			
Human Requestor (0..n)			
Destination (Form Archiver) (1)			
urce (Form Filler) (1)			
Subject (1)			
FormData (1)			

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 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.

675

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Audit Source	*AuditSourceID*	*U*	*not specialized*
AuditMessage/ AuditSourceIdentific ation	*AuditEnterpriseSiteID*	*U*	*not specialized*
	AuditSourceTypeCode	*U*	*not specialized*

Subject	ParticipantObjectTypeCode	M	"1" (Person)
(AuditMessage/ ParticipantObjectI dentification)	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*
	PARTICIPANTOBJECTQUER Y	*U*	*not specialized*
	ParticipantObjectDetail	*U*	*not specialized*

FormData	ParticipantObjectTypeCode	M	"2" (System)
(AuditMessage/ ParticipantObjectI dentification)	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*
	PARTICIPANTOBJECTQUER Y	*U*	*not specialized*
	ParticipantObjectDetail	*U*	*not specialized*

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5.Z3.3.2 Form Archiver audit message:

	Field Name	**Opt**	**Value Constraints**
Event	EventID	M	EV(110106, DCM, "Import")
AuditMessage/ EventIdentificati on	EventActionCode	M	"R" (Read)
	EventDateTime	*M*	*not specialized*
	EventOutcomeIndicator	*M*	*not specialized*
	EventTypeCode	M	-36", "IHE Transactions", "Archive Form")
Form Filler) (1)			
Requestor (0..n)			
Destination (Form Archiver) (1)			
Audit Source (Form Archiver) (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*	

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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 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	ParticipantObjectTypeCode	M	"2" (System)
(AuditMessage/ ParticipantObjectIdentification)	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*

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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: No Exceptions.

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

	Field Name	**Opt**	**Value Constraints**
Event	EventID	M	EV(110106, DCM, "Export")
AuditMessage/ EventIdentification	EventActionCode	M	"R" (Read)
	EventDateTime	*M*	*not specialized*
	EventOutcomeIndicator	*M*	*not specialized*
	EventTypeCode	M	EV("QRPH-36", "IHE Transactions", "ArchiveSourceDocuments")
Form Filler) (1)			
Human Requestor (0..n)			
ion (Form Archiver) (1)			
urce (Form Filler) (1)			
Subject (1)			
prepopData (1)			

Where:

Source	UserID	M	Host system name
AuditMessage/ ActiveParticipant	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 AuditMessage/ AuditSourceIdentific ation	*AuditSourceID*	*U*	*not specialized*
	AuditEnterpriseSiteID	*U*	*not specialized*
	AuditSourceTypeCode	*U*	*not specialized*

Subject (AuditMessage/ ParticipantObjectI dentification)	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*

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prepopData (AuditMessage/ ParticipantObjectI dentification)	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/ EventIdentificati on	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")

Form Filler) (1)
Requestor (0..n)
ion (Form Archiver) (1)
urce (Form Archiver) (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.

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	UserID	M	SOAP endpoint URI
AuditMessage/ ActiveParticipant	*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	*AuditSourceID*	*U*	*not specialized*
AuditMessage/ AuditSourceIdentific ation	*AuditEnterpriseSiteID*	*U*	*not specialized*
	AuditSourceTypeCode	*U*	*not specialized*

Subject	ParticipantObjectTypeCode	M	"1" (Person)
(AuditMessage/ ParticipantObjectI dentification)	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	ParticipantObjectTypeCode	M	"2" (System)
(AuditMessage/ ParticipantObjectI dentification)	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*

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Volume 3 – Content Modules

6 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

745   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

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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
755 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.

760 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
765 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
O	VisitNum	workflowData/context/ VisitNum

Optionality	Data element	Data Location
R	VisDatTim	workflowData/context/ VisDatTim
R2	PrePopArchiveID	workflowData/context/ PrePopArchiveID

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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 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 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:

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```
<workflowData>
<formID>a String identifying the form</formID>
<encodedResponse> false</encodedResponse>
<archiveURL />
<instanceID/>
780 <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 >
785  <VisDatTim>
     <effectiveTime xsi:type='TS'>
     <low value=' '/>
     <high value=' '/>
     </effectiveTime>
790  </ VisDatTim >
     < PrePopArchiveID> a String identifying the Prepopulation Archive
     XDSDocumentEntry.uniqueId </ PrePopArchiveID>
     </context>
     </workflowData>
```

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The content of workflowData parameter SHALL *optimally* be:
```
     <workflowData>
     <formID>a String identifying the form</formID>
     <encodedResponse> false</encodedResponse>
800  <archiveURL />
     <instanceID/>
     <context>
     <StudyID> a String identifying the Protocol/Study
     Identifier </ StudyID >
805  <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 >
810  <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>
815  <effectiveTime xsi:type='TS'>
     <low value=' '/>
     <high value=' '/>
     </effectiveTime>
     </ VisDatTim >
820  < PrePopArchiveID> a String identifying the Prepopulation Archive
     XDSDocumentEntry.uniqueId </ PrePopArchiveID>
     </context>
     </workflowData>
```

825   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
830   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.

835 **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
840 element along with the instance form is not profiled, and is under the responsibility of the Form Manager.

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Appendices

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

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

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CRD Reference	CDASH Domain	Clinical Database Variable Name	Optionality	Definition
				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.
		CMYN	O	General prompt question to aid in monitoring and data cleaning.

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	CCD-CDASH mapping and CRD constraints			
CRD Reference	**CDASH Domain**	**Clinical Database Variable Name**	**Optionality**	**Definition**
Current Medications	**Concomitant Medication**	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.
		CMSTTM (Note: If collected, will be derived into CMSTDTC.)	R2	Time the medication was started.

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

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CRD Reference	CCD-CDASH mapping and CRD constraints			
	CDASH Domain	Clinical Database Variable Name	Optionality	Definition
				measurement SHOULD be taken
Vital Signs	**Vital Signs**	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.
		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	O	Captures the criteria required by

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CRD Reference	CCD-CDASH mapping and CRD constraints			
	CDASH Domain	**Clinical Database Variable Name**	**Optionality**	**Definition**
Allergies and Other Adverse Reactions	**Adverse Events**	AESCAN AESCONG AESDISAB AESDTH AESHOSP AESLIFE AESOD AESMIE (see below)		protocol for determining why an event is "Serious".
		AESCAN	O	Captures the criteria required by protocol for determining why an event is "Serious".
		AESCONG	O	Captures the criteria required by protocol for determining why an event is "Serious".
		AESDISAB	O	Captures the criteria required by protocol for determining why an event is "Serious".
		AESDTH	O	Captures the criteria required by protocol for determining why an event is "Serious".
		AESHOSP	O	Captures the criteria required by protocol for determining why an event is "Serious".
		AESLIFE	O	Captures the criteria required by protocol for determining why an event is "Serious".
		AESOD	O	Captures the criteria required by protocol for determining why an event is "Serious".
		AESMIE	O	Captures the criteria required by protocol for determining why an event is "Serious".
		AESTDTC	R2	Date when the adverse event started.
		AESTTM (Note: If collected, will be derived into AESTDTC.)	R2	Time when the adverse event started.
		AEENDTC	R2	Date when the adverse event resolved.
		AEENRF AEONGO	O	Indicates AE is ongoing when no End/Stop date is provided.
		AEENTM (Note: If collected, will be derived into AEENDTC.)	R2	Time when the adverse event resolved.
		AESEV And/or	R2	Description of the severity of the

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

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

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

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CRD Reference	CCD-CDASH mapping and CRD constraints			
	CDASH Domain	**Clinical Database Variable Name**	**Optionality**	**Definition**
Coded Results	**ECG Test Results - Scenario 2: Local reading: ECGs…**	EGSTAT	R2	Status of whether or not ECG was done.
		EGREASND	O	Describes why the ECG was not done (e.g., BROKEN EQUIPMENT, SUBJECT REFUSED).
		EGDTC	R2	Date of ECG.
		EGTM (Note: If collected, will be derived into EGDTC.)	R2	Time of ECG.
		EGTPT	R2	Text description of planned time point when measurements SHOULD be taken for use when multiple sequential assessments are done
		EGTESTCD And/or EGTEST	R	Verbatim name of the test or examination used to obtain the measurement or finding.
		EGORRES	R	Result of the measurement or finding as originally received or collected.
		EGORRESU	R2	Original units in which the data were collected.
		EGCLSG (Note: If collected will be mapped to SUPPQUAL domain.)	O	Whether ECG results were clinically significant.
		EGPOS, EGMETHOD (for example)	O	Condition for testing defined in the protocol.
		EGEVAL	O	Role of the person who provided the evaluation. This SHOULD only be used for results that are subjective (e.g., assigned by a person or a group) and do not apply to quantitative results (i.e., ADJUDICATION COMMITTEE, INVESTIGATOR).
		EGREFID	O	Internal or external identifier.
	ECG Test Results - Scenario 3: Central reading (as in Scenario 1): But…	EGSTAT	R2	Status of whether or not ECG was done.
		EGREASND	O	Describes why the ECG was not done (e.g., BROKEN EQUIPMENT, SUBJECT REFUSED).
		EGDTC	R2	Date of ECG.
		EGTM (Note: If collected, will be	R2	Time of ECG.

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CRD Reference	CDASH Domain	CCD-CDASH mapping and CRD constraints		
		Clinical Database Variable Name	**Optionality**	**Definition**
		derived into EGDTC.)		
		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
855 ## (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
860 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 -->
```

```
900        <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"
905   namespace="http://www.cdisc.org/ns/odm/v1.3">
             <xsl:attribute name="LocationOID">100</xsl:attribute>
           </xsl:element>
           <!-- StudyEventData element -->
           <xsl:element name="StudyEventData"
910   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"/>
915        <!-- medical history -->
           <xsl:call-template name="medicalHistory"/>
           <!-- conMeds -->
           <xsl:call-template name="conMeds"/>
           <!-- substance use -->
920        <xsl:call-template name="substanceAbuse"/>
           <!-- vitals -->
           <xsl:call-template name="vitalSigns"/>
           <!-- physical exam -->
           <!-- AE -->
925        <xsl:call-template name="adverseEvents"/>
           <!-- lab results -->
           <!-- ECG results -->
           </xsl:element>
         </xsl:element>
930   </xsl:element>
      </xsl:element>
      </xsl:template>

      <!-- ODM Templates -->
935   <!-- demography -->
      <xsl:template name="demography">
      <!-- get the patient node, from which we can get the sex and date of birth -
      ->
         <xsl:variable name="patientNode"
940   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>
945        <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"
950   namespace="http://www.cdisc.org/ns/odm/v1.3">
               <xsl:attribute name="ItemOID">SEX</xsl:attribute>
```

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

975
    <!-- Medical History
      looking for entries in any of the following CDA sections:
        Conditions
        Past Medical History
980     Procedures
    -->
    <xsl:template name="medicalHistory">
      <xsl:variable name="ccdConditions"
select="cda:component/cda:structuredBody/cda:component/cda:section[cda:code/@
985 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"
990 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)"/>
995   <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 -->
1000  <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
1005 standardized; it also might be that all med history items SHOULD be in one
     ItemGroup -->
         <xsl:for-each select="$ccdConditions/cda:entry">
          <xsl:element name="ItemGroupData"
     namespace="http://www.cdisc.org/ns/odm/v1.3">
1010         <xsl:attribute name="ItemGroupOID">CONDITION</xsl:attribute>
             <xsl:call-template name="problemItemData"><xsl:with-param
     name="theNode" select="."/></xsl:call-template>
          </xsl:element>
         </xsl:for-each>
1015     <xsl:for-each select="$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
1020 name="theNode" select="."/></xsl:call-template>
          </xsl:element>
         </xsl:for-each>
         <xsl:for-each select="$ccdProcedures/cda:entry">
          <xsl:element name="ItemGroupData"
1025 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>
1030     </xsl:for-each>
       </xsl:element>
      </xsl:if>
     </xsl:template>

1035
     <!-- CON MEDS -->
     <xsl:template name="conMeds">
      <xsl:variable name="ccdMedication"
     select="cda:component/cda:structuredBody/cda:component/cda:section[cda:code/@
1040 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">
1045     <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"
1050 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"/>
1055     <!--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 -->
1110    <xsl:variable name="medEndDate"
     select="cda:substanceAdministration/cda:effectiveTime[@xsi:type='IVL_TS']/cda
     :high/@value"/>
        <xsl:if test="$medEndDate">
          <!--ItemData ItemDataOID='CMENDDTC'-->
1115      <xsl:element name="ItemData"
     namespace="http://www.cdisc.org/ns/odm/v1.3">
            <xsl:attribute name="ItemOID">CMENDDTC</xsl:attribute>
            <!-- transform stupid non-ISO8601-XML date to ISO8601 date -->
            <xsl:variable name="ISODATE">
1120          <xsl:call-template name="HL7DateToISO8601">
                <xsl:with-param name="HL7Date" select="$medEndDate"/>
              </xsl:call-template>
            </xsl:variable>
            <!--xsl:attribute name="Value"><xsl:value-of
1125 select="$medEndDate"/></xsl:attribute-->
            <xsl:attribute name="Value"><xsl:value-of
     select="$ISODATE"/></xsl:attribute>
          </xsl:element><!--/ItemData-->
        </xsl:if>
1130    </xsl:element>
        <!--/ItemGroupData-->
      </xsl:for-each>
      </xsl:element>
    </xsl:if>
1135 </xsl:template>


    <!-- SUBSTANCE ABUSE -->
    <xsl:template name="substanceAbuse">
     <!-- we could look into the social history for any of a specific list of
1140 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>


1145
    <!-- Vital Signs -->
    <xsl:template name="vitalSigns">
    <!-- if we have a vitals section with at least one organizer then we're going
    for all organizers -->
1150 <xsl:variable name="vitalsSection"
     select="cda:component/cda:structuredBody/cda:component/cda:section[cda:code/@
     code='8716-3']"/>
    <xsl:if test="$vitalsSection/cda:entry/cda:organizer">
      <!--FormData FormDataOID='VSForm'-->
1155  <xsl:element name="FormData" namespace="http://www.cdisc.org/ns/odm/v1.3">
        <xsl:attribute name="FormOID">VSFORM</xsl:attribute>
        <!-- for each organizer -->
        <xsl:for-each select="$vitalsSection/cda:entry/cda:organizer">
          <!-- at the organizer level we have the date (and MAY be the time) -->
1160      <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'-->
```

Line numbers in margin: 1165, 1170, 1175, 1180, 1185, 1190, 1195, 1200, 1205, 1210

```
1215          <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>
1220           </xsl:element><!--/ItemData-->
             </xsl:otherwise>
           </xsl:choose>
         </xsl:for-each>
         </xsl:element><!--/ItemGroupData-->
1225     </xsl:for-each>
       </xsl:element><!--/FormData-->
       </xsl:if>
       </xsl:template>


1230   <!-- AE -->
       <xsl:template name="adverseEvents">
       <xsl:variable name="aeSection"
       select="cda:component/cda:structuredBody/cda:component/cda:section[cda:code/@
       code='48765-2']"/>
1235   <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">
1240       <!--ItemDataGroup ItemDataGroupOID='AE'-->
           <xsl:element name="ItemGroupData"
       namespace="http://www.cdisc.org/ns/odm/v1.3">
             <xsl:attribute name="ItemGroupOID">AE</xsl:attribute>
             <!-- AETERM -->
1245         <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"
1250   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">
1255           <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>
1260             <xsl:otherwise><xsl:value-of
       select="$codedDisplayName"/></xsl:otherwise>
                 </xsl:choose>
               </xsl:attribute>
             </xsl:element><!--/ItemData-->
1265         <!-- 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>
1320            <xsl:when test="string-length($codedValue)>0"><xsl:value-of
        select="$codedValue"/></xsl:when>
                <xsl:otherwise>???</xsl:otherwise>
              </xsl:choose>
            </xsl:attribute>
1325     </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>
1330       <xsl:attribute name="Value">
            <xsl:choose>
              <xsl:when
        test="$problemStatusNode/cda:value/@displayName='Active'">ONGOING</xsl:when>
                <xsl:when test="//*[@ID=substring-
1335    after($problemStatusRef,'#')]='Active'">ONGOING</xsl:when>
                <xsl:otherwise>RESOLVED</xsl:otherwise>
              </xsl:choose>
            </xsl:attribute>
         </xsl:element><!--/ItemData-->
1340
         <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 -->
1345     <xsl:if test="$problemOnset">
           <!--ItemData ItemDataOID='MHSTDTC'-->
           <xsl:element name="ItemData" namespace="http://www.cdisc.org/ns/odm/v1.3">
             <!-- transform stupid non-ISO8601-XML date to ISO8601 date -->
             <xsl:variable name="ISODATE">
1350            <xsl:call-template name="HL7DateToISO8601">
                  <xsl:with-param name="HL7Date" select="$problemOnset"/>
                </xsl:call-template>
              </xsl:variable>
             <xsl:attribute name="ItemOID">MHSTDTC</xsl:attribute>
1355         <!--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-->
1360     </xsl:if>
         <!-- MHENDDTC -->
         <xsl:if test="$problemResolved">
           <!--ItemData ItemDataOID='MHENDDTC'-->
           <xsl:element name="ItemData" namespace="http://www.cdisc.org/ns/odm/v1.3">
1365         <xsl:attribute name="ItemOID">MHENDDTC</xsl:attribute>
             <xsl:attribute name="Value"><xsl:value-of
        select="$problemResolved"/></xsl:attribute>
           </xsl:element><!--/ItemData-->
         </xsl:if>
1370  </xsl:template>
```

```
     <xsl:template name="procedureItemData">
     <xsl:param name="theNode"/>
       <xsl:variable name="originalTextRef"
1375 select="$theNode/cda:procedure/cda:code/cda:originalText/cda:reference/@value
     "/>
       <xsl:variable name="codedValue"
     select="$theNode/cda:procedure/cda:code/@displayName"/>
       <!-- MHTERM -->
1380   <!--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>
1385         <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>
1390       </xsl:choose>
         </xsl:attribute>
       </xsl:element><!--/ItemData-->
       <!-- NOTE: is this true = procedures are RESOLVED -->
       <!-- MHONG -->
1395   <!--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>
1400   <xsl:comment>??? what to do about an effectiveTime of center
     ???</xsl:comment>
     </xsl:template>

     <xsl:template name="HL7DateToISO8601">
1405   <xsl:param name="HL7Date"></xsl:param>
       <xsl:choose>
         <xsl:when test="string-length($HL7Date) = 4">
           <xsl:value-of select="$HL7Date"/>
         </xsl:when>
1410     <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,'-',$MONTH)"/>
         </xsl:when>
1415     <xsl:when test="string-length($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)"/>
1420     </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($HL7Date,7,2)"/>
1425            <xsl:variable name="HOUR" select="substring($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)"/>
1430            <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,'-
1435  ',$DAY,'T',$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)"/>
1440            <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,'-
1445  ',$DAY,'T',$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>
1450      </xsl:choose>

        </xsl:template>


1455  </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-
1460   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"/>
1465       <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"/>
1470           <ItemData ItemOID="BRTHDTC" Value="1932-09-24"/>
              </ItemGroupData>
            </FormData>
            <FormData FormOID="MedicalHistory">
              <ItemGroupData ItemGroupOID="CONDITION">
```

```
1475        <ItemData ItemOID="MHTERM" Value="Asthma"/>
            <ItemData ItemOID="MHONG" Value="ONGOING"/>
            <!--research adding type and category (MHCAT, MHSCAT)-->
            <ItemData ItemOID="MHSTDTC" Value="1950"/>
          </ItemGroupData>
1480      <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"/>
1485      </ItemGroupData>
          <ItemGroupData ItemGroupOID="CONDITION">
            <ItemData ItemOID="MHTERM" Value="Pneumonia"/>
            <ItemData ItemOID="MHONG" Value="RESOLVED"/>
            <!--research adding type and category (MHCAT, MHSCAT)-->
1490        <ItemData ItemOID="MHSTDTC" Value="1999-03"/>
          </ItemGroupData>
          <ItemGroupData ItemGroupOID="CONDITION">
            <ItemData ItemOID="MHTERM" Value="Myocardial infarction"/>
            <ItemData ItemOID="MHONG" Value="RESOLVED"/>
1495        <!--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"/>
1500        <ItemData ItemOID="MHONG" Value="RESOLVED"/>
            <!--??? what to do about an effectiveTime of center ???-->
          </ItemGroupData>
        </FormData>
        <FormData FormOID="ConMedForm">
1505      <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>
1510      <ItemGroupData ItemGroupOID="CM">
            <ItemData ItemOID="CMTRT" Value="Clopidogrel"/>
            <!--need table to translate HL7 frequency, e.g., 6h to BID-->
          </ItemGroupData>
          <ItemGroupData ItemGroupOID="CM">
1515        <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"/>
1520        <!--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"/>
1525        <!--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>
1530      <FormData FormOID="VSFORM">
           <ItemGroupData ItemGroupOID="VS">
             <ItemData ItemOID="VSDTC" Value="1999-11-14"/>
             <ItemData ItemOID="VSTEST" Value="Body height"/>
             <ItemData ItemOID="VSORRES" Value="177"/>
1535         <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"/>
1540         <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]"/>
1545       </ItemGroupData>
           <ItemGroupData ItemGroupOID="VS">
             <ItemData ItemOID="VSDTC" Value="2000-04-07"/>
             <ItemData ItemOID="VSTEST" Value="Body height"/>
             <ItemData ItemOID="VSORRES" Value="177"/>
1550         <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"/>
1555         <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]"/>
1560       </ItemGroupData>
          </FormData>
          <FormData FormOID="AEForm">
           <ItemGroupData ItemGroupOID="AE">
             <ItemData ItemOID="AETERM" Value="Penicillin"/>
1565       </ItemGroupData>
           <ItemGroupData ItemGroupOID="AE">
             <ItemData ItemOID="AETERM" Value="Aspirin"/>
           </ItemGroupData>
           <ItemGroupData ItemGroupOID="AE">
1570         <ItemData ItemOID="AETERM" Value="Codeine"/>
           </ItemGroupData>
          </FormData>
        </StudyEventData>
      </SubjectData>
1575  </ClinicalData>
    </ODM>
```

Volume 4 – National Extensions

Add appropriate Country section

1580

Not applicable