Integrating the Healthcare Enterprise

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IHE Quality, Research and Public Health (QRPH)

10
Technical Framework Supplement

Clinical Research Document (CRD)

15

Trial Implementation

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Foreword

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

This supplement is submitted for Trial Implementation as of August 30, 2010 and will 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 forthcoming Quality, Research, and Public Health Technical Framework. Comments are invited and may be submitted on the IHE forums at http://forums.rsna.org/forumdisplay.php?f=371 or by email to qrph@ihe.net.

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

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

Replace Section X.X by the following:

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

Information about IHE Quality, Research, and Public Health can be found at: http://www.ihe.net/Domains/index.cfm

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

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

Contents

80 **Introduction**

Forthcoming.

Profile Abstract

The Clinical Research Document Profile (CRD) describes the content and format to be used within the Retrieve Form Request described within the RFD Integration Profile and an additional
85 Archive CRD Data transaction that reuses the Provide and Register Set transaction with Web-Services as transport described within the IHE ITI XDR Integration Profile (for cross-enterprise document reliable interchange). The purpose of this profile is to support a standard set of pre-population and workflow data in which the Form Filler provides for use in Clinical Research. This profile also extends the Form Filler's capability and provides for an additional Archive
90 CRD Data transaction for the pre-population and workflow data.

Volume 1 – Integration Profiles

1 Clinical Research Document (CRD)

1.1 Dependencies

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

1.2 Profile Name

The Clinical Research Document Profile (CRD) describes the content and format to be used within the Retrieve Form Request [ITI-34] and an additional Archive CRD Data transaction which reuses the Provide and Register Set transaction [ITI-41] with Web-Services as transport described within the IHE ITI XDR Integration Profile (for cross-enterprise document reliable interchange). The purpose of this profile is to support a standard set of pre-population and workflow data in which the Form Filler provides for use in Clinical Research. This profile also extends the Form Filler's capability and provides for an additional Archive CRD Data transaction for the pre-population and workflow data.

1.3 Use Case

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

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

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satisfactorily and the site is selected for the trial, the financial aspects are addressed and the site then sends the required regulatory documentation to the Sponsor. The Sponsor then provides Protocol-specific training to the Physician Investigator and other study personnel.

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

135   Patricia, under the supervision of the Investigator contacts Corey Jones, a patient at Holbin, about participating in the trial, and Corey agrees to participate as a subject. Patricia registers Corey in the EHR as a subject in trial #1234, using the EHR's patient index. She schedules Corey's study visits using the EHR scheduling module, and flags the visits as pertaining to the trial #1234. After the set-up stage, the site initiates clinical trial care and trial-specific
140   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.

1.4 Current State

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

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

In addition to trial #1234, Bob performs data entry on eight additional EDC systems, five on
165   dedicated laptops and three that are web-based. The web-based EDC systems save on table

space, but still require entries in the three ring binders where Bob puts his 'crib sheets'. It is a chore to make sure that data from a particular trial gets entered into the corresponding laptop with its unique login ritual and data capture form, so Bob experiences much frustration in dealing with this unwieldy set of systems. Bob is a conscientious employee, and stays current in his

170   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.

1.5 Desired State

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

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

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

200   ## 1.6 Actors/Transaction

This content profile addresses the Retrieve Form [ITI-34] transaction with the pre-population and workflow argument between the two actors, Form Filler and Form Manager. This profile also extends the Form Filler's capability and provides for an additional Archive CRD Data transaction which reuses the Provide and Register Set transaction [ITI-41]. The RFD Integration

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205   profile embodies the Form Filler Actor, Form Manager Actor, and the Form Archiver Actor as well as the Retrieve Form [ITI-34]. The IHE ITI XDR Integration Profile describes the Provide and Register Set transaction [ITI-41]. The sharing of content or updates from one actor to the other is addressed by the use of appropriate IHE profiles the Retrieve Form for Data Capture (RFD) supplement is described by the 2007-2008 Trial Implementation Supplements to ITI-TF v. 4.0

210   and the Provide and Register Set transaction is described by the ITI TF-2:3.41.
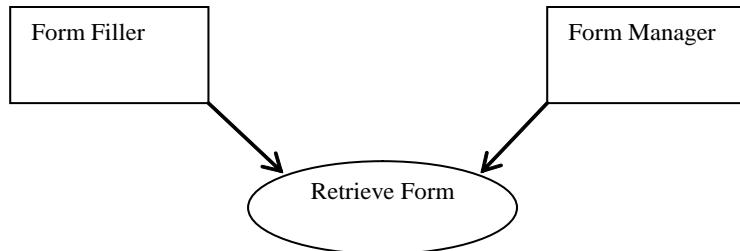

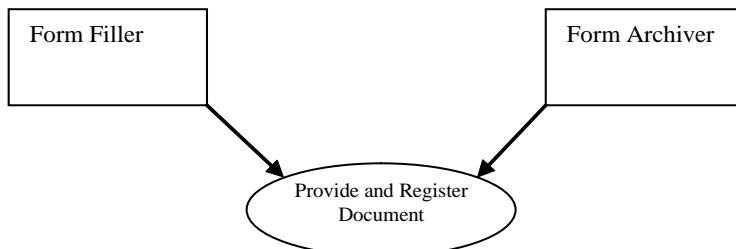**Figure 1.6-1: Clinical Research Document Retrieve Form Actor Diagram**

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Figure 1.6-2: Clinical Research Document Archive CRD Data Actor Diagram

1.7 Grouping

For more details on these profiles, see the IHE IT Infrastructure Technical Framework. Content

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

1.7.1 Content Bindings with RFD

The Retrieve Form for Data Capture Profile (RFD) provides a method for gathering data within a user's current application to meet the requirements of an external system. RFD supports the

225   retrieval of forms by a form source, display and completion of a form, and return of instance data from the display application to the source application.

1.7.2 Content Bindings with XDR

The cross-enterprise document reliable interchange (XDR) Integration Profile provides a mechanism by which a document source can provide and register a document with a document

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230   recipient. In this profile, the Form Filler shall be grouped with the XDR Document Source and the Form Archiver shall be grouped with the XDR Document Recipient.

1.7.3 Options

Options that may be selected for this Profile are listed in the table 1.7.3-1 along with the Actors
235   to which they apply.

Table 1.7.3-1 Actors and Options

Actor	Options
Form Filler	Pre-population
	Archive CRD
Form Manager	Pre-population
Form Archiver	Archive CRD

Note [1]: The Archive CRD option for the Form Filler is dependent on the Pre-population option. Thus a Form Filler may choose to only adhere to the pre-population option, but if the Archive CRD option is selected the Form Filler must also comply with the Pre-population option.

240   ### 1.7.4 Form Archiver Options

1.7.4.1 Archive CRD Option

In this option the Form Archiver offers the ability to receive and process both the pre-population and workflow data further constrained in volume 2 of this profile, using a HTTP web-service based on the Provide and Register Document [ITI-41] transaction. This pre-population and
245   workflow data shall be constructed as content for this Provide and Register Document in the same structure as the pre-population and workflow data in the Retrieve Form [ITI-34] transaction. In addition the document metadata shall conform to the same set of requirements as outlined in Vol. 3 (ITI TF-3): Section 4 Cross-Transaction Specifications. The Form Archiver mirrors the role of the Document Recipient.

250   ### 1.7.5 Form Filler Options

1.7.5.1 Pre-population Option

This option defines that the Form Filler can produce a standard set of pre-population and workflow data as content for the Retrieve Form Request [ITI-34] transaction as defined in RFD. This standard set of data will be further constrained in volume 2 of this profile.

255   #### 1.7.5.2 Archive CRD Option

In this option the Form Filler offers the ability to submit both the pre-population and workflow data further constrained in volume 2 of this profile, using a HTTP web-service based on the Provide and Register Document [ITI-41] transaction. This pre-population and workflow data shall

260 be constructed as content for this Provide and Register Document in the same structure as the pre-population and workflow data in the Retrieve Form [ITI-34] transaction. In addition the document metadata shall conform to the same set of requirements as outlined in Vol. 3 (ITI TF-3): Section 4 Cross-Transaction Specifications. The Form Filler mirrors the role of the Document Source.

1.7.6 Form Manager Options

1.7.6.1 Pre-population Option

265 This option defines that the Form Manager can receive a standard set of pre-population and workflow data as content for Retrieve Form Request [ITI-34] transaction as defined in RFD. This standard set of data will be further constrained in volume 2 of this profile.
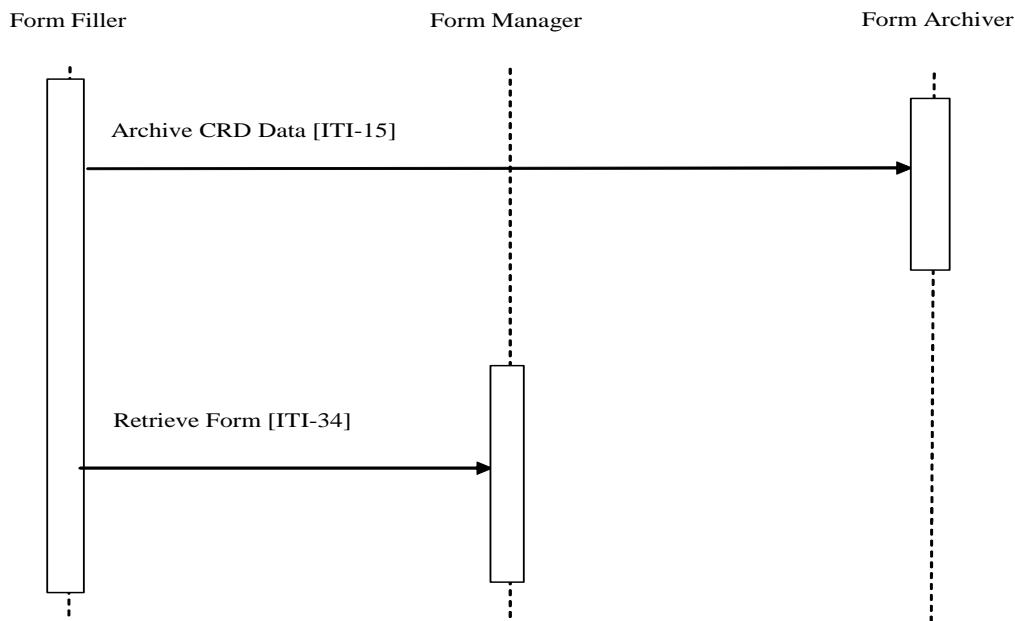
1.7.7 Process Flow

Figure 1.7.7-1 Clinical Research Document Process Flow

In this Process Flow, the Form Filler knows which form it wants to retrieve from the Form Manager. The Form Filler wants to send pre-population and workflow data for this form. In 275 addition the Form Filler wants to archive the pre-population and workflow data.

The CRD Profile requires that this pre-population and workflow data conform to the xml data constrained in volume 2 of this profile. The Archive CRD Option requires the Form Filler to submit the CRD and the Form Archiver to accept the CRD. The Archive CRD transaction if selected must be completed first in order to provide the Form Manager with the context id related

280   to the archived CRD (volume 2 of this profile provides the description of where this id will be introduced). The Pre-population Option requires the Form Filler to submit the CRD and the Form Manager to accept the CRD.

1.7.8 Actor Definitions

The actors described below are directly referenced from the RFD profile for more details on
285   these actors, see the IHE IT Infrastructure Technical Framework.

1.7.8.1 Form Archiver

The Form Archiver actor receives completed or partially completed forms instance data and stores these for archival purposes. This profile optionally extends the role of the Form Archiver actor as described in RFD and requires it to take on the qualities of a Document Recipient.

290   #### 1.7.8.2 Form Manager

The Form Manager supplies forms to Form Fillers based upon form retrieval requests. In some cases, the Form Manager may simply return a form from a store of forms, whereas in other cases the returned form may be selected or even constructed based upon context information supplied in the form retrieval request.

295   #### 1.7.8.3 Form Filler

The Form Filler actor retrieves forms from a Form Manager as and when required. When requesting a form, the Form Filler actor can optionally provide context information by providing pre-population xml data in the request for use by the Form Manager, as well as workflow data that may be used to facilitate form selection. This profile optionally extends the role of the Form
300   Filler actor as described in RFD and requires it to take on the qualities of a Document Source.

1.7.9 Transaction Definitions

The Retrieve Form transaction and the Provide and Register transaction described below are directly referenced from ITI-34 and ITI-41 respectfully from the IHE IT Infrastructure Technical Framework.

305   #### 1.7.9.1 Archive CRD Data

The Archive CRD Data reuses the Provide and Register transaction. The Provide and Register is used by the Document Source to provide a set of documents to the Document Repository or to Document Recipient(s), and to request that the repository store these documents and then register them with the Document Registry.

310   The Provide and Register Document Set transaction describes only the interaction between the Document Source and Document Repository or Document Recipient actors.

1.7.9.2 Retrieve Form [ITI-34]

The Retrieve Form transaction carries the form identifier from a Form Filler to a Form Manager. Additional data containing context information as well as workflow information may be supplied with the request to facilitate the selection and pre-population of the requested form. The value of the assigned form identifier determines the format of the form. Assignment of form identifiers is not profiled and is assumed to take place as a part of the setup configuration process necessary between Form Fillers and Form Managers.

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Glossary

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

CDASH – Clinical Data Acquisition Standards Harmonization (CDASH)

Context Data – The xml specifics of workflow context.

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

Pre-population Data– The xml context information supplied by a Form Filler for use in pre-populating form fields.

RFD – [ITI TF-1:17] Retrieve Form for Data Capture Profile (RFD)

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

Workflow Data – The xml representation of workflow specific values.

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

Volume 2 - Transactions

1.8 Clinical Research Document Content

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It is noted that the implementers of the Form Filler and Form Manager actors may agree to redact certain data from the pre-population and workflow data described below (i.e., time ranges, number of results, volume of data, or type of results) to comply with practical, confidentiality, and consent restraints at time of implementation.

340

While the following sections describe separately the requirements for pre-population and workflow data, these sections are considered to be one content profile and thus are not optionally sent independent of the other. The Retrieve Form and Document Archive transactions shall contain both pre-population and workflow data that is compliant with the following sections.

1.8.1 Pre-population Data

345 This section corresponds to the pre-population data sent via the Retrieve Form [ITI-34] transaction or the Archive CRD Data transaction.

1.8.1.1 Scope

This CCD content corresponds to the constrained set of pre-population data necessary to claim conformance to CRD.

1.8.1.2 Referenced Standards

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

CDASH – Clinical Data Acquisition Standards Harmonization (Draft)

XML – Extensible Markup Language (XML) 1.0 (Second Edition). W3C Recommendation 6 October 2000.

1.8.1.3 Data Element Reference

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CDASH describes recommended (minimal) data collection sets for all therapeutic areas and types of clinical research. CDASH has defined domains and elements within these domains. The pre-population data described below references the CDASH specification in these domains. This Data Element Reference describes which CRD sections map to which CDASH domains.

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Table 1.8.1.3-1 Clinical Research Document Pre-population Data Elements

CDASH Domains	CRD Reference
Demography	Header Information
Medical History	Active Problems, Past Medical History, and Procedures and Interventions

CDASH Domains	CRD Reference
Concomitant Medication	Current Medications
Substance Use	Social History
Vital Signs	Vital Signs
Physical Exam	Physical Exam
Adverse Events	Allergies and Other Adverse Reactions
Lab Test Results	Coded Results
ECG Test Results	Coded Results

1.8.1.4 Data Element Index

Many of the template identifiers defined or referenced below are detailed in the IHE PCC Technical Framework. For more details on these template identifiers, see the IHE Patient Care Coordination Technical Framework.

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Table 1.8.1.4-1 Clinical Research Document Pre-population Constraints

Data Element	Optionality	PCC: Template Identifiers
Date of Birth	R	patientRole/patient/birthTime
Gender	R	patientRole/patient/administrativeGenderCode
Ethnicity	O	patientRole/patient/ethnicGroupCode
Race	R2	patientRole/patient/raceCode
Active Problems	R	1.3.6.1.4.1.19376.1.5.3.1.3.6
Past Medical History	R2	1.3.6.1.4.1.19376.1.5.3.1.3.8
Procedures and Interventions	R2	1.3.6.1.4.1.19376.1.5.3.1.1.13.2.11
Social History	R2	1.3.6.1.4.1.19376.1.5.3.1.3.16
Current Medications	R	1.3.6.1.4.1.19376.1.5.3.1.3.19
Vital Signs	R2	1.3.6.1.4.1.19376.1.5.3.1.1.5.3.2
Physical Exam	R2	1.3.6.1.4.1.19376.1.5.3.1.1.9.15
Allergies and Other Adverse Reactions	R	1.3.6.1.4.1.19376.1.5.3.1.3.13
Coded Results	R2	1.3.6.1.4.1.19376.1.5.3.1.3.28

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

1.8.1.5 Header Sample

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

```
     <recordTarget>
375    <patientRole classCode="PAT">
         <id root="27143B24-E580-4F47-9405-3D0DC2BF1223" extension="1022"/>
         <addr>
           <streetAddressLine/>
           <city/>
380        <state>FM</state>
           <postalCode/>
           <country>Canada</country>
         </addr>
         <telecom nullFlavor="UNK" use="HP"/>
385      <patient classCode="PSN" determinerCode="INSTANCE">
           <name>
             <prefix/>
             <given>Christine</given>
             <family>Smith</family>
390          <suffix/>
           </name>
           <ethnicGroupCode code="364699009" displayName="ethnic group"
             codeSystem="2.16.840.1.113883.6.96" codeSystemName="SNOMED CT"/>
           <administrativeGenderCode code="F"
395 codeSystem="2.16.840.1.113883.5.1"/>
           <birthTime value="20040725"/>
           <raceCode code="2106-3" codeSystem="2.16.840.1.113883.5.104"/>
         </patient>
         <providerOrganization classCode="ORG" determinerCode="INSTANCE">
400        <id root="2.16.840.1.113883.19.5"/>
         </providerOrganization>
       </patientRole>
     </recordTarget>
```

1.8.1.6 Active Problems Sample (1.3.6.1.4.1.19376.1.5.3.1.3.6)

```
405 <component>
     <section>
       <templateId root='2.16.840.1.113883.10.20.1.11'/>
       <templateId root='1.3.6.1.4.1.19376.1.5.3.1.3.6'/>
       <id root=' ' extension=' '/>
410    <code code='11450-4' displayName='PROBLEM LIST'
         codeSystem='2.16.840.1.113883.6.1' codeSystemName='LOINC'/>
       <text>
         Text as described above
       </text>
415    <entry>
             :
         <!-- Required Problem Concern Entry element -->
```

```
            <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.5.2'/>
               :
420        </entry>

        </section>
    </component>
```

1.8.1.7 Past Medical History Sample (1.3.6.1.4.1.19376.1.5.3.1.3.8)

```
425  <component>
       <section>
         <templateId root='1.3.6.1.4.1.19376.1.5.3.1.3.8'/>
         <id root=' ' extension=' '/>
         <code code='11348-0' displayName='HISTORY OF PAST ILLNESS'
430        codeSystem='2.16.840.1.113883.6.1' codeSystemName='LOINC'/>
         <text>
           Text as described above
         </text>
         <entry>
435          :
           <!-- Required Problem Concern Entry element -->
             <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.5.2'/>
               :
         </entry>
440
       </section>
    </component>
```

1.8.1.8 Procedures and Interventions Sample (1.3.6.1.4.1.19376.1.5.3.1.1.13.2.11)

```
    <component>
445    <section>
         <templateId root='1.3.6.1.4.1.19376.1.5.3.1.1.13.2.11'/>
         <id root=' ' extension=' '/>
         <code code='X-PROC' displayName='PROCEDURES PERFORMED'
           codeSystem='2.16.840.1.113883.6.1' codeSystemName='LOINC'/>
450      <text>
           Text as described above
         </text>
         <entry>
           Required and optional entries as described above
455      </entry>

       </section>
    </component>
```

1.8.1.9 Social History Sample (1.3.6.1.4.1.19376.1.5.3.1.3.16)

```
460  <component>
       <section>
         <templateId root='2.16.840.1.113883.10.20.1.15'/>
         <templateId root='1.3.6.1.4.1.19376.1.5.3.1.3.16'/>
         <id root=' ' extension=' '/>
465      <code code='29762-2' displayName='SOCIAL HISTORY'
```

17

```
          codeSystem='2.16.840.1.113883.6.1' codeSystemName='LOINC'/>
        <text>
          Text as described above
        </text>
470
    </section>
</component>
```

1.8.1.10 Current Medications Sample (1.3.6.1.4.1.19376.1.5.3.1.3.19)

```
<component>
475   <section>    <templateId root='2.16.840.1.113883.10.20.1.8'/>
        <templateId root='1.3.6.1.4.1.19376.1.5.3.1.3.19'/>
        <id root=' ' extension=' '/>
        <code code='10160-0' displayName='HISTORY OF MEDICATION USE'
          codeSystem='2.16.840.1.113883.6.1' codeSystemName='LOINC'/>
480   <text>
          Text as described above
        </text>
        <entry>
          :
485     <!-- Required Medications element -->
          <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.7'/>
          :
        </entry>

490   </section>
</component>
```

1.8.1.11 Vital Signs Sample (1.3.6.1.4.1.19376.1.5.3.1.1.5.3.2)

```
<component>
   <section>
495   <templateId root='1.3.6.1.4.1.19376.1.5.3.1.3.25'/>
        <templateId root='1.3.6.1.4.1.19376.1.5.3.1.1.5.3.2'/>
        <id root=' ' extension=' '/>
        <code code='8716-3' displayName='VITAL SIGNS'
          codeSystem='2.16.840.1.113883.6.1' codeSystemName='LOINC'/>
500   <text>
          Text as described above
        </text>
        <entry>
          :
505     <!-- Required Vital Signs Organizer element -->
          <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.13.1'/>
          :
        </entry>

510   </section>
</component>
```

1.8.1.12 Physical Exam Sample (1.3.6.1.4.1.19376.1.5.3.1.1.9.15)

```
<component>
```

```
      <section>
515     <templateId root='1.3.6.1.4.1.19376.1.5.3.1.3.24'/>
        <templateId root='1.3.6.1.4.1.19376.1.5.3.1.1.9.15'/>
        <id root=' ' extension=' '/>
        <code code='29545-1' displayName='PHYSICAL EXAMINATION'
          codeSystem='2.16.840.1.113883.6.1' codeSystemName='LOINC'/>
520     <text>
          Text as described above
        </text>
        <component>
          <section>
525         <templateId root='1.3.6.1.4.1.19376.1.5.3.1.3.25'/>
            <!-- Optional Vital Signs Section content -->
          </section>
        </component>
        <component>
530       <section>
            <templateId root='1.3.6.1.4.1.19376.1.5.3.1.1.9.16'/>
            <!-- Optional General Appearance Section content -->
          </section>
        </component>
535     <component>
          <section>
            <templateId root='1.3.6.1.4.1.19376.1.5.3.1.1.9.48'/>
            <!-- Optional Visible Implanted Medical Devices Section content -->
          </section>
540     </component>
        <component>
          <section>
            <templateId root='1.3.6.1.4.1.19376.1.5.3.1.1.9.17'/>
            <!-- Optional Integumentary System Section content -->
545       </section>
        </component>
        <component>
          <section>
            <templateId root='1.3.6.1.4.1.19376.1.5.3.1.1.9.18'/>
550         <!-- Optional Head Section content -->
          </section>
        </component>
        <component>
          <section>
555         <templateId root='1.3.6.1.4.1.19376.1.5.3.1.1.9.19'/>
            <!-- Optional Eyes Section content -->
          </section>
        </component>
        <component>
560       <section>
            <templateId root='1.3.6.1.4.1.19376.1.5.3.1.1.9.20'/>
            <!-- Optional Ears, Nose, Mouth and Throat Section content -->
          </section>
        </component>
565     <component>
```

```
          <section>
            <templateId root='1.3.6.1.4.1.19376.1.5.3.1.1.9.21'/>
            <!-- Optional Ears Section content -->
          </section>
570     </component>
        <component>
          <section>
            <templateId root='1.3.6.1.4.1.19376.1.5.3.1.1.9.22'/>
            <!-- Optional Nose Section content -->
575       </section>
        </component>
        <component>
          <section>
            <templateId root='1.3.6.1.4.1.19376.1.5.3.1.1.9.23'/>
580         <!-- Optional Mouth, Throat, and Teeth Section content -->
          </section>
        </component>
        <component>
          <section>
585         <templateId root='1.3.6.1.4.1.19376.1.5.3.1.1.9.24'/>
            <!-- Optional Neck Section content -->
          </section>
        </component>
        <component>
590       <section>
            <templateId root='1.3.6.1.4.1.19376.1.5.3.1.1.9.25'/>
            <!-- Optional Endocrine System Section content -->
          </section>
        </component>
595     <component>
          <section>
            <templateId root='1.3.6.1.4.1.19376.1.5.3.1.1.9.26'/>
            <!-- Optional Thorax and Lungs Section content -->
          </section>
600     </component>
        <component>
          <section>
            <templateId root='1.3.6.1.4.1.19376.1.5.3.1.1.9.27'/>
            <!-- Optional Chest Wall Section content -->
605       </section>
        </component>
        <component>
          <section>
            <templateId root='1.3.6.1.4.1.19376.1.5.3.1.1.9.28'/>
610         <!-- Optional Breasts Section content -->
          </section>
        </component>
        <component>
          <section>
615         <templateId root='1.3.6.1.4.1.19376.1.5.3.1.1.9.29'/>
            <!-- Optional Heart Section content -->
          </section>
```

```
        </component>
        <component>
620       <section>
            <templateId root='1.3.6.1.4.1.19376.1.5.3.1.1.9.30'/>
            <!-- Optional Respiratory System Section content -->
          </section>
        </component>
625     <component>
          <section>
            <templateId root='1.3.6.1.4.1.19376.1.5.3.1.1.9.31'/>
            <!-- Optional Abdomen Section content -->
          </section>
630     </component>
        <component>
          <section>
            <templateId root='1.3.6.1.4.1.19376.1.5.3.1.1.9.32'/>
            <!-- Optional Lymphatic System Section content -->
635       </section>
        </component>
        <component>
          <section>
            <templateId root='1.3.6.1.4.1.19376.1.5.3.1.1.9.34'/>
640         <!-- Optional Musculoskeletal System Section content -->
          </section>
        </component>
        <component>
          <section>
645         <templateId root='1.3.6.1.4.1.19376.1.5.3.1.1.9.35'/>
            <!-- Optional Neurologic System Section content -->
          </section>
        </component>
        <component>
650       <section>
            <templateId root='1.3.6.1.4.1.19376.1.5.3.1.1.9.36'/>
            <!-- Optional Genitalia Section content -->
          </section>
        </component>
655     <component>
          <section>
            <templateId root='1.3.6.1.4.1.19376.1.5.3.1.1.9.37'/>
            <!-- Optional Rectum Section content -->
          </section>
660     </component>

      </section>
    </component>
```

1.8.1.13 Allergies and Other Adverse Reactions Sample (1.3.6.1.4.1.19376.1.5.3.1.3.13)

```
<component>
  <section>
```

```
      <templateId root='2.16.840.1.113883.10.20.1.2'/>
      <templateId root='1.3.6.1.4.1.19376.1.5.3.1.3.13'/>
670   <id root=' ' extension=' '/>
      <code code='48765-2' displayName='Allergies, adverse reactions, alerts'
        codeSystem='2.16.840.1.113883.6.1' codeSystemName='LOINC'/>
      <text>
        Text as described above
675   </text>
      <entry>
             :
        <!-- Required Allergies and Intolerances Concern element -->
          <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.5.3'/>
680          :
      </entry>

    </section>
  </component>
```

1.8.1.14 Coded Results Sample ([1.3.6.1.4.1.19376.1.5.3.1.3.28](1.3.6.1.4.1.19376.1.5.3.1.3.28))

685

```
  <component>
    <section>
      <templateId root='1.3.6.1.4.1.19376.1.5.3.1.3.28'/>
      <id root=' ' extension=' '/>
690   <code code='30954-2' displayName='STUDIES SUMMARY'
        codeSystem='2.16.840.1.113883.6.1' codeSystemName='LOINC'/>
      <text>
        Text as described above
      </text>
695   <entry>
             :
        <!-- Required Procedure Entry element -->
          <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.16'/>
             :
700   </entry>
      <entry>
             :
        <!-- Required if known References Entry element -->
          <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.4'/>
705          :
      </entry>

    </section>
  </component>
```

1.8.2 Workflow Data

710

This section corresponds to the workflow data sent via the Retrieve Form [ITI-34] transaction or the Archive CRD Data transaction.

1.8.2.1 Scope

This well-formed xml content corresponds to the constrained set of workflow data necessary to claim conformance to CRD.

1.8.2.2 Referenced Standards

CDASH – Clinical Data Acquisition Standards Harmonization (Draft)

XML – Extensible Markup Language (XML) 1.0 (Second Edition). W3C Recommendation 6 October 2000.

1.8.2.3 Data Element Reference

CDASH describes a set of Common Identifier Variables. The workflow data described below references the CDASH Common Identifier Variables. This Data Element Reference describes the Variables.

Table 1.8.2.3-1 CDASH Common Identifier Variables

Data Collection Field	Definition
Protocol/Study Identifier	Unique Identifier for a study within a submission
Site Identifier Within a Study	Unique identifier for the study site
Subject Identifier	Subject identifier for the study
Unique Subject Identifier	Unique subject identifier within a submission
Investigator Identifier	Investigator identifier
Sponsor-Defined Identifier	Sponsor-defined reference number
Visit	Visit Name / Visit Number
Date of Visit	Date the visit took place
Time of Visit	Time the visit took place

1.8.2.4 Data Element Index

Table 1.8.2.4-1 Clinical Research Document Workflow Data Constraints

Data Element	Optionality	Data Location
formID	R	workflowData/formid
context	R	workflowData/context
instanceID	R	workflowData/instanceID
StudyID	R	workflowData/context/ StudyID
SiteID	R	workflowData/context/ SiteID
SubjID	R	workflowData/context/ SubjID
USubjID	O	workflowData/context/ USubjID
InvID	O	workflowData/context/ InvID

23

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

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

1.8.2.5 Workflow Data Sample

The content of workflowData parameter shall *minimally* be:

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

The content of workflowData parameter shall *optimally* be:

```
750    <workflowData>
       <formID>a String identifying the form</formID>
       <encodedResponse> false</encodedResponse>
       <archiveURL />
755    <instanceID/>
       <context>
       <StudyID> a String identifying the Protocol/Study
       Identifier </ StudyID >
       <SiteID> a String identifying the Site Identifier </ SiteID >
```

```
760   <SubjID> a String identifying the Subject Identifier </ SubjID >
      <USubjID> a String identifying the Unique Subject
       Identifier </ USubjID >
      <InvID> a String identifying the Investigator Identifier </ InvID >
      <SpID> a String identifying the Sponsor-Defined
765   Identifier </ SpID >
      <Visit> a String identifying the Visit Name </ Visit >
      <VisitNum> a String identifying the Visit Number </ VisitNum >
      <VisDatTim>
      <effectiveTime xsi:type='TS'>
770   <low value=' '/>
      <high value=' '/>
      </effectiveTime>
      </ VisDatTim >
      < PrePopArchiveID> a String identifying the Prepopulation Archive
775   XDSDocumentEntry.uniqueId </ PrePopArchiveID>
      </context>
      </workflowData>
```

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

1.8.3 Reference Implementation

1.8.3.1 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 pre-population and workflow data structure into a CDASH compliant ODM
785 structure (Standard CRF). The adopted format for this transformation from one structure to the
other is an XSLT. The intent is to have this XSLT not be presented here within the CRD profile
and remain static, but to further develop and refine this XSLT as supplemental material. The goal
is to allow additional Use Cases to drive different flavors of transformations all of which might
be available to be referenced.

790 ### 1.8.3.2 XSLT Sample

```
<?xml version="1.0" encoding="UTF-8"?>
<!-- mapping CCD to CDASH elements -->
<xsl:stylesheet version="1.0"
xmlns:xsl="http://www.w3.org/1999/XSL/Transform"
795   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">
800   <xsl:output method="xml" version="1.0" encoding="UTF-8" indent="yes" omit-
xml-declaration="no"/>

      <!-- kick off the transformation with this default template -->
      <xsl:template match="cda:ClinicalDocument">
```

```
805     <!--odm:ODM xmlns:ds="http://www.w3.org/2000/09/xmldsig#"
        xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance" ODMVersion="1.3"
        FileOID="CLL.003" PriorFileOID="CRF_CLL_v1.6" FileType="SnapShot"
        Description="IHE CDASH from CCD"-->
          <!-- TODO: add attributes for the following
810         AsOfDateTime="2008-04-28T14:03:56"
            CreationDateTime="2008-04-28T14:03:56"
          -->
         <xsl:element name="ODM" namespace="http://www.cdisc.org/ns/odm/v1.3">
          <xsl:attribute name="AsOfDateTime"><xsl:value-of select="current-
815     dateTime()"/></xsl:attribute>
          <xsl:attribute name="ODMVersion">1.3</xsl:attribute>
          <xsl:attribute name="FileType">Transactional</xsl:attribute>
          <xsl:attribute name="FileOID">TEST</xsl:attribute>
          <xsl:attribute name="CreationDateTime"><xsl:value-of select="current-
820     dateTime()"/></xsl:attribute>
          <!-- ClinicalData element -->
          <xsl:element name="ClinicalData"
        namespace="http://www.cdisc.org/ns/odm/v1.3">
            <xsl:attribute name="StudyOID">CLL.001</xsl:attribute>
825         <xsl:attribute name="MetaDataVersionOID">001</xsl:attribute>
            <!-- SubjectData element -->
            <xsl:element name="SubjectData"
        namespace="http://www.cdisc.org/ns/odm/v1.3">
              <xsl:attribute name="SubjectKey">1038</xsl:attribute>
830           <!-- SiteRef element -->
              <xsl:element name="SiteRef"
        namespace="http://www.cdisc.org/ns/odm/v1.3">
                <xsl:attribute name="LocationOID">100</xsl:attribute>
              </xsl:element>
835           <!-- StudyEventData element -->
              <xsl:element name="StudyEventData"
        namespace="http://www.cdisc.org/ns/odm/v1.3">
                <xsl:attribute name="StudyEventOID">CLL_CRF</xsl:attribute>
              <!-- multiple FormData Elements, representing CDASH Domains -->
840           <!-- demography -->
              <xsl:call-template name="demography"/>
              <!-- medical history -->
              <xsl:call-template name="medicalHistory"/>
              <!-- conMeds -->
845           <xsl:call-template name="conMeds"/>
              <!-- substance use -->
              <xsl:call-template name="substanceAbuse"/>
              <!-- vitals -->
              <xsl:call-template name="vitalSigns"/>
850           <!-- physical exam -->
              <!-- AE -->
              <xsl:call-template name="adverseEvents"/>
              <!-- lab results -->
              <!-- ECG results -->
855           </xsl:element>
            </xsl:element>
```

```
    </xsl:element>
    </xsl:element>
  </xsl:template>
860
  <!-- ODM Templates -->
  <!-- demography -->
  <xsl:template name="demography">
  <!-- get the patient node, from which we can get the sex and date of birth -
865 ->
    <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>
870     <xsl:comment>check on whether or not we can get Ethnicity and
Race</xsl:comment>
      <xsl:element name="ItemGroupData"
namespace="http://www.cdisc.org/ns/odm/v1.3">
        <xsl:attribute name="ItemGroupOID">DM</xsl:attribute>
875       <!-- SEX -->
        <xsl:element name="ItemData"
namespace="http://www.cdisc.org/ns/odm/v1.3">
          <xsl:attribute name="ItemOID">SEX</xsl:attribute>
          <xsl:attribute name="Value"><xsl:value-of
880 select="$patientNode/cda:administrativeGenderCode/@code"/></xsl:attribute>
        </xsl:element>
        <!-- BRTHDTC -->
        <xsl:element name="ItemData"
namespace="http://www.cdisc.org/ns/odm/v1.3">
885       <xsl:attribute name="ItemOID">BRTHDTC</xsl:attribute>
          <!-- transform stupid non-ISO8601-XML date to ISO8601 date -->
          <xsl:variable name="ISODATE">
            <xsl:call-template name="HL7DateToISO8601">
              <xsl:with-param name="HL7Date"
890 select="$patientNode/cda:birthTime/@value"/>
            </xsl:call-template>
          </xsl:variable>
          <xsl:attribute name="Value">
            <xsl:value-of select="$ISODATE"/>
895         <!--xsl:value-of select="$patientNode/cda:birthTime/@value"/-->
          </xsl:attribute>
        </xsl:element>
      </xsl:element>
    </xsl:element>
900 </xsl:template>


<!-- Medical History
  looking for entries in any of the following CDA sections:
905   Conditions
    Past Medical History
    Procedures
-->
```

```
910
      <xsl:template name="medicalHistory">
       <xsl:variable name="ccdConditions"
      select="cda:component/cda:structuredBody/cda:component/cda:section[cda:code/@
      code='11450-4']"/>
       <xsl:variable name="ccdPMH"
      select="cda:component/cda:structuredBody/cda:component/cda:section[cda:code/@
915   code='11348-0']"/>
       <xsl:variable name="ccdProcedures"
      select="cda:component/cda:structuredBody/cda:component/cda:section[cda:code/@
      code='47519-4']"/>
       <xsl:variable name="conditionsCount"
920   select="count($ccdConditions/cda:entry)"/>
       <xsl:variable name="pmhCount" select="count($ccdPMH/cda:entry)"/>
       <xsl:variable name="proceduresCount"
      select="count($ccdProcedures/cda:entry)"/>

925    <!-- if we have any of the above then we output this section, i.e., FormData
      element -->
       <xsl:if test="($conditionsCount+$pmhCount+$proceduresCount)>0">
         <xsl:element name="FormData" namespace="http://www.cdisc.org/ns/odm/v1.3">
          <xsl:attribute name="FormOID">MedicalHistory</xsl:attribute>
930       <!-- just loop thru the entry elements in each of the sections -->
          <!-- NOTE:  we're making up the ItemGroupOID's....these should be
      standardized; it also might be that all med history items should be in one
      ItemGroup -->
          <xsl:for-each select="$ccdConditions/cda:entry">
935        <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>
940        </xsl:element>
          </xsl:for-each>
          <xsl:for-each select="$ccdPMH/cda:entry">
           <xsl:element name="ItemGroupData"
      namespace="http://www.cdisc.org/ns/odm/v1.3">
945         <xsl:attribute name="ItemGroupOID">PASTCONDITION</xsl:attribute>
             <xsl:call-template name="problemItemData"><xsl:with-param
      name="theNode" select="."/></xsl:call-template>
           </xsl:element>
          </xsl:for-each>
950       <xsl:for-each select="$ccdProcedures/cda:entry">
           <xsl:element name="ItemGroupData"
      namespace="http://www.cdisc.org/ns/odm/v1.3">
             <xsl:attribute name="ItemGroupOID">PROCEDURE</xsl:attribute>
             <xsl:call-template name="procedureItemData"><xsl:with-param
955   name="theNode" select="."/></xsl:call-template>
           </xsl:element>
          </xsl:for-each>
         </xsl:element>
        </xsl:if>
960   </xsl:template>
```

```
<!-- CON MEDS -->
<xsl:template name="conMeds">
 <xsl:variable name="ccdMedication"
select="cda:component/cda:structuredBody/cda:component/cda:section[cda:code/@
code='10160-0']"/>
 <xsl:variable name="conMedCount" select="count($ccdMedication/cda:entry)"/>
 <xsl:if test="$conMedCount>0">
  <!--FormData FormDataOID='ConMedForm'-->
  <xsl:element name="FormData" namespace="http://www.cdisc.org/ns/odm/v1.3">
   <xsl:attribute name="FormOID">ConMedForm</xsl:attribute>
   <xsl:for-each select="$ccdMedication/cda:entry">
   <!-- we may be pointed to the text of the med, or we may just have the
text-->
   <xsl:variable name="originalTextRef"
select="cda:substanceAdministration/cda:consumable/cda:manufacturedProduct/cd
a:manufacturedMaterial/cda:code/cda:originalText/cda:reference/@value"/>
   <xsl:variable name="originalText"
select="cda:substanceAdministration/cda:consumable/cda:manufacturedProduct/cd
a:manufacturedMaterial/cda:code/cda:originalText"/>
   <!--ItemGroupData ItemGroupOID='CM'-->
   <xsl:element name="ItemGroupData"
namespace="http://www.cdisc.org/ns/odm/v1.3">
    <xsl:attribute name="ItemGroupOID">CM</xsl:attribute>
    <!-- CMTRT -->
    <!--ItemData ItemDataOID='CMTRT'-->
    <xsl:element name="ItemData"
namespace="http://www.cdisc.org/ns/odm/v1.3">
     <xsl:attribute name="ItemOID">CMTRT</xsl:attribute>
     <xsl:attribute name="Value">
      <xsl:choose>
       <xsl:when test="$originalTextRef"><xsl:value-of
select="//*[@ID=substring-after($originalTextRef,'#')]"/></xsl:when>
       <xsl:otherwise><xsl:value-of
select="$originalText"/></xsl:otherwise>
      </xsl:choose>
     </xsl:attribute>
    </xsl:element>
    <!-- CMDOSFREQ -->
    <xsl:comment>need table to translate HL7 frequency, e.g., 6h to
BID</xsl:comment>
    <!-- CMROUTE -->
    <xsl:variable name="routeCode"
select="cda:substanceAdministration/cda:routeCode/@displayName"/>
    <xsl:if test="$routeCode">
     <!--ItemData ItemDataOID='CMROUTE'-->
     <xsl:element name="ItemData"
namespace="http://www.cdisc.org/ns/odm/v1.3">
      <xsl:attribute name="ItemOID">CMROUTE</xsl:attribute>
      <xsl:attribute name="Value"><xsl:value-of
select="$routeCode"/></xsl:attribute>
```

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```
        </xsl:element><!--/ItemData-->
        </xsl:if>
1015    <!-- CMSTDTC -->
        <xsl:variable name="medStartDate"
select="cda:substanceAdministration/cda:effectiveTime[@xsi:type='IVL_TS']/cda
:low/@value"/>
        <xsl:if test="$medStartDate">
1020     <!--ItemData ItemDataOID='CMSTDTC'-->
         <xsl:element name="ItemData"
namespace="http://www.cdisc.org/ns/odm/v1.3">
           <!-- transform stupid non-ISO8601-XML date to ISO8601 date -->
           <xsl:variable name="ISODATE">
1025        <xsl:call-template name="HL7DateToISO8601">
             <xsl:with-param name="HL7Date" select="$medStartDate"/>
            </xsl:call-template>
           </xsl:variable>
           <xsl:attribute name="ItemOID">CMSTDTC</xsl:attribute>
1030       <!--xsl:attribute name="Value"><xsl:value-of
select="$medStartDate"/></xsl:attribute-->
           <xsl:attribute name="Value"><xsl:value-of
select="$ISODATE"/></xsl:attribute>
         </xsl:element><!--/ItemData-->
1035    </xsl:if>
        <!-- CMENDTC -->
        <xsl:variable name="medEndDate"
select="cda:substanceAdministration/cda:effectiveTime[@xsi:type='IVL_TS']/cda
:high/@value"/>
1040    <xsl:if test="$medEndDate">
         <!--ItemData ItemDataOID='CMENDDTC'-->
         <xsl:element name="ItemData"
namespace="http://www.cdisc.org/ns/odm/v1.3">
           <xsl:attribute name="ItemOID">CMENDDTC</xsl:attribute>
1045       <!-- transform stupid non-ISO8601-XML date to ISO8601 date -->
           <xsl:variable name="ISODATE">
             <xsl:call-template name="HL7DateToISO8601">
               <xsl:with-param name="HL7Date" select="$medEndDate"/>
             </xsl:call-template>
1050       </xsl:variable>
           <!--xsl:attribute name="Value"><xsl:value-of
select="$medEndDate"/></xsl:attribute-->
           <xsl:attribute name="Value"><xsl:value-of
select="$ISODATE"/></xsl:attribute>
1055      </xsl:element><!--/ItemData-->
        </xsl:if>
      </xsl:element>
      <!--/ItemGroupData-->
    </xsl:for-each>
1060    </xsl:element>
  </xsl:if>
</xsl:template>

<!-- SUBSTANCE ABUSE -->
```

```
1065   <xsl:template name="substanceAbuse">
         <!-- we could look into the social history for any of a specific list of
       substance abuse entries...if any are present then we emit the section -->
         <!-- however, there are probably too many codes to consider....just quickly
       looking we see several SNOMED codes for smoking, cigarette smoking, .... -->
1070   </xsl:template>


       <!-- Vital Signs -->
       <xsl:template name="vitalSigns">
1075   <!-- 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']"/>
1080   <xsl:if test="$vitalsSection/cda:entry/cda:organizer">
         <!--FormData FormDataOID='VSForm'-->
         <xsl:element name="FormData" namespace="http://www.cdisc.org/ns/odm/v1.3">
           <xsl:attribute name="FormOID">VSFORM</xsl:attribute>
           <!-- for each organizer -->
1085       <xsl:for-each select="$vitalsSection/cda:entry/cda:organizer">
             <!-- at the organizer level we have the date (and maybe the time) -->
             <xsl:variable name="vitalsDateTime" select="cda:effectiveTime/@value"/>
             <!--ItemGroupData ItemGroupDataOID='VS'-->
             <xsl:element name="ItemGroupData"
1090   namespace="http://www.cdisc.org/ns/odm/v1.3">
               <xsl:attribute name="ItemGroupOID">VS</xsl:attribute>
               <!-- VSDTC -->
               <!--ItemData ItemDataOID='VSDTC'-->
               <xsl:element name="ItemData"
1095   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="$vitalsDateTime"/>
1100               </xsl:call-template>
                 </xsl:variable>
                 <xsl:attribute name="ItemOID">VSDTC</xsl:attribute>
                 <!--xsl:attribute name="Value"><xsl:value-of
       select="$vitalsDateTime"/></xsl:attribute-->
1105             <xsl:attribute name="Value"><xsl:value-of
       select="$ISODATE"/></xsl:attribute>
               </xsl:element><!--/ItemData-->
             <!-- now go get all of the components from this recording -->
             <xsl:for-each select="cda:component">
1110           <xsl:variable name="vitalsResultNode"
       select="cda:observation/cda:value"/>
               <!-- VSTEST -->
               <!--ItemData ItemDataOID='VSTEST'-->
               <xsl:element name="ItemData"
1115   namespace="http://www.cdisc.org/ns/odm/v1.3">
                 <xsl:attribute name="ItemOID">VSTEST</xsl:attribute>
```

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```
                <xsl:attribute name="Value"><xsl:value-of
        select="cda:observation/cda:code/@displayName"/></xsl:attribute>
            </xsl:element>
1120          <xsl:choose>
              <xsl:when test="$vitalsResultNode/@xsi:type='PQ'">
              <!-- VSORRES -->
                <!--ItemData ItemDataOID='VSORRES'-->
                <xsl:element name="ItemData"
1125    namespace="http://www.cdisc.org/ns/odm/v1.3">
                    <xsl:attribute name="ItemOID">VSORRES</xsl:attribute>
                    <xsl:attribute name="Value"><xsl:value-of
        select="$vitalsResultNode/@value"/></xsl:attribute>
                </xsl:element><!--/ItemData-->
1130            <!-- VSORRESU -->
                <!--ItemData ItemDataOID='VSORRESU'-->
                <xsl:element name="ItemData"
        namespace="http://www.cdisc.org/ns/odm/v1.3">
                    <xsl:attribute name="ItemOID">VSORRESU</xsl:attribute>
1135            <xsl:attribute name="Value"><xsl:value-of
        select="$vitalsResultNode/@unit"/></xsl:attribute>
                </xsl:element><!--/ItemData-->
              </xsl:when>
              <xsl:otherwise>
1140            <!-- VSORRES ...no units -->
                <!--ItemData ItemDataOID='VSORRES'-->
                <xsl:element name="ItemData"
        namespace="http://www.cdisc.org/ns/odm/v1.3">
                    <xsl:attribute name="ItemOID">VSORRES</xsl:attribute>
1145            <xsl:attribute name="Value"><xsl:value-of
        select="$vitalsResultNode"/></xsl:attribute>
                </xsl:element><!--/ItemData-->
              </xsl:otherwise>
            </xsl:choose>
1150      </xsl:for-each>
        </xsl:element><!--/ItemGroupData-->
      </xsl:for-each>
    </xsl:element><!--/FormData-->
  </xsl:if>
1155  </xsl:template>

      <!-- AE -->
      <xsl:template name="adverseEvents">
      <xsl:variable name="aeSection"
1160  select="cda:component/cda:structuredBody/cda:component/cda:section[cda:code/@
      code='48765-2']"/>
      <xsl:if test="$aeSection/cda:entry/cda:act">
        <!--FormData FormDataOID='AEForm'-->
        <xsl:element name="FormData" namespace="http://www.cdisc.org/ns/odm/v1.3">
1165      <xsl:attribute name="FormOID">AEForm</xsl:attribute>
          <xsl:for-each select="$aeSection/cda:entry">
            <!--ItemDataGroup ItemDataGroupOID='AE'-->
```

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```
      <xsl:element name="ItemGroupData"
namespace="http://www.cdisc.org/ns/odm/v1.3">
      <xsl:attribute name="ItemGroupOID">AE</xsl:attribute>
      <!-- AETERM -->
      <xsl:variable name="originalTextRef"
select="cda:act/cda:entryRelationship/cda:observation/cda:participant/cda:par
ticipantRole/cda:playingEntity/cda:code/cda:originalText/cda:reference/@value
"/>
      <xsl:variable name="codedDisplayName"
select="cda:act/cda:entryRelationship/cda:observation/cda:participant/cda:par
ticipantRole/cda:playingEntity/cda:code/@displayName"/>
      <!--ItemData ItemDataOID='AETERM'-->
      <xsl:element name="ItemData"
namespace="http://www.cdisc.org/ns/odm/v1.3">
        <xsl:attribute name="ItemOID">AETERM</xsl:attribute>
        <xsl:attribute name="Value">
         <xsl:choose>
           <xsl:when test="$originalTextRef"><xsl:value-of
select="//*[@ID=substring-after($originalTextRef,'#')]"/></xsl:when>
           <xsl:otherwise><xsl:value-of
select="$codedDisplayName"/></xsl:otherwise>
         </xsl:choose>
        </xsl:attribute>
      </xsl:element><!--/ItemData-->
      <!-- AESTDTC -->
      <xsl:variable name="aeStartDateTime"
select="cda:act/cda:entryRelationship/cda:observation/cda:effectiveTime/@valu
e"/>
      <xsl:if test="$aeStartDateTime">
       <!--ItemData ItemDataOID='AESTDTC'-->
       <xsl:element name="ItemData"
namespace="http://www.cdisc.org/ns/odm/v1.3">
         <xsl:attribute name="ItemOID">AESTDTC</xsl:attribute>
         <xsl:attribute name="value"><xsl:value-of
select="$aeStartDateTime"/></xsl:attribute>
       </xsl:element><!--/ItemData-->
      </xsl:if>
     </xsl:element><!--/ItemDataGroup-->
   </xsl:for-each>
  </xsl:element><!--/FormData-->
</xsl:if>

</xsl:template>

<!-- helper templates -->

<!-- CDASH a med history item -->
<xsl:template name="problemItemData">
<xsl:param name="theNode"/>
  <!-- we may be pointed to the text of the condition, or we may just have a
coded value display name -->
```

```
       <xsl:variable name="originalTextRef"
1220   select="$theNode/cda:act/cda:entryRelationship/cda:observation/cda:text/cda:r
       eference/@value"/>
         <xsl:variable name="codedValue"
       select="$theNode/cda:act/cda:entryRelationship/cda:observation/cda:value/@dis
       playName"/>
1225     <!-- problem status translates into the CDASH MHONG -->
         <xsl:variable name="problemStatusNode"
       select="$theNode/cda:act/cda:entryRelationship/cda:observation/cda:entryRelat
       ionship/cda:observation[cda:code/@code='33999-4']"/>
         <!-- can have status coded or by reference -->
1230     <xsl:variable name="problemStatusRef"
       select="$problemStatusNode/cda:text/cda:reference/@value"/>
         <!-- onset and end dates for problems -->
         <xsl:variable name="problemOnset"
       select="$theNode/cda:act/cda:entryRelationship/cda:observation/cda:effectiveT
1235   ime/cda:low/@value"/>
         <xsl:variable name="problemResolved"
       select="$theNode/cda:act/cda:entryRelationship/cda:observation/cda:effectiveT
       ime/cda:high/@value"/>
         <!-- MHTERM -->
1240     <!--ItemData ItemOID='MHTERM'-->
         <xsl:element name="ItemData" namespace="http://www.cdisc.org/ns/odm/v1.3">
           <xsl:attribute name="ItemOID">MHTERM</xsl:attribute>
           <xsl:attribute name="Value">
            <xsl:choose>
1245         <xsl:when test="string-length($originalTextRef)>0"><xsl:value-of
       select="//*[@ID=substring-after($originalTextRef,'#')]"/></xsl:when>
             <xsl:when test="string-length($codedValue)>0"><xsl:value-of
       select="$codedValue"/></xsl:when>
             <xsl:otherwise>???</xsl:otherwise>
1250        </xsl:choose>
           </xsl:attribute>
         </xsl:element><!--/ItemData-->
         <!-- MHONG -->
         <!--ItemData ItemOID='MHONG'-->
1255     <xsl:element name="ItemData" namespace="http://www.cdisc.org/ns/odm/v1.3">
           <xsl:attribute name="ItemOID">MHONG</xsl:attribute>
           <xsl:attribute name="Value">
            <xsl:choose>
             <xsl:when
1260   test="$problemStatusNode/cda:value/@displayName='Active'">ONGOING</xsl:when>
             <xsl:when test="//*[@ID=substring-
       after($problemStatusRef,'#')]='Active'">ONGOING</xsl:when>
             <xsl:otherwise>RESOLVED</xsl:otherwise>
            </xsl:choose>
1265        </xsl:attribute>
         </xsl:element><!--/ItemData-->

         <xsl:comment>research adding type and category (MHCAT, MHSCAT)</xsl:comment>
         <!-- NOTE:  might need a more generic template to handle the multiple ways
1270   that time can be reported in ccd -->
```

```
         <!-- MSSTDTC -->
         <xsl:if test="$problemOnset">
          <!--ItemData ItemDataOID='MHSTDTC'-->
          <xsl:element name="ItemData" namespace="http://www.cdisc.org/ns/odm/v1.3">
1275       <!-- transform stupid non-ISO8601-XML date to ISO8601 date -->
           <xsl:variable name="ISODATE">
               <xsl:call-template name="HL7DateToISO8601">
                 <xsl:with-param name="HL7Date" select="$problemOnset"/>
               </xsl:call-template>
1280        </xsl:variable>
           <xsl:attribute name="ItemOID">MHSTDTC</xsl:attribute>
           <!--xsl:attribute name="Value"><xsl:value-of
      select="$problemOnset"/></xsl:attribute-->
           <xsl:attribute name="Value"><xsl:value-of
1285  select="$ISODATE"/></xsl:attribute>
          </xsl:element><!--/ItemData-->
         </xsl:if>
         <!-- MHENDDTC -->
         <xsl:if test="$problemResolved">
1290      <!--ItemData ItemDataOID='MHENDDTC'-->
          <xsl:element name="ItemData" namespace="http://www.cdisc.org/ns/odm/v1.3">
           <xsl:attribute name="ItemOID">MHENDDTC</xsl:attribute>
           <xsl:attribute name="Value"><xsl:value-of
      select="$problemResolved"/></xsl:attribute>
1295      </xsl:element><!--/ItemData-->
         </xsl:if>
      </xsl:template>

      <xsl:template name="procedureItemData">
1300  <xsl:param name="theNode"/>
       <xsl:variable name="originalTextRef"
      select="$theNode/cda:procedure/cda:code/cda:originalText/cda:reference/@value
      "/>
       <xsl:variable name="codedValue"
1305  select="$theNode/cda:procedure/cda:code/@displayName"/>
       <!-- MHTERM -->
       <!--ItemData ItemOID='MHTERM'-->
       <xsl:element name="ItemData" namespace="http://www.cdisc.org/ns/odm/v1.3">
         <xsl:attribute name="ItemOID">MHTERM</xsl:attribute>
1310     <xsl:attribute name="Value">
          <xsl:choose>
           <xsl:when test="string-length($originalTextRef)>0"><xsl:value-of
      select="//*[@ID=substring-after($originalTextRef,'#')]"/></xsl:when>
           <xsl:when test="string-length($codedValue)>0"><xsl:value-of
1315  select="$codedValue"/></xsl:when>
           <xsl:otherwise>???</xsl:otherwise>
          </xsl:choose>
         </xsl:attribute>
       </xsl:element><!--/ItemData-->
1320   <!-- NOTE: is this true = procedures are RESOLVED -->
       <!-- MHONG -->
       <!--ItemData ItemDataOID='MHONG' value='RESOLVED'/-->
```

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```
      <xsl:element name="ItemData" namespace="http://www.cdisc.org/ns/odm/v1.3">
        <xsl:attribute name="ItemOID">MHONG</xsl:attribute>
1325    <xsl:attribute name="Value">RESOLVED</xsl:attribute>
      </xsl:element>
      <xsl:comment>??? what to do about an effectiveTime of center
???</xsl:comment>
    </xsl:template>
1330
    <xsl:template name="HL7DateToISO8601">
      <xsl:param name="HL7Date"></xsl:param>
      <xsl:choose>
        <xsl:when test="string-length($HL7Date) = 4">
1335      <xsl:value-of select="$HL7Date"/>
        </xsl:when>
        <xsl:when test="string-length($HL7Date) = 6">
          <xsl:variable name="YEAR" select="substring($HL7Date,1,4)"/>
          <xsl:variable name="MONTH" select="substring($HL7Date,5,2)"/>
1340      <xsl:value-of select="concat($YEAR,'-',$MONTH)"/>
        </xsl:when>
        <xsl:when test="string-length($HL7Date) = 8">
          <xsl:variable name="YEAR" select="substring($HL7Date,1,4)"/>
          <xsl:variable name="MONTH" select="substring($HL7Date,5,2)"/>
1345      <xsl:variable name="DAY" select="substring($HL7Date,7,2)"/>
          <xsl:value-of select="concat($YEAR,'-',$MONTH,'-',$DAY)"/>
        </xsl:when>
        <xsl:when test="string-length($HL7Date) = 10">
          <xsl:variable name="YEAR" select="substring($HL7Date,1,4)"/>
1350      <xsl:variable name="MONTH" select="substring($HL7Date,5,2)"/>
          <xsl:variable name="DAY" select="substring($HL7Date,7,2)"/>
          <xsl:variable name="HOUR" select="substring($HL7Date,9,2)"/>
          <xsl:value-of select="concat($YEAR,'-',$MONTH,'-',$DAY,'T',$HOUR)"/>
        </xsl:when>
1355    <xsl:when test="string-length($HL7Date) = 12">
          <xsl:variable name="YEAR" select="substring($HL7Date,1,4)"/>
          <xsl:variable name="MONTH" select="substring($HL7Date,5,2)"/>
          <xsl:variable name="DAY" select="substring($HL7Date,7,2)"/>
          <xsl:variable name="HOUR" select="substring($HL7Date,9,2)"/>
1360      <xsl:variable name="MINUTE" select="substring($HL7Date,11,2)"/>
          <xsl:value-of select="concat($YEAR,'-',$MONTH,'-
',$DAY,'T',$HOUR,':',$MINUTE)"/>
        </xsl:when>
        <xsl:when test="string-length($HL7Date) = 14">
1365      <xsl:variable name="YEAR" select="substring($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)"/>
1370      <xsl:variable name="SECOND" select="substring($HL7Date,13,2)"/>
          <xsl:value-of select="concat($YEAR,'-',$MONTH,'-
',$DAY,'T',$HOUR,':',$MINUTE,':',$SECOND)"/>
        </xsl:when>
        <!-- can still be extended for the case milliseconds are given -->
```

```
1375        <!-- CASE NOT FOUND -->
            <xsl:otherwise><xsl:value-of select="$HL7Date"/></xsl:otherwise>
          </xsl:choose>

          </xsl:template>
1380

          </xsl:stylesheet>
```

1.8.3.3 Sample Standard CRF output from the Sample XSLT

```
      <?xml version="1.0" encoding="UTF-8"?>
1385  <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">
1390        <SiteRef LocationOID="100"/>
            <StudyEventData StudyEventOID="CLL_CRF">
              <FormData FormOID="DemographicsForm">
                <!--check on whether or not we can get Ethnicity and Race-->
                <ItemGroupData ItemGroupOID="DM">
1395              <ItemData ItemOID="SEX" Value="M"/>
                  <ItemData ItemOID="BRTHDTC" Value="1932-09-24"/>
                </ItemGroupData>
              </FormData>
              <FormData FormOID="MedicalHistory">
1400            <ItemGroupData ItemGroupOID="CONDITION">
                  <ItemData ItemOID="MHTERM" Value="Asthma"/>
                  <ItemData ItemOID="MHONG" Value="ONGOING"/>
                  <!--research adding type and category (MHCAT, MHSCAT)-->
                  <ItemData ItemOID="MHSTDTC" Value="1950"/>
1405            </ItemGroupData>
                <ItemGroupData ItemGroupOID="CONDITION">
                  <ItemData ItemOID="MHTERM" Value="Pneumonia"/>
                  <ItemData ItemOID="MHONG" Value="RESOLVED"/>
                  <!--research adding type and category (MHCAT, MHSCAT)-->
1410              <ItemData ItemOID="MHSTDTC" Value="1997-01"/>
                </ItemGroupData>
                <ItemGroupData ItemGroupOID="CONDITION">
                  <ItemData ItemOID="MHTERM" Value="Pneumonia"/>
                  <ItemData ItemOID="MHONG" Value="RESOLVED"/>
1415              <!--research adding type and category (MHCAT, MHSCAT)-->
                  <ItemData ItemOID="MHSTDTC" Value="1999-03"/>
                </ItemGroupData>
                <ItemGroupData ItemGroupOID="CONDITION">
                  <ItemData ItemOID="MHTERM" Value="Myocardial infarction"/>
1420              <ItemData ItemOID="MHONG" Value="RESOLVED"/>
                  <!--research adding type and category (MHCAT, MHSCAT)-->
                  <ItemData ItemOID="MHSTDTC" Value="1997-01"/>
                </ItemGroