

Integrating the Healthcare Enterprise



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

10 **Clinical Research Document
(CRD)**

15 **Trial Implementation**

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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

30 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 September 9, 2016 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, 35 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.

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<i>Amend Section X.X by the following:</i>
--

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.

45

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 50 <http://www.ihe.net/Profiles>.

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

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Introduction to this Supplement

140 The Clinical Research Document Profile (CRD) specifies a standard way to generate a clinical
research document from EHR data provided in the CDA^{®1} 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 enables the
145 archiving of the prepop and workflow data. This supplement 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

None.

Closed Issues

- 150 1. The definition of four new actors – “CRD Form Filler”, “CRD Form Manager”, “CRD
Form Receiver” and “CRD Form Archiver” were discussed as a method to more clearly
describe the roles being played by the actors in the profile. In addition, new actor
diagrams were considered to show how these actors are paired with actors from the RFD
Profile.
 - 155 a. After discussion, it was determined that IHE guidance directs profile authors
toward reuse of actors where appropriate and the existing “Form Filler” “Form
Manager” “Form Receiver” and “Form Archiver” actors were appropriate.

¹ CDA is the registered trademark of Health Level Seven International.

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Volume 1 – Profiles

X Clinical Research Document (CRD) Profile

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

165 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.

170 The profile uses the transaction framework defined in the IHE ITI Retrieve Form for Data Capture (RFD) Profile. It further constrains the prepopData and workflowData data elements of the Retrieve Form [ITI-34] 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.

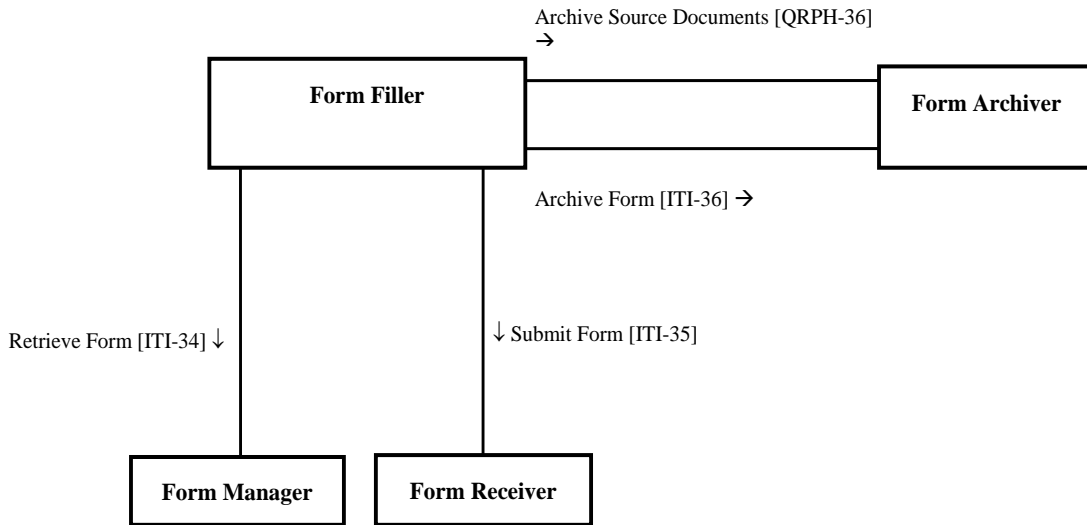
The CRD Profile uses the ArchiveSourceDocuments [QRPH-36] transaction to enable the CRD actors to meet data auditing requirements of the FDA when creating clinical research documents. It enables a Form Filler actor, which provides a pre-population document and some workflow data when retrieving a form, to archive the pre-population document it supplied.

175 The profile also enables FDA security requirements by the optionally grouping CRD actors with actors in the IHE ITI Consistent Time (CT), Audit Trail and Node Authentication (ATNA), or Cross-Enterprise User Assertion (XUA) Profiles. See Section X.5 Security Considerations.

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

X.1 CRD Actors, Transactions, and Content Modules

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



190

Figure X.1-1: CRD Actor Diagram

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

195

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

Actors	Transactions	Optionality	Reference	Note
Form Filler	Retrieve Form	R	ITITF-2b: 3.34	
	ArchiveSourceDocuments	O	QRPH TF-2: 3.36	
	Submit Form	R	ITITF-2b: 3.35	This transaction is further constrained in this profile (see QRPH TF-3: 6.3.1.D1).
	Archive Form	O	ITITF-2b: 3.36	This transaction is further constrained in this profile (see QRPH TF-3: 6.3.1.D1).
Form Manager	Retrieve Form	R	ITITF-2b: 3.34	
Form Receiver	Submit Form	R	ITITF-2b: 3.35	
Form Archiver	ArchiveSourceDocuments	R	QRPH TF-2: 3.36	
	Archive Form	R	ITITF-2b: 3.36	

200 Table X.1-2 lists the content module(s) defined in the CRD Profile. To claim support with this profile, an actor shall support all required content modules (labeled “R”) and may support optional content modules (labeled “O”).

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

205 **X.1.1 Actor Descriptions and Actor Profile Requirements**

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

210 **X.1.1.1 Form Filler**

In addition to its role as defined in the RFD Profile in ITI TF-1:17, the Form Filler SHALL support the generation of the pre-population data in the form of the two content modules hereafter named “CRD prepop data” and “CRD workflow data”.

X.1.1.2 Form Manager

215 In addition to its role as defined in the RFD Profile in ITI TF-1:17, 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.

X.1.1.3 Form Receiver

220 The role of the Form Receiver in this profile is the one defined in the RFD Profile in ITI TF-1:17.

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-1:17.

225 **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

230 “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	ITITF-2b: 3.36
Form Manager	None	-
Form Receiver	None	-
Form Archiver	None	

Note: In the CRD Profile, the pre-population data is not an option; it is required as the profile is precisely about defining it. The CRD Profile requires that this prepop and workflow data conform to the xml data constrained in QRPH TF-3: 6.3.1.D and 6.3.1.D1. The “ArchiveSourceDocuments” Option requires the Form Filler to submit the Prepop and Workflow data to the Form Archiver through the [QRPH-36] transaction. If the Form Filler supports this option, that transaction must be completed first in order to provide the Form Manager with the context id related to the archived CRD (see QRPH TF-3: 6.3.1.D1).

235

X.3 CRD Required Actor Groupings

240 An Actor from this profile (Column 1) shall implement all of the required transactions and/or content modules in this profile *in addition to* all of the transactions required for the grouped actor (Column 2).

Table X.3-1: CRFD - Required Actor Groupings

CRD Actor	Actor to be grouped with	Reference	Content Bindings Reference
Form Filler	None	--	--
Form Manager	None	--	--
Form Receiver	None	--	--
Form Archiver	None	--	--

245 **X.4 CRD Overview**

X.4.1 Concepts

X.4.2 Use Case #1: Clinical Trial Visit

250 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

255 The setting for the clinical research use case is a physician practice where patient care is delivered side-by-side with clinical research activities. The site, Holbin Medical Group, is a multi-site physician practice, employing over 100 physicians in a variety of specialties. Holbin's CEO encourages the physicians to participate as site investigators for pharmaceutical-sponsored clinical trials; Holbin provides support for clinical research activities in the form of a Research Department of twelve dedicated study coordinators, mostly RNs, along with clerical and data-entry support personnel. Holbin Medical Group uses an Electronic Health Record (EHR) and a number of sponsor-provided Electronic Data Capture (EDC) systems for documenting clinical trial activities. EDC is a system for documenting clinical trial activities. EDC is a remote data entry system, provided by the research sponsor, which uses either a laptop (thick or thin client) or a web site. For our purposes, an EHR is any application which is the primary site for documenting patient care, and retrieving patient care information. Thus we include in our span of interest many systems installed today that are not quite EHRs in the strictest sense, but which 265 would still benefit from this approach.

Holbin's involvement in a clinical study begins when the Research Department receives a request for proposal (RFP) or a request for a feasibility assessment (EU) from a study Sponsor. The Investigator or the Study Coordinator, Patricia Zone, RN, evaluates the RFP to assess if their facility has the required patient population (clinical condition and required numbers required by the study protocol) as specified in the clinical study protocol, as well as the business viability. A major issue that must be addressed is the time needed to perform the clinical study and whether or not the site has the time to perform the study appropriately. Once these concerns are addressed satisfactorily and the site is selected for the trial, the financial aspects are addressed and the site then sends the required regulatory documentation to the Sponsor. The Sponsor then provides 275 Protocol-specific training to the Physician Investigator and other study personnel.

During the trial set-up period, Patricia, together with the Investigator ensures that the appropriate system security is in place for this protocol, recruits patients to participate as subjects according to inclusion and exclusion criteria described in the study protocol schedules patient visits, manages data capture and data entry, ensures that IRB approval has been obtained, maintains 280 required regulatory documents and performs all the attendant financial tasks.

Patricia, under the supervision of the Investigator contacts Corey Jones, a patient at Holbin, about participating in the trial and Corey agrees to participate as a subject. Patricia registers Corey in the EHR as a subject in trial #1234, using the EHR's patient index. She schedules Corey's study visits using the EHR scheduling module, and flags the visits as pertaining to the 285 trial #1234. After the set-up stage, the site initiates clinical trial care and trial-specific documentation.

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

290 **X.4.2.1.1 Current State**

Mrs. Corey Jones arrives at the clinic for a scheduled trial visit and meets with Patricia Zone (Registered Nurse) for a face-to-face interview. Patricia logs into the EHR and documents the visit with a terse entry: ‘Mrs. Jones comes in for a clinical trial visit associated with study #1234.’ Patricia interviews Mrs. Jones, makes some observations, and records her observation on
295 a source paper document. She looks up recent lab results in the EHR and records them in the Case Report Form (CRF). The EHR provides only a portion of the data required to complete the form, the rest comes from the interview and observations. (Estimates on the percentage of data required for a clinical trial that would be available in an EHR vary from 5% to 40%. Even in the best case, the EHR typically captures only a subset of the data required by a study protocol.)

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

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

X.4.2.1.2 Desired State

320 Mrs. Jones arrives for a visit and Patricia logs into the EHR, pulls up Mrs. Jones’s record, and identifies the scheduled clinical trial visit. Because of the patient identification and scheduling steps that took place in the set-up stage, and because Mrs. Jones informed consent indicated that it was permissible to do so, the EHR recognizes Mrs. Jones as a subject in Trial 1234, and requests an electronic case report form from trial #1234’s, using RFD. If the trial is sufficiently
325 complex, the retrieved form MAY contain a list of relevant forms from the RFD Forms Manager system from which Patricia MAY choose. Patricia selects the appropriate form, the EHR checks

330 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.)

335 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 variables² that appear on the clinical trial form as they are consistently collected in all types/phases of clinical trials. Applicable data from the EHR database are now archived for future regulatory auditing and used to pre-populate some of the clinical trial data fields. Additional data MAY need to be captured interactively via the forms (which MAY have built-in edit checks). Upon completing the form, Patricia hits the submit button, and the EHR returns the complete form to the EDC system, using RFD. A copy of the document is archived in the site clinical trial document vault as part of the permanent source record of the trial.

340 **X.4.2.2 Clinical Trial Visit Process Flow**

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. Additional data collection fields will have been added to the CDASH collection variables to capture the required therapeutic area or required fields by the study Sponsor.

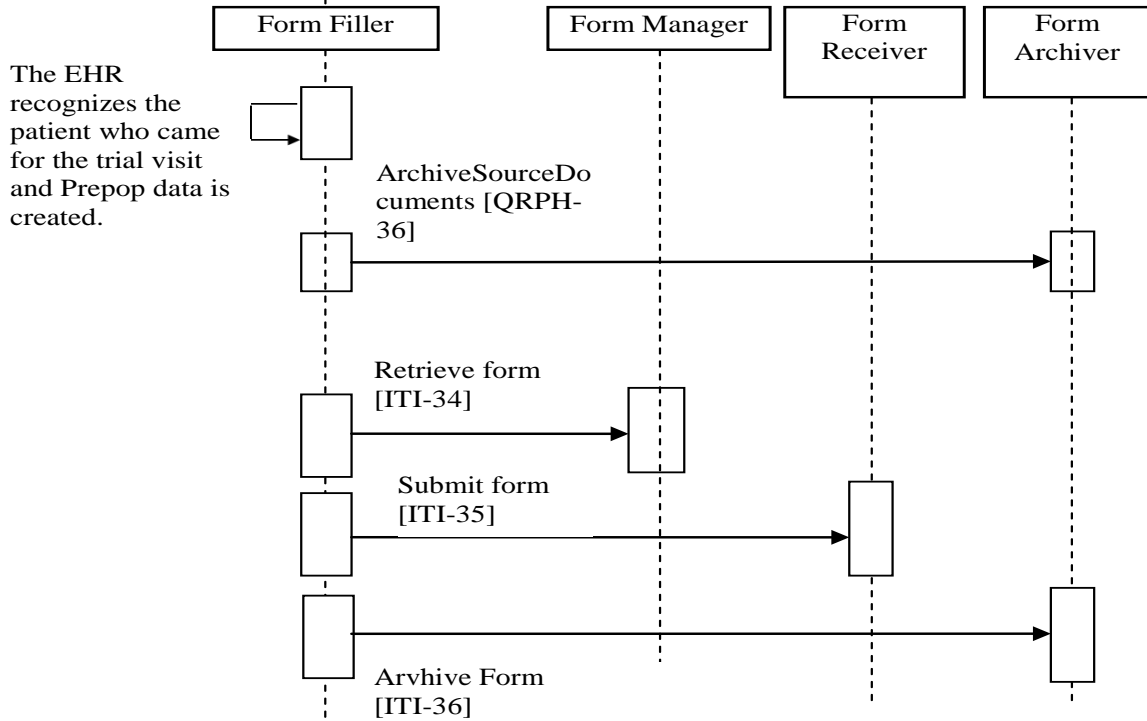


Figure X.4.2.2-1: Basic Process Flow in CRD Profile

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

X.5 CRD Security Considerations

350 X.5.1 Consistent Time (CT)

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

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

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

360 X.5.3 Cross Enterprise User Assertion (XUA)

In order to address identified security risks all actors in CRD may be grouped with Cross-Enterprise User Assertion (XUA) Profile actors. The Form Filler would be the XUA X-Service

365 User and the other actors would be the XUA X-Service Provider. These groupings support user based access control.

X.6 CRD Cross Profile Considerations

Not applicable

Appendices

370

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.
- 375 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.
- 380 4. **Form Archiver** - a system or a module in a CRD framework, the purpose of which is to receive the raw CCD and the completed form from the Form Filler.

Transaction Summary Definitions

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

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

390

395

Glossary

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

400

None

Volume 2 – Transactions

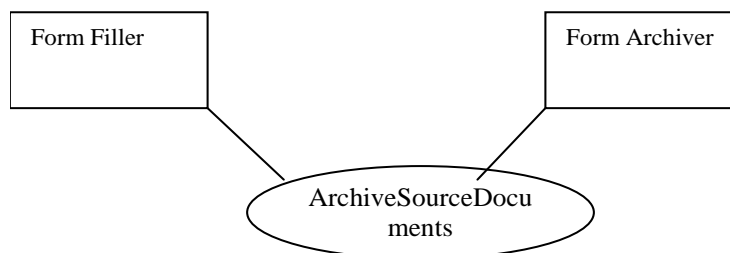
3.36 ArchiveSourceDocuments

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

3.36.1 Scope

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

3.36.2 Use Case Roles



Actor: Form Filler

415 **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

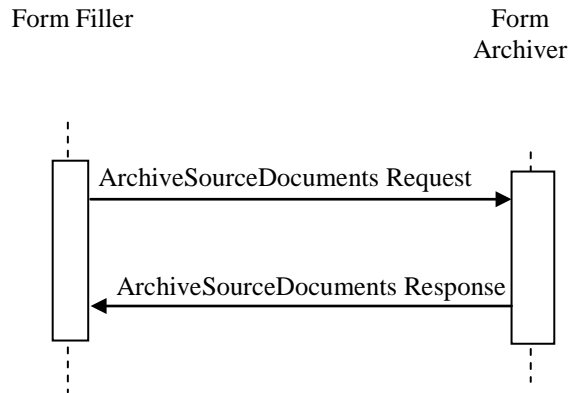
420 Implementors of this transaction shall comply with all requirements described in ITI TF-2x: Appendix V: Web Services for IHE Transactions.

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

IETF RFC2616 HyperText Transfer Protocol HTTP/1.1

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

3.36.4 Interaction Diagram



3.36.4.1 ArchiveSourceDocuments Request

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

3.36.4.1.1 Trigger Events

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

3.36.4.1.2 Message Semantics

435 The content to be archived includes both the prepoppedata and the workflowData as defined in QRPH TF-3: 6.3.1.

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

The following parameters are specified for this transaction.

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

440

3.36.4.1.3 Expected Actions

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

See the Protocol Requirements and the support materials.

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

Table 3.36.4.1.3-1: SOAP Faults

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

450 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>
```

465 **3.36.4.1.4 Security Considerations**

The ArchiveSourceDocuments is a PHI-Export event, as defined in ITI TF-2a: Table 3.20.4.1.1.1-1.

3.36.4.2.1 Trigger Events

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

3.36.4.2.2 Message Semantics

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

3.36.4.2.3 Expected Actions

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

3.36.5 Protocol Requirements

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

480 The ArchiveSourceDocuments transaction shall use SOAP 12.

WSDL Namespace Definitions

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

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

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

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

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

3.36.5.1 Sample SOAP Messages

The samples in the following two sections show a typical SOAP request and its relative SOAP response. The sample messages also show the WS-Addressing headers <Action/>, <MessageID/>, .; these WS-Addressing headers are populated according to the
510 ITI TF-2x: Appendix V: Web Services for IHE Transactions. Some of the body of the SOAP message is omitted for brevity.

3.36.5.1.1 Sample ArchiveSourceDocuments SOAP Request

```
515 <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>
520   <wsa:Action soap:mustUnderstand="1">urn:ihe:qrphi:
2012:RetrieveForm</wsa:Action>
  </soap:Header>
  <soap:Body>
    <ArchiveSourceDocumentsRequest xmlns="urn:ihe:qrph:crd:2012">
525     <archiveContent>
    </ArchiveSourceDocumentsRequest >
  </soap:Body>
</soap:Envelope>
```

530 3.36.5.1.2 Sample ArchiveSourceDocuments SOAP Response

```
535 <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>
540   <wsa:Action soap:mustUnderstand="1">urn:ihe:qrph:
2012:ArchiveSourceDocumentsResponse</wsa:Action>
  </soap:Header>
  <soap:Body>
    <ArchiveSourceDocumentsResponse xmlns="urn:ihe:qrph:crd:2012">
545     <responseCode>OK</responseCode>
    </ArchiveSourceDocumentsResponse>
  </soap:Body>
</soap:Envelope>
```

Audit Messages

550 5.Z3 Audit Record Considerations

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

The Retrieve Form transaction MAY be a PHI-Export event as defined in ITI TF-2a: Table 3.20.4.1.1.1-1. Actors that audit this transaction SHALL create audit data in conformance with DICOM³ “Data Export”/“Data Import”, with the following exceptions.

555 **5.23.1.1 Form Filler audit message:**

	Field Name	Opt	Value Constraints
Event AuditMessage/ EventIdentification	EventID	M	EV(110106,DCM, “Export”)
	EventActionCode	M	“R” (Read)
	EventDateTime	M	<i>not specialized</i>
	EventOutcomeIndicator	M	<i>not specialized</i>
	EventTypeCode	M	EV(“ITI-34”, “IHE Transactions”, “Retrieve Form”)
Source (Form Filler) (1)			
Human Requestor (0..n)			
Destination (Form Manager or Form Processor) (1)			
Audit Source (Form Filler) (1)			
Subject (1)			
prepopData(1)			

Where:

Source	Field Name	Opt	Value Constraints
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	<i>not specialized</i>
	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

Human Requestor (if known)	Field Name	Opt	Value Constraints
AuditMessage/ ActiveParticipant	UserID	M	Identity of the human that initiated the transaction.
	AlternativeUserID	U	<i>not specialized</i>
	UserName	U	<i>not specialized</i>
	UserIsRequestor	M	“true”
	RoleIDCode	U	Access Control role(s) the user holds that allows this transaction.
	NetworkAccessPointTypeCode	NA	
	NetworkAccessPointID	NA	

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

560

Destination AuditMessage/ ActiveParticipant	UserID	M	SOAP endpoint URI.
	<i>AlternativeUserID</i>	U	<i>not specialized</i>
	<i>UserName</i>	U	<i>not specialized</i>
	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

Audit Source AuditMessage/ AuditSourceIdentification	<i>AuditSourceID</i>	U	<i>not specialized</i>
	<i>AuditEnterpriseSiteID</i>	U	<i>not specialized</i>
	<i>AuditSourceTypeCode</i>	U	<i>not specialized</i>

Subject (AuditMessage/ ParticipantObject Identification)	ParticipantObjectTypeCode	M	“1” (Person)
	ParticipantObjectTypeCodeRole	M	“1” (Patient)
	<i>ParticipantObjectDataLifeCycle</i>	U	<i>not specialized</i>
	ParticipantObjectIDTypeCode	M	EV(2, RFC-3881, “Subject Number”)
	<i>ParticipantObjectSensitivity</i>	U	<i>not specialized</i>
	PARTICIPANTOBJECID	M	The subject ID in HL7 CX format.
	<i>ParticipantObjectName</i>	U	<i>not specialized</i>
	PARTICIPANTOBJECTQUERY	U	<i>not specialized</i>
<i>ParticipantObjectDetail</i>	U	<i>not specialized</i>	

prepopData (AuditMessage/ ParticipantObject Identification)	ParticipantObjectTypeCode	M	“2” (System)
	ParticipantObjectTypeCodeRole	M	“20” (job)
	<i>ParticipantObjectDataLifeCycle</i>	U	<i>not specialized</i>
	ParticipantObjectIDTypeCode	M	EV(2, RFC-3881, “Document ID”)
	<i>ParticipantObjectSensitivity</i>	U	<i>not specialized</i>
	PARTICIPANTOBJECID	M	The prepopData Document unique ID
	<i>ParticipantObjectName</i>	U	<i>not specialized</i>
	PARTICIPANTOBJECTQUERY	U	<i>not specialized</i>
	<i>ParticipantObjectDetail</i>	U	<i>not specialized</i>

5.Z3.1.2 Form Manager audit message:

	Field Name	Opt	Value Constraints
Event	EventID	M	EV(110107, DCM, “Import”)

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	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 Manager) (1)			
Audit Source (Form Manager) (1)			
Subject (1)			
prepopData(1)			

565

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

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

Audit Source AuditMessage/ AuditSourceIdentification	AuditSourceID	U	not specialized
	AuditEnterpriseSiteID	U	not specialized
	AuditSourceTypeCode	U	not specialized

Subject (AuditMessage/ ParticipantObject identification)	ParticipantObjectTypeCode	M	“1” (Person)
	ParticipantObjectTypeCodeRole	M	“1” (Patient)
	<i>ParticipantObjectDataLifeCycle</i>	<i>U</i>	<i>not specialized</i>
	ParticipantObjectIDTypeCode	M	EV(2, RFC-3881, “Subject Number”)
	<i>ParticipantObjectSensitivity</i>	<i>U</i>	<i>not specialized</i>
	PARTICIPANTOBJEC IID	M	The subject ID in HL7 CX format.
	<i>ParticipantObjectName</i>	<i>U</i>	<i>not specialized</i>
	PARTICIPANTOBJECTQUERY	<i>U</i>	<i>not specialized</i>
	<i>ParticipantObjectDetail</i>	<i>U</i>	<i>not specialized</i>

570

prepopData (AuditMessage/ ParticipantObject identification)	ParticipantObjectTypeCode	M	“2” (System)
	ParticipantObjectTypeCodeRole	M	“20” (job)
	<i>ParticipantObjectDataLifeCycle</i>	<i>U</i>	<i>not specialized</i>
	ParticipantObjectIDTypeCode	M	EV(2, RFC-3881, “Document ID”)
	<i>ParticipantObjectSensitivity</i>	<i>U</i>	<i>not specialized</i>
	PARTICIPANTOBJEC IID	M	The prepopData Document unique ID
	<i>ParticipantObjectName</i>	<i>U</i>	<i>not specialized</i>
	PARTICIPANTOBJECTQUERY	<i>U</i>	<i>not specialized</i>
	<i>ParticipantObjectDetail</i>	<i>U</i>	<i>not specialized</i>

5.Z3.1.2 Form Processor audit message:

Event	Field Name	Opt	Value Constraints
AuditMessage/ Event Identifica tion	EventID	M	EV(110107, DCM, “Import”)
	EventActionCode	M	“C” (Create)
	<i>EventDateTime</i>	<i>M</i>	<i>not specialized</i>
	<i>EventOutcomeIndicator</i>	<i>M</i>	<i>not specialized</i>
	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
	<i>AlternativeUserID</i>	<i>U</i>	<i>not specialized</i>
	<i>UserName</i>	<i>U</i>	<i>not specialized</i>
	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

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

575

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	<i>not specialized</i>
	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,

Audit Source AuditMessage/ AuditSourceIdentification	AuditSourceID	U	<i>not specialized</i>
	AuditEnterpriseSiteID	U	<i>not specialized</i>
	AuditSourceTypeCode	U	<i>not specialized</i>

Subject (AuditMessage/ ParticipantObjectIdentification)	ParticipantObjectTypeCode	M	“1” (Person)
	ParticipantObjectTypeCodeRole	M	“1” (Patient)
	ParticipantObjectDataLifeCycle	U	<i>not specialized</i>
	ParticipantObjectIDTypeCode	M	EV(2, RFC-3881, “Subject Number”)
	ParticipantObjectSensitivity	U	<i>not specialized</i>
	PARTICIPANTOBJECTID	M	The subject ID in HL7 CX format.
	ParticipantObjectName	U	<i>not specialized</i>
	PARTICIPANTOBJECTQUERY	U	<i>not specialized</i>
ParticipantObjectDetail	U	<i>not specialized</i>	

580

prepopData (AuditMessage/ ParticipantObject identification)	ParticipantObjectTypeCode	M	“2” (System)
	ParticipantObjectTypeCodeRole	M	“20” (job)
	<i>ParticipantObjectDataLifeCycle</i>	<i>U</i>	<i>not specialized</i>
	ParticipantObjectIDTypeCode	M	EV(2, RFC-3881, “Document ID”)
	<i>ParticipantObjectSensitivity</i>	<i>U</i>	<i>not specialized</i>
	PARTICIPANTOBJECTID	M	The prepopData Document unique ID
	<i>ParticipantObjectName</i>	<i>U</i>	<i>not specialized</i>
	PARTICIPANTOBJECTQUERY	<i>U</i>	<i>not specialized</i>
<i>ParticipantObjectDetail</i>	<i>U</i>	<i>not specialized</i>	

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

585 The Submit Form transaction MAY be a PHI-Export event as defined in ITI TF-2a: Table 3.20. 4.1.1.1-1. Actors that audit this transaction SHALL create audit data in conformance with DICOM “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)
	<i>EventDateTime</i>	<i>M</i>	<i>not specialized</i>
	<i>EventOutcomeIndicator</i>	<i>M</i>	<i>not specialized</i>
	EventTypeCode	M	EV(“ITI-35”, “IHE Transactions”, “Submit Form”)
Source (Form Filler) (1)			
Human Requestor (0..n)			
Destination (Form Receiver or Form Processor) (1)			
Audit Source (Form Filler) (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.
	<i>UserName</i>	<i>U</i>	<i>not specialized</i>
	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

590

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

Audit Source AuditMessage/ AuditSourceIdentification	AuditSourceID	U	not specialized
	AuditEnterpriseSiteID	U	not specialized
	AuditSourceTypeCode	U	not specialized

Subject (AuditMessage/ ParticipantObjectIdentification)	ParticipantObjectTypeCode	M	“1” (Person)
	ParticipantObjectTypeCodeRole	M	“1” (Patient)
	ParticipantObjectDataLifeCycle	U	not specialized
	ParticipantObjectIDTypeCode	M	EV(2, RFC-3881, “Subject Number”)
	ParticipantObjectSensitivity	U	not specialized
	PARTICIPANTOBJECTID	M	The subject ID in HL7 CX format.
	ParticipantObjectName	U	not specialized
	PARTICIPANTOBJECTQUERY	U	not specialized
	ParticipantObjectDetail	U	not specialized

FormData (AuditMessage/ ParticipantObject identification)	ParticipantObjectTypeCode	M	“2” (System)
	ParticipantObjectTypeCodeRole	M	“20” (job)
	<i>ParticipantObjectDataLifeCycle</i>	<i>U</i>	<i>not specialized</i>
	ParticipantObjectIDTypeCode	M	EV(2, RFC-3881, “Form ID”)
	<i>ParticipantObjectSensitivity</i>	<i>U</i>	<i>not specialized</i>
	PARTICIPANTOBJECTID	M	A form identifier
	<i>ParticipantObjectName</i>	<i>U</i>	<i>not specialized</i>
	PARTICIPANTOBJECTQUERY	<i>U</i>	<i>not specialized</i>
	<i>ParticipantObjectDetail</i>	<i>U</i>	<i>not specialized</i>

5.Z3.2.2 Form Receiver audit message:

	Field Name	Opt	Value Constraints
Event AuditMessage/ EventIdentification	EventID	M	EV(110107, DCM, “Import”)
	EventActionCode	M	“C” (Create)
	<i>EventDateTime</i>	<i>M</i>	<i>not specialized</i>
	<i>EventOutcomeIndicator</i>	<i>M</i>	<i>not specialized</i>
	EventTypeCode	M	EV(“ITI-35”, “IHE Transactions”, “Submit Form”)
Source (Form Filler) (1)			
Human Requestor (0..n)			
Destination (Form Receiver) (1)			
Audit Source (Form Receiver) (1)			
Subject (1)			
FormData (1)			

Where:

Source AuditMessage/ ActiveParticipant	UserID	M	Host system name
	AlternativeUserID	<i>U</i>	<i>not specialized</i>
	<i>UserName</i>	<i>U</i>	<i>not specialized</i>
	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

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

Destination AuditMessage/ ActiveParticipant	UserID	M	SOAP endpoint URI
	<i>AlternativeUserID</i>	M	The process ID as used within the local operating system in the local system logs.
	<i>UserName</i>	U	<i>not specialized</i>
	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

Audit Source AuditMessage/ AuditSourceIdentification	<i>AuditSourceID</i>	U	<i>not specialized</i>
	<i>AuditEnterpriseSiteID</i>	U	<i>not specialized</i>
	<i>AuditSourceTypeCode</i>	U	<i>not specialized</i>

Subject (AuditMessage/ ParticipantObjectIdentification)	ParticipantObjectTypeCode	M	“1” (Person)
	ParticipantObjectTypeCodeRole	M	“1” (Patient)
	<i>ParticipantObjectDataLifeCycle</i>	U	<i>not specialized</i>
	ParticipantObjectIDTypeCode	M	EV(2, RFC-3881, “Subject Number”)
	<i>ParticipantObjectSensitivity</i>	U	<i>not specialized</i>
	PARTICIPANTOBJECTID	M	The subject ID in HL7 CX format.
	<i>ParticipantObjectName</i>	U	<i>not specialized</i>
	PARTICIPANTOBJECTQUERY	U	<i>not specialized</i>
	<i>ParticipantObjectDetail</i>	U	<i>not specialized</i>

Form Data (AuditMessage/ ParticipantObjectIdentification)	ParticipantObjectTypeCode	M	“2” (System)
	ParticipantObjectTypeCodeRole	M	“20” (job)
	<i>ParticipantObjectDataLifeCycle</i>	U	<i>not specialized</i>
	ParticipantObjectIDTypeCode	M	EV(2, RFC-3881, “Form ID”)
	<i>ParticipantObjectSensitivity</i>	U	<i>not specialized</i>
	PARTICIPANTOBJECTID	M	An identifier for the form
	<i>ParticipantObjectName</i>	U	<i>not specialized</i>
	PARTICIPANTOBJECTQUERY	U	<i>not specialized</i>
	<i>ParticipantObjectDetail</i>	U	<i>not specialized</i>

5.Z3.2.3 Form Processor audit message:

	Field Name	Opt	Value Constraints
Event AuditMessage/ EventIdentification	EventID	M	EV(110107,DCM,“Import”)
	EventActionCode	M	“C” (Create)
	<i>EventDateTime</i>	M	<i>not specialized</i>
	<i>EventOutcomeIndicator</i>	M	<i>not specialized</i>
	EventTypeCode	M	EV(“ITI-35”,“IHE Transactions”,“Submit Form”)
Source (Form Filler) (1)			
Human Requestor (0..n)			
Destination (Form Processor) (1)			
Audit Source (Form Processor) (1)			
Subject (1)			
FormData (1)			

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Where:

Source	Field Name	Opt	Value Constraints
AuditMessage/ ActiveParticipant	UserID	M	Host system name
	AlternativeUserID	U	<i>not specialized</i>
	<i>UserName</i>	U	<i>not specialized</i>
	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

Human Requestor (if known)	Field Name	Opt	Value Constraints
AuditMessage/ ActiveParticipant	UserID	M	Identity of the human that initiated the transaction.
	AlternativeUserID	U	<i>not specialized</i>
	<i>UserName</i>	U	<i>not specialized</i>
	UserIsRequestor	M	“true”
	RoleIDCode	U	Access Control role(s) the user holds that allows this transaction.
	<i>NetworkAccessPointTypeCode</i>	NA	
	<i>NetworkAccessPointID</i>	NA	

Destination	Field Name	Opt	Value Constraints
AuditMessage/ ActiveParticipant	UserID	M	SOAP endpoint URI
	AlternativeUserID	M	The process ID as used within the local operating system in the local system logs.
	<i>UserName</i>	U	<i>not specialized</i>
	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

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Audit Source AuditMessage/ AuditSourceIdentification	<i>AuditSourceID</i>	<i>U</i>	<i>not specialized</i>
	<i>AuditEnterpriseSiteID</i>	<i>U</i>	<i>not specialized</i>
	<i>AuditSourceTypeCode</i>	<i>U</i>	<i>not specialized</i>

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

Form Data (AuditMessage/ ParticipantObjectIdentification)	<i>ParticipantObjectTypeCode</i>	<i>M</i>	"2" (System)
	<i>ParticipantObjectTypeCodeRole</i>	<i>M</i>	"20" (job)
	<i>ParticipantObjectDataLifeCycle</i>	<i>U</i>	<i>not specialized</i>
	<i>ParticipantObjectIDTypeCode</i>	<i>M</i>	EV(2, RFC-3881, "Form ID")
	<i>ParticipantObjectSensitivity</i>	<i>U</i>	<i>not specialized</i>
	PARTICIPANTOBJECTID	<i>M</i>	An identifier for the form
	<i>ParticipantObjectName</i>	<i>U</i>	<i>not specialized</i>
	PARTICIPANTOBJECTQUERY	<i>U</i>	<i>not specialized</i>
<i>ParticipantObjectDetail</i>	<i>U</i>	<i>not specialized</i>	

5.23.3 Archive Form [ITI-36] audit messages

620 The Archive Form transaction MAY be a PHI-Export event as defined in ITI TF-2a: Table 3.20. 4.1.1.1-1. Actors that audit this transaction SHALL create audit data in conformance with DICOM "Data Export"/"Data Import", with the following exceptions:

5.23.3.1 Form Filler audit message:

	Field Name	Opt	Value Constraints
Event AuditMessage/ EventIdentification	EventID	<i>M</i>	EV(110106, DCM, "Export")
	EventActionCode	<i>M</i>	"R" (Read)
	<i>EventDateTime</i>	<i>M</i>	<i>not specialized</i>
	<i>EventOutcomeIndicator</i>	<i>M</i>	<i>not specialized</i>
	EventTypeCode	<i>M</i>	EV("ITI-36", "IHE Transactions", "ArchiveForm")
Source (Form Filler) (1)			
Human Requestor (0..n)			
Destination (Form Archiver) (1)			

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Audit Source (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.
	<i>UserName</i>	<i>U</i>	<i>not specialized</i>
	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

625

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

Destination AuditMessage/ ActiveParticipant	UserID	M	SOAP endpoint URI.
	<i>AlternativeUserID</i>	<i>U</i>	<i>not specialized</i>
	<i>UserName</i>	<i>U</i>	<i>not specialized</i>
	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

Audit Source AuditMessage/ AuditSourceIdentification	<i>AuditSourceID</i>	<i>U</i>	<i>not specialized</i>
	<i>AuditEnterpriseSiteID</i>	<i>U</i>	<i>not specialized</i>
	<i>AuditSourceTypeCode</i>	<i>U</i>	<i>not specialized</i>

Subject	ParticipantObjectTypeCode	M	“1” (Person)
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	ParticipantObjectTypeCodeRole	M	“1” (Patient)
	<i>ParticipantObjectDataLifeCycle</i>	<i>U</i>	<i>not specialized</i>
	ParticipantObjectIDTypeCode	M	EV(2, RFC-3881, “Subject Number”)
	<i>ParticipantObjectSensitivity</i>	<i>U</i>	<i>not specialized</i>
	PARTICIPANTOBJEC TID	M	The subject ID in HL7 CX format.
	<i>ParticipantObjectName</i>	<i>U</i>	<i>not specialized</i>
	PARTICIPANTOBJECTQUERY	<i>U</i>	<i>not specialized</i>
	<i>ParticipantObjectDetail</i>	<i>U</i>	<i>not specialized</i>

FormData (AuditMessage/ ParticipantObjectI dentification)	ParticipantObjectTypeCode	M	“2” (System)
	ParticipantObjectTypeCodeRole	M	“20” (job)
	<i>ParticipantObjectDataLifeCycle</i>	<i>U</i>	<i>not specialized</i>
	ParticipantObjectIDTypeCode	M	EV(2, RFC-3881, “Form ID”)
	<i>ParticipantObjectSensitivity</i>	<i>U</i>	<i>not specialized</i>
	PARTICIPANTOBJEC TID	M	A form identifier
	<i>ParticipantObjectName</i>	<i>U</i>	<i>not specialized</i>
	PARTICIPANTOBJECTQUERY	<i>U</i>	<i>not specialized</i>
	<i>ParticipantObjectDetail</i>	<i>U</i>	<i>not specialized</i>

630

5.Z3.3.2 Form Archiver audit message:

	Field Name	Opt	Value Constraints
Event AuditMessage/ EventIdentificati on	EventID	M	EV(110106, DCM, “Import”)
	EventActionCode	M	“R” (Read)
	<i>EventDateTime</i>	<i>M</i>	<i>not specialized</i>
	<i>EventOutcomeIndicator</i>	<i>M</i>	<i>not specialized</i>
	EventTypeCode	M	EV(“ITI-36”, “IHE Transactions”, “ArchiveForm”)
Source (Form Filler) (1)			
Human 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.
	<i>UserName</i>	<i>U</i>	<i>not specialized</i>
	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

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

Destination AuditMessage/ ActiveParticipant	UserID	M	SOAP endpoint URI.
	<i>AlternativeUserID</i>	<i>U</i>	<i>not specialized</i>
	<i>UserName</i>	<i>U</i>	<i>not specialized</i>
	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

635

Audit Source AuditMessage/ AuditSourceIdentification	<i>AuditSourceID</i>	<i>U</i>	<i>Not specialized.</i>
	<i>AuditEnterpriseSiteID</i>	<i>U</i>	<i>not specialized</i>
	<i>AuditSourceTypeCode</i>	<i>U</i>	<i>not specialized</i>

Subject (AuditMessage/ ParticipantObjectIdentification)	ParticipantObjectTypeCode	M	“1” (Person)
	ParticipantObjectTypeCodeRole	M	“1” (Patient)
	<i>ParticipantObjectDataLifeCycle</i>	<i>U</i>	<i>not specialized</i>
	ParticipantObjectIDTypeCode	M	EV(2, RFC-3881, “Subject Number”)
	<i>ParticipantObjectSensitivity</i>	<i>U</i>	<i>not specialized</i>
	PARTICIPANTOBJECTID	M	The subject ID in HL7 CX format.
	<i>ParticipantObjectName</i>	<i>U</i>	<i>not specialized</i>
	PARTICIPANTOBJECTQUERY	<i>U</i>	<i>not specialized</i>
<i>ParticipantObjectDetail</i>	<i>U</i>	<i>not specialized</i>	

FormData (AuditMessage/ ParticipantObject identification)	ParticipantObjectTypeCode	M	“2” (System)
	ParticipantObjectTypeCodeRole	M	“20” (job)
	<i>ParticipantObjectDataLifeCycle</i>	<i>U</i>	<i>not specialized</i>
	ParticipantObjectIDTypeCode	M	EV(2, RFC-3881, “Form ID”)
	<i>ParticipantObjectSensitivity</i>	<i>U</i>	<i>not specialized</i>
	PARTICIPANTOBJECTID	M	A form identifier
	<i>ParticipantObjectName</i>	<i>U</i>	<i>not specialized</i>
	PARTICIPANTOBJECTQUERY	<i>U</i>	<i>not specialized</i>
<i>ParticipantObjectDetail</i>	<i>U</i>	<i>not specialized</i>	

640 **5.23.4 ArchiveSourceDocuments [QRPH-36] audit messages**

The Retrieve Form transaction MAY be a PHI-Export event as defined in ITI TF-2a: Table 3.20.4.1.1.1-1. Actors that audit this transaction SHALL create audit data in conformance with DICOM “Data Export”/“Data Import”, with the following exceptions.

5.23.4.1 Form Filler audit message:

	Field Name	Opt	Value Constraints
Event AuditMessage/ EventIdentification	EventID	M	EV(110106, DCM, “Export”)
	EventActionCode	M	“R” (Read)
	<i>EventDateTime</i>	<i>M</i>	<i>not specialized</i>
	<i>EventOutcomeIndicator</i>	<i>M</i>	<i>not specialized</i>
	EventTypeCode	M	EV(“QRPH-36”, “IHE Transactions”, “ArchiveSourceDocuments”)
Source (Form Filler) (1)			
Human Requestor (0..n)			
Destination (Form Archiver) (1)			
Audit Source (Form Filler) (1)			
Subject (1)			
prepopData (1)			

645 **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.
	<i>UserName</i>	<i>U</i>	<i>not specialized</i>
	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

650

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

Audit Source AuditMessage/ AuditSourceIdentification	AuditSourceID	U	not specialized
	AuditEnterpriseSiteID	U	not specialized
	AuditSourceTypeCode	U	not specialized

Subject (AuditMessage/ ParticipantObjectIdentification)	ParticipantObjectTypeCode	M	“1” (Person)
	ParticipantObjectTypeCodeRole	M	“1” (Patient)
	ParticipantObjectDataLifeCycle	U	not specialized
	ParticipantObjectIDTypeCode	M	EV(2, RFC-3881, “Subject Number”)
	ParticipantObjectSensitivity	U	not specialized
	PARTICIPANTOBJECTID	M	The subject ID in HL7 CX format.
	ParticipantObjectName	U	not specialized
	PARTICIPANTOBJECTQUERY	U	not specialized
	ParticipantObjectDetail	U	not specialized

prepopData (AuditMessage/ ParticipantObject identification)	ParticipantObjectTypeCode	M	“2” (System)
	ParticipantObjectTypeCodeRole	M	“20” (job)
	<i>ParticipantObjectDataLifeCycle</i>	<i>U</i>	<i>not specialized</i>
	ParticipantObjectIDTypeCode	M	EV(2, RFC-3881, “Document ID”)
	<i>ParticipantObjectSensitivity</i>	<i>U</i>	<i>not specialized</i>
	PARTICIPANTOBJECTID	M	The prepopData Document unique ID
	<i>ParticipantObjectName</i>	<i>U</i>	<i>not specialized</i>
	PARTICIPANTOBJECTQUERY	<i>U</i>	<i>not specialized</i>
<i>ParticipantObjectDetail</i>	<i>U</i>	<i>not specialized</i>	

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)
	<i>EventDateTime</i>	<i>M</i>	<i>not specialized</i>
	<i>EventOutcomeIndicator</i>	<i>M</i>	<i>not specialized</i>
	EventTypeCode	M	EV(“QRPH-36”, “IHE Transactions”, “ArchiveSourceDocuments”)
Source (Form Filler) (1)			
Human Requestor (0..n)			
Destination (Form Archiver) (1)			
Audit Source (Form Archiver) (1)			
Subject (1)			
prepopData (1)			

655

Where:

Source AuditMessage/ ActiveParticipant	UserID	M	Host system name
	AlternativeUserID	<i>U</i>	<i>not specialized</i>
	<i>UserName</i>	<i>U</i>	<i>not specialized</i>
	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

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

Destination	UserID	M	SOAP endpoint URI
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	<i>AlternativeUserID</i>	M	The process ID as used within the local operating system in the local system logs.
	<i>UserName</i>	U	<i>not specialized</i>
	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

Audit Source AuditMessage/ AuditSourceIdentification	<i>AuditSourceID</i>	U	<i>not specialized</i>
	<i>AuditEnterpriseSiteID</i>	U	<i>not specialized</i>
	<i>AuditSourceTypeCode</i>	U	<i>not specialized</i>

Subject (AuditMessage/ ParticipantObjectIdentification)	ParticipantObjectTypeCode	M	“1” (Person)
	ParticipantObjectTypeCodeRole	M	“1” (Patient)
	<i>ParticipantObjectDataLifeCycle</i>	U	<i>not specialized</i>
	ParticipantObjectIDTypeCode	M	EV(2, RFC-3881, “Subject Number”)
	<i>ParticipantObjectSensitivity</i>	U	<i>not specialized</i>
	PARTICIPANTOBJEC TID	M	The subject ID in HL7 CX format.
	<i>ParticipantObjectName</i>	U	<i>not specialized</i>
	PARTICIPANTOBJECTQUER Y	U	<i>not specialized</i>
<i>ParticipantObjectDetail</i>	U	<i>not specialized</i>	

660

prepopData (AuditMessage/ ParticipantObjectIdentification)	ParticipantObjectTypeCode	M	“2” (System)
	ParticipantObjectTypeCodeRole	M	“20” (job)
	<i>ParticipantObjectDataLifeCycle</i>	U	<i>not specialized</i>
	ParticipantObjectIDTypeCode	M	EV2, RFC-3881, “Document ID”)
	<i>ParticipantObjectSensitivity</i>	U	<i>not specialized</i>
	PARTICIPANTOBJEC TID	M	The prepopData Document unique ID
	<i>ParticipantObjectName</i>	U	<i>not specialized</i>
	PARTICIPANTOBJECTQUER Y	U	<i>not specialized</i>
	<i>ParticipantObjectDetail</i>	U	<i>not specialized</i>

Volume 3 – Content Modules

665

6 HL7^{®4} CDA Content Modules

6.3.1 CDA Document Content Modules

Add to Section 6.3.1

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

675

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

Parameter Name	REQ	Description	Value
prepopData	R	The xml for pre-population	As defined in ITI TF-2b: 3.34
workflowData	R	The xml representation of workflow specific values.	This value is a well-formed xml document.as defined below.
formID	R	The identifier of a form.	A string identifying the form
encodedResponse	R	Tells the Form Archiver whether or not to return an encoded response	{true,false}
archiveURL	R	Tells the Form Archiver whether or not the Form Filler is exercising the Archive Option	the URL of any Form Filler identified Form Archiver or the null string
context	R	The xml specifics of workflow context	As defined in Section 6.3.1.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.

680

Table 6.3.1-2: Optionality Key

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

⁴ HL7 is the registered trademarks of Health Level Seven International.

6.3.1.D CRD prepopData Document Content Module

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

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

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

R2	Detailed Physical Examination	1.3.6.1.4.1.19376.1.5.3.1.1.9.15	PCC TF-2: 6.3.3.4.2	
R	Allergies and Other Adverse Reactions	1.3.6.1.4.1.19376.1.5.3.1.3.13	PCC TF-2: 6.3.3.2.11	
R2	Coded Results	1.3.6.1.4.1.19376.1.5.3.1.3.28	PCC TF-2:6.3.3.5.2	

690

6.3.1.D1 CRD Workflow Data Content Module

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

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

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

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

705 The sub element “PrePopArchiveID” (Table 6.3.1.D1-1) contains the “documentId” of the prepopulation and workflow data submitted to the Form Archiver through the transaction ArchiveSourceDocuments transaction. Recall that this archiving of the prepopulation and workflow data (when the required option is selected) takes place before the Retrieve Form [ITI-34]transaction.

710

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

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

Table 6.3.1.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 supplCRD: Section 3.Z.2.1	VisDatTim
Time of Visit	Time the visit took place	CDASH Standard, version 1.1: section 5.2.5/5.2.6 QRPH-TF supplCRD: Section 3.Z.2.1	VisDatTim

6.3.1.D1.1 Workflow Data Sample

715 The content of workflowData parameter SHALL *minimally* be:

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

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

The content of workflowData parameter SHALL *optimally* be:

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

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

Submit Form [ITI-35] transaction constraint

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

Archive Form [ITI-36] transaction constraint

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

785

Appendices

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

CCD-CDASH mapping and CRD constraints				
CRD Reference	CDASH Domain	Clinical Database Variable Name	Optionality	Definition
	Common Identifiers	STUDYID	R2	Unique Identifier for a study within a submission.
		SITEID	R2	Unique identifier for the site.
		SUBJID	R2	Subject identifier.
		INVID	O	Investigator identifier.
		VISIT	O	Visit Name.
Header Information	Demography	BRTHYR	R	Year of subject's birth.
		BRTHMO	R	Month of subject's birth.
		BRTHDY	R2	Day of subject's birth.
		BRHTM	O	Time of subject's birth,
		SEX	R	The assemblage of physical properties or qualities by which male is distinguished from female; the physical difference between male and female; the distinguishing peculiarity of male or female. (NCI – CDISC Definition).
		AGE	O	Numeric Age of Subject.
		AGEU	O	Age units.
		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

CCD-CDASH mapping and CRD constraints				
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.

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.

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

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

CCD-CDASH mapping and CRD constraints				
CRD Reference	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

CCD-CDASH mapping and CRD constraints				
CRD Reference	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	LBDMTC	R	Date of sample collection.
		LBTM (Note: If collected, will be derived into LBDMTC.)	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.
		LBFAS (for example)	R2	Conditions for sampling defined in the protocol.
		LBREFID	R2	Internal or external specimen identifier.
	Lab Test Results - Scenario 2: Local processing	LBDMTC	R	Date of sample collection.
		LBTM (Note: If collected, will be derived into LBDMTC.)	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.

CCD-CDASH mapping and CRD constraints				
CRD Reference	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.
		LBORNRL0 LBORNRLHI 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 SUPQUAL domain.)	R2	Whether lab test results were clinically significant.
		LBNAM	R2	Name of lab analyzing sample.
		LBREFID	R2	Internal or external specimen identifier.
	Lab Test Results - Scenario 3: Central processing but CRF includes site assessment...	LBDMC	R	Date of sample collection.
		LBDM (Note: If collected, will be derived into LBDMC.)	R2	Time of collection.
		LBSTAT	R2	Status of whether or not lab was done.
		LBCAT LBSCAT	R2	Type of draw / category / panel name. Used to define a category of related records.
		LBTP	R2	Relative time for use when multiple sequential assessments are done,
		LBFAST (for example)	R2	Conditions for sampling defined in the protocol.
		LBTEST	R	Verbatim name of the test or examination used to obtain the

CCD-CDASH mapping and CRD constraints				
CRD Reference	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 SUPQUAL domain.)	R2	Whether lab test results were clinically significant.
		LBNAM	R2	Name of lab analyzing sample.
		LBREFID	R2	Internal or external specimen identifier.
	ECG Test Results - Scenario 1: Central reading...	LBDMC	R	Date of sample collection.
		LBDM (Note: If collected, will be derived into LBDMC.)	O	Time of collection.
		SBSTAT	R2	Status of whether or not lab was done.
		LBCATLBSCAT	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.

CCD-CDASH mapping and CRD constraints				
CRD Reference	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 SUPQUAL 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.

CCD-CDASH mapping and CRD constraints				
CRD Reference	CDASH Domain	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 SUPQUAL 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

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

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

B.1 XSLT Sample

```
805 <?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"
810   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-
815 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#"
820  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"
825  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>
830  <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>
835  <!-- 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>
840  <!-- SubjectData element -->
```

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

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

```

      <xsl:attribute name="Value"><xsl:value-of
895   select="$patientNode/cda:administrativeGenderCode/@code"/></xsl:attribute>
      </xsl:element>
      <!-- BRTHDTC -->
      <xsl:element name="ItemData"
namespace="http://www.cdisc.org/ns/odm/v1.3">
      <xsl:attribute name="ItemOID">BRTHDTC</xsl:attribute>
900   <!-- transform stupid non-ISO8601-XML date to ISO8601 date -->
      <xsl:variable name="ISODATE">
        <xsl:call-template name="HL7DateToISO8601">
          <xsl:with-param name="HL7Date"
905   select="$patientNode/cda:birthTime/@value"/>
        </xsl:call-template>
      </xsl:variable>
      <xsl:attribute name="Value">
        <xsl:value-of select="$ISODATE"/>
        <!--xsl:value-of select="$patientNode/cda:birthTime/@value"/-->
910   </xsl:attribute>
      </xsl:element>
    </xsl:element>
  </xsl:element>
</xsl:template>
915

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

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

```
945     <!-- NOTE: we're making up the ItemGroupOID's...these SHOULD be
standardized; it also might be that all med history items SHOULD be in one
ItemGroup -->
     <xsl:for-each select="$ccdConditions/cda:entry">
950       <xsl:element name="ItemGroupData"
namespace="http://www.cdisc.org/ns/odm/v1.3">
         <xsl:attribute name="ItemGroupOID">CONDITION</xsl:attribute>
         <xsl:call-template name="problemItemData"><xsl:with-param
name="theNode" select="."/;></xsl:call-template>
         </xsl:element>
955       </xsl:for-each>
     <xsl:for-each select="$ccdPMH/cda:entry">
       <xsl:element name="ItemGroupData"
namespace="http://www.cdisc.org/ns/odm/v1.3">
960         <xsl:attribute name="ItemGroupOID">PASTCONDITION</xsl:attribute>
         <xsl:call-template name="problemItemData"><xsl:with-param
name="theNode" select="."/;></xsl:call-template>
         </xsl:element>
       </xsl:for-each>
     <xsl:for-each select="$ccdProcedures/cda:entry">
965       <xsl:element name="ItemGroupData"
namespace="http://www.cdisc.org/ns/odm/v1.3">
         <xsl:attribute name="ItemGroupOID">PROCEDURE</xsl:attribute>
         <xsl:call-template name="procedureItemData"><xsl:with-param
name="theNode" select="."/;></xsl:call-template>
970       </xsl:element>
     </xsl:for-each>
   </xsl:element>
 </xsl:if>
</xsl:template>
975

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

```

    <xsl:element name="ItemGroupData"
namespace="http://www.cdisc.org/ns/odm/v1.3">
1000   <xsl:attribute name="ItemGroupOID">CM</xsl:attribute>
    <!-- CMTRT -->
    <!--ItemData ItemDataOID='CMTRT'-->
    <xsl:element name="ItemData"
namespace="http://www.cdisc.org/ns/odm/v1.3">
1005   <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
1010 select="$originalText" /></xsl:otherwise>
    </xsl:choose>
    </xsl:attribute>
    </xsl:element>
    <!-- CMDOSFREQ -->
1015   <xsl:comment>need table to translate HL7 frequency, e.g., 6h to
    BID</xsl:comment>
    <!-- CMROUTE -->
    <xsl:variable name="routeCode"
1020 select="cda:substanceAdministration/cda:routeCode/@displayName" />
    <xsl:if test="$routeCode">
    <!--ItemData ItemDataOID='CMROUTE'-->
    <xsl:element name="ItemData"
namespace="http://www.cdisc.org/ns/odm/v1.3">
1025   <xsl:attribute name="ItemOID">CMROUTE</xsl:attribute>
    <xsl:attribute name="Value"><xsl:value-of
select="$routeCode" /></xsl:attribute>
    </xsl:element><!--/ItemData-->
    </xsl:if>
    <!-- CMSTDTC -->
1030   <xsl:variable name="medStartDate"
select="cda:substanceAdministration/cda:effectiveTime[@xsi:type='IVL_TS']/cda
:low/@value" />
    <xsl:if test="$medStartDate">
    <!--ItemData ItemDataOID='CMSTDTC'-->
1035   <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">
1040   <xsl:call-template name="HL7DateToISO8601">
    <xsl:with-param name="HL7Date" select="$medStartDate" />
    </xsl:call-template>
    </xsl:variable>
    <xsl:attribute name="ItemOID">CMSTDTC</xsl:attribute>
    <!--xsl:attribute name="Value"><xsl:value-of
1045 select="$medStartDate" /></xsl:attribute-->
    <xsl:attribute name="Value"><xsl:value-of
select="$ISODATE" /></xsl:attribute>
    </xsl:element><!--/ItemData-->
    </xsl:if>

```

```
1050     <!-- CMENDTDC -->
        <xsl:variable name="medEndDate"
select="cda:substanceAdministration/cda:effectiveTime[@xsi:type='IVL_TS']/cda
:high/@value"/>
1055     <xsl:if test="$medEndDate">
        <!--ItemData ItemDataOID='CMENDDDTC'-->
        <xsl:element name="ItemData"
namespace="http://www.cdisc.org/ns/odm/v1.3">
        <xsl:attribute name="ItemOID">CMENDDDTC</xsl:attribute>
1060     <!-- transform stupid non-ISO8601-XML date to ISO8601 date -->
        <xsl:variable name="ISODATE">
        <xsl:call-template name="HL7DateToISO8601">
        <xsl:with-param name="HL7Date" select="$medEndDate"/>
        </xsl:call-template>
        </xsl:variable>
1065     <!--xsl:attribute name="Value"><xsl:value-of
select="$medEndDate"/></xsl:attribute-->
        <xsl:attribute name="Value"><xsl:value-of
select="$ISODATE"/></xsl:attribute>
        </xsl:element><!--/ItemData-->
1070     </xsl:if>
        </xsl:element>
        <!--/ItemGroupData-->
        </xsl:for-each>
        </xsl:element>
1075     </xsl:if>
    </xsl:template>

    <!-- SUBSTANCE ABUSE -->
    <xsl:template name="substanceAbuse">
1080     <!-- we could look into the social history for any of a specific list of
substance abuse entries...if any are present then we emit the section -->
        <!-- however, there are probably too many codes to consider....just quickly
looking we see several SNOMED codes for smoking, cigarette smoking, .... -->
    </xsl:template>
1085

    <!-- Vital Signs -->
    <xsl:template name="vitalSigns">
1090     <!-- if we have a vitals section with at least one organizer then we're going
for all organizers -->
        <xsl:variable name="vitalsSection"
select="cda:component/cda:structuredBody/cda:component/cda:section[cda:code/@
code='8716-3']"/>
        <xsl:if test="$vitalsSection/cda:entry/cda:organizer">
1095     <!--FormData FormDataOID='VSForm'-->
        <xsl:element name="FormData" namespace="http://www.cdisc.org/ns/odm/v1.3">
        <xsl:attribute name="FormOID">VSFORM</xsl:attribute>
        <!-- for each organizer -->
        <xsl:for-each select="$vitalsSection/cda:entry/cda:organizer">
1100     <!-- at the organizer level we have the date (and MAY be the time) -->
        <xsl:variable name="vitalsDateTime" select="cda:effectiveTime/@value"/>
        <!--ItemGroupData ItemGroupDataOID='VS'-->
```

```
1105     <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"
1110 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="$vitalsDateTime"/>
    </xsl:call-template>
1115 </xsl:variable>
    <xsl:attribute name="ItemOID">VSDTC</xsl:attribute>
    <!--xsl:attribute name="Value"><xsl:value-of
select="$vitalsDateTime"/></xsl:attribute-->
    <xsl:attribute name="Value"><xsl:value-of
1120 select="$ISODATE"/></xsl:attribute>
    </xsl:element><!--/ItemData-->
    <!-- now go get all of the components from this recording -->
    <xsl:for-each select="cda:component">
    <xsl:variable name="vitalsResultNode"
1125 select="cda:observation/cda:value"/>
    <!-- VSTEST -->
    <!--ItemData ItemDataOID='VSTEST'-->
    <xsl:element name="ItemData"
namespace="http://www.cdisc.org/ns/odm/v1.3">
1130 <xsl:attribute name="ItemOID">VSTEST</xsl:attribute>
    <xsl:attribute name="Value"><xsl:value-of
select="cda:observation/cda:code/@displayName"/></xsl:attribute>
    </xsl:element>
    <xsl:choose>
1135 <xsl:when test="$vitalsResultNode/@xsi:type='PQ'">
    <!-- VSORRES -->
    <!--ItemData ItemDataOID='VSORRES'-->
    <xsl:element name="ItemData"
namespace="http://www.cdisc.org/ns/odm/v1.3">
1140 <xsl:attribute name="ItemOID">VSORRES</xsl:attribute>
    <xsl:attribute name="Value"><xsl:value-of
select="$vitalsResultNode/@value"/></xsl:attribute>
    </xsl:element><!--/ItemData-->
    <!-- VSORRESU -->
1145 <!--ItemData ItemDataOID='VSORRESU'-->
    <xsl:element name="ItemData"
namespace="http://www.cdisc.org/ns/odm/v1.3">
    <xsl:attribute name="ItemOID">VSORRESU</xsl:attribute>
    <xsl:attribute name="Value"><xsl:value-of
1150 select="$vitalsResultNode/@unit"/></xsl:attribute>
    </xsl:element><!--/ItemData-->
    </xsl:when>
    <xsl:otherwise>
    <!-- VSORRES ...no units -->
1155 <!--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
1160 select="$vitalsResultNode"/></xsl:attribute>
        </xsl:element><!--/ItemData-->
        </xsl:otherwise>
        </xsl:choose>
    </xsl:for-each>
1165 </xsl:element><!--/ItemGroupData-->
    </xsl:for-each>
    </xsl:element><!--/FormData-->
</xsl:if>
</xsl:template>
1170 <!-- AE -->
<xsl:template name="adverseEvents">
<xsl:variable name="aeSection"
1175 select="cda:component/cda:structuredBody/cda:component/cda:section[cda:code/@
code='48765-2']"/>
<xsl:if test="$aeSection/cda:entry/cda:act">
    <!--FormData FormDataOID='AEForm'-->
    <xsl:element name="FormData" namespace="http://www.cdisc.org/ns/odm/v1.3">
    <xsl:attribute name="FormOID">AEForm</xsl:attribute>
1180 <xsl:for-each select="$aeSection/cda:entry">
        <!--ItemDataGroup ItemDataGroupOID='AE'-->
        <xsl:element name="ItemGroupData"
namespace="http://www.cdisc.org/ns/odm/v1.3">
        <xsl:attribute name="ItemGroupOID">AE</xsl:attribute>
1185 <!-- AETERM -->
        <xsl:variable name="originalTextRef"
select="cda:act/cda:entryRelationship/cda:observation/cda:participant/cda:par
ticipantRole/cda:playingEntity/cda:code/cda:originalText/cda:reference/@value
"/>
1190 <xsl:variable name="codedDisplayName"
select="cda:act/cda:entryRelationship/cda:observation/cda:participant/cda:par
ticipantRole/cda:playingEntity/cda:code/@displayName"/>
        <!--ItemData ItemDataOID='AETERM'-->
        <xsl:element name="ItemData"
1195 namespace="http://www.cdisc.org/ns/odm/v1.3">
        <xsl:attribute name="ItemOID">AETERM</xsl:attribute>
        <xsl:attribute name="Value">
        <xsl:choose>
        <xsl:when test="$originalTextRef"><xsl:value-of
1200 select="//*[@ID=substring-after($originalTextRef,'#')]"></xsl:when>
        <xsl:otherwise><xsl:value-of
select="$codedDisplayName"/></xsl:otherwise>
        </xsl:choose>
        </xsl:attribute>
1205 </xsl:element><!--/ItemData-->
    <!-- AESTDTC -->
```

```

    <xsl:variable name="aeStartDateTime"
select="cda:act/cda:entryRelationship/cda:observation/cda:effectiveTime/@valu
e"/>
1210     <xsl:if test="$aeStartDateTime">
        <!--ItemData ItemDataOID='AESTDTC'-->
        <xsl:element name="ItemData"
namespace="http://www.cdisc.org/ns/odm/v1.3">
1215         <xsl:attribute name="ItemOID">AESTDTC</xsl:attribute>
        <xsl:attribute name="value"><xsl:value-of
select="$aeStartDateTime"/></xsl:attribute>
        </xsl:element><!--/ItemData-->
        </xsl:if>
1220     </xsl:element><!--/ItemDataGroup-->
    </xsl:for-each>
    </xsl:element><!--/FormData-->
</xsl:if>

</xsl:template>
1225 <!-- helper templates -->

<!-- CDASH a med history item -->
1230 <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="$theNode/cda:act/cda:entryRelationship/cda:observation/cda:text/cda:r
eference/@value"/>
1235 <xsl:variable name="codedValue"
select="$theNode/cda:act/cda:entryRelationship/cda:observation/cda:value/@dis
playName"/>
    <!-- problem status translates into the CDASH MHONG -->
1240 <xsl:variable name="problemStatusNode"
select="$theNode/cda:act/cda:entryRelationship/cda:observation/cda:entryRelat
ionship/cda:observation[cda:code/@code='33999-4']"/>
    <!-- can have status coded or by reference -->
    <xsl:variable name="problemStatusRef"
1245 select="$problemStatusNode/cda:text/cda:reference/@value"/>
    <!-- onset and end dates for problems -->
    <xsl:variable name="problemOnset"
select="$theNode/cda:act/cda:entryRelationship/cda:observation/cda:effectivE
ime/cda:low/@value"/>
1250 <xsl:variable name="problemResolved"
select="$theNode/cda:act/cda:entryRelationship/cda:observation/cda:effectivE
ime/cda:high/@value"/>
    <!-- MHTERM -->
    <!--ItemData ItemOID='MHTERM'-->
1255 <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>
```

```
1260     <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>???
```

```
1315 <xsl:template name="procedureItemData">
<xsl:param name="theNode"/>
  <xsl:variable name="originalTextRef"
select="$theNode/cda:procedure/cda:code/cda:originalText/cda:reference/@value
"/>
  <xsl:variable name="codedValue"
select="$theNode/cda:procedure/cda:code/@displayName"/>
1320 <!-- 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">
1325 <xsl:choose>
  <xsl:when test="string-length($originalTextRef)>0"><xsl:value-of
select="//*[@ID=substring-after($originalTextRef,'#')]" /></xsl:when>
  <xsl:when test="string-length($codedValue)>0"><xsl:value-of
select="$codedValue" /></xsl:when>
1330 <xsl:otherwise>???
```

```

1365     <xsl:variable name="DAY" select="substring($HL7Date,7,2)"/>
        <xsl:variable name="HOUR" select="substring($HL7Date,9,2)"/>
        <xsl:value-of select="concat($YEAR,'-',$MONTH,'-',$DAY,'T',$HOUR)"/>
    </xsl:when>
    <xsl:when test="string-length($HL7Date) = 12">
1370     <xsl:variable name="YEAR" select="substring($HL7Date,1,4)"/>
        <xsl:variable name="MONTH" select="substring($HL7Date,5,2)"/>
        <xsl:variable name="DAY" select="substring($HL7Date,7,2)"/>
        <xsl:variable name="HOUR" select="substring($HL7Date,9,2)"/>
        <xsl:variable name="MINUTE" select="substring($HL7Date,11,2)"/>
1375     <xsl:value-of select="concat($YEAR,'-',$MONTH,'-
', $DAY,'T',$HOUR,':',$MINUTE)"/>
    </xsl:when>
    <xsl:when test="string-length($HL7Date) = 14">
1380     <xsl:variable name="YEAR" select="substring($HL7Date,1,4)"/>
        <xsl:variable name="MONTH" select="substring($HL7Date,5,2)"/>
        <xsl:variable name="DAY" select="substring($HL7Date,7,2)"/>
        <xsl:variable name="HOUR" select="substring($HL7Date,9,2)"/>
        <xsl:variable name="MINUTE" select="substring($HL7Date,11,2)"/>
        <xsl:variable name="SECOND" select="substring($HL7Date,13,2)"/>
1385     <xsl:value-of select="concat($YEAR,'-',$MONTH,'-
', $DAY,'T',$HOUR,':',$MINUTE,':',$SECOND)"/>
    </xsl:when>
    <!-- can still be extended for the case milliseconds are given -->
    <!-- CASE NOT FOUND -->
1390     <xsl:otherwise><xsl:value-of select="$HL7Date"/></xsl:otherwise>
    </xsl:choose>

</xsl:template>

1395 </xsl:stylesheet>

```

B.2 Sample Standard CRF output from the Sample XSLT

```

1400 <?xml version="1.0" encoding="UTF-8"?>
    <ODM xmlns="http://www.cdisc.org/ns/odm/v1.3" AsOfDateTime="2008-09-
23T22:28:40.739+02:00" ODMVersion="1.3" FileType="Transactional"
FileOID="TEST" CreationDateTime="2008-09-23T22:28:40.739+02:00">
    <ClinicalData StudyOID="CLL.001" MetaDataVersionOID="001">
    <SubjectData SubjectKey="1038">
1405     <SiteRef LocationOID="100"/>
        <StudyEventData StudyEventOID="CLL_CRF">
        <FormData FormOID="DemographicsForm">
            <!--check on whether or not we can get Ethnicity and Race-->
            <ItemGroupData ItemGroupOID="DM">
1410         <ItemData ItemOID="SEX" Value="M"/>
            <ItemData ItemOID="BRTHDTC" Value="1932-09-24"/>
        </ItemGroupData>
        </FormData>
        <FormData FormOID="MedicalHistory">
1415     <ItemGroupData ItemGroupOID="CONDITION">

```

```
1420     <ItemData ItemOID="MHTERM" Value="Asthma"/>
        <ItemData ItemOID="MHONG" Value="ONGOING"/>
        <!--research adding type and category (MHCAT, MHSCAT)-->
        <ItemData ItemOID="MHSTDTC" Value="1950"/>
    </ItemGroupData>
    <ItemGroupData ItemGroupOID="CONDITION">
        <ItemData ItemOID="MHTERM" Value="Pneumonia"/>
        <ItemData ItemOID="MHONG" Value="RESOLVED"/>
        <!--research adding type and category (MHCAT, MHSCAT)-->
1425     <ItemData ItemOID="MHSTDTC" Value="1997-01"/>
    </ItemGroupData>
    <ItemGroupData ItemGroupOID="CONDITION">
        <ItemData ItemOID="MHTERM" Value="Pneumonia"/>
        <ItemData ItemOID="MHONG" Value="RESOLVED"/>
1430     <!--research adding type and category (MHCAT, MHSCAT)-->
        <ItemData ItemOID="MHSTDTC" Value="1999-03"/>
    </ItemGroupData>
    <ItemGroupData ItemGroupOID="CONDITION">
        <ItemData ItemOID="MHTERM" Value="Myocardial infarction"/>
1435     <ItemData ItemOID="MHONG" Value="RESOLVED"/>
        <!--research adding type and category (MHCAT, MHSCAT)-->
        <ItemData ItemOID="MHSTDTC" Value="1997-01"/>
    </ItemGroupData>
    <ItemGroupData ItemGroupOID="PROCEDURE">
1440     <ItemData ItemOID="MHTERM" Value="Total hip replacement, left"/>
        <ItemData ItemOID="MHONG" Value="RESOLVED"/>
        <!--??? what to do about an effectiveTime of center ???-->
    </ItemGroupData>
</FormData>
1445 <FormData FormOID="ConMedForm">
    <ItemGroupData ItemGroupOID="CM">
        <ItemData ItemOID="CMTRT" Value="Albuterol inhalant"/>
        <!--need table to translate HL7 frequency, e.g., 6h to BID-->
        <ItemData ItemOID="CMROUTE" Value="Inhalation, oral"/>
1450    </ItemGroupData>
    <ItemGroupData ItemGroupOID="CM">
        <ItemData ItemOID="CMTRT" Value="Clopidogrel"/>
        <!--need table to translate HL7 frequency, e.g., 6h to BID-->
    </ItemGroupData>
1455    <ItemGroupData ItemGroupOID="CM">
        <ItemData ItemOID="CMTRT" Value="Metoprolol"/>
        <!--need table to translate HL7 frequency, e.g., 6h to BID-->
    </ItemGroupData>
    <ItemGroupData ItemGroupOID="CM">
1460     <ItemData ItemOID="CMTRT" Value="Prednisone"/>
        <!--need table to translate HL7 frequency, e.g., 6h to BID-->
        <ItemData ItemOID="CMSTDTC" Value="2000-03-28"/>
    </ItemGroupData>
    <ItemGroupData ItemGroupOID="CM">
1465     <ItemData ItemOID="CMTRT" Value="Cephalexin"/>
        <!--need table to translate HL7 frequency, e.g., 6h to BID-->
        <ItemData ItemOID="CMSTDTC" Value="2000-03-28"/>
        <ItemData ItemOID="CMENDDTC" Value="2000-04-04"/>
    </ItemGroupData>
</FormData>
```

```
1470     </ItemGroupData>
</FormData>
<FormData FormOID="VSFORM">
  <ItemGroupData ItemGroupOID="VS">
    <ItemData ItemOID="VSDTC" Value="1999-11-14"/>
1475     <ItemData ItemOID="VSTEST" Value="Body height"/>
    <ItemData ItemOID="VSORRES" Value="177"/>
    <ItemData ItemOID="VSORRESU" Value="cm"/>
    <ItemData ItemOID="VSTEST" Value="Body weight"/>
    <ItemData ItemOID="VSORRES" Value="86"/>
1480     <ItemData ItemOID="VSORRESU" Value="kg"/>
    <ItemData ItemOID="VSTEST" Value="Systolic BP"/>
    <ItemData ItemOID="VSORRES" Value="132"/>
    <ItemData ItemOID="VSORRESU" Value="mm[Hg]"/>
    <ItemData ItemOID="VSTEST" Value="Diastolic BP"/>
    <ItemData ItemOID="VSORRES" Value="86"/>
1485     <ItemData ItemOID="VSORRESU" Value="mm[Hg]"/>
  </ItemGroupData>
  <ItemGroupData ItemGroupOID="VS">
    <ItemData ItemOID="VSDTC" Value="2000-04-07"/>
1490     <ItemData ItemOID="VSTEST" Value="Body height"/>
    <ItemData ItemOID="VSORRES" Value="177"/>
    <ItemData ItemOID="VSORRESU" Value="cm"/>
    <ItemData ItemOID="VSTEST" Value="Body weight"/>
    <ItemData ItemOID="VSORRES" Value="88"/>
1495     <ItemData ItemOID="VSORRESU" Value="kg"/>
    <ItemData ItemOID="VSTEST" Value="Systolic BP"/>
    <ItemData ItemOID="VSORRES" Value="145"/>
    <ItemData ItemOID="VSORRESU" Value="mm[Hg]"/>
    <ItemData ItemOID="VSTEST" Value="Diastolic BP"/>
    <ItemData ItemOID="VSORRES" Value="88"/>
1500     <ItemData ItemOID="VSORRESU" Value="mm[Hg]"/>
  </ItemGroupData>
</FormData>
<FormData FormOID="AEForm">
  <ItemGroupData ItemGroupOID="AE">
1505     <ItemData ItemOID="AETERM" Value="Penicillin"/>
  </ItemGroupData>
  <ItemGroupData ItemGroupOID="AE">
    <ItemData ItemOID="AETERM" Value="Aspirin"/>
  </ItemGroupData>
1510  <ItemGroupData ItemGroupOID="AE">
    <ItemData ItemOID="AETERM" Value="Codeine"/>
  </ItemGroupData>
</FormData>
</StudyEventData>
1515 </SubjectData>
</ClinicalData>
</ODM>
```

Volume 4 – National Extensions

1520 Not applicable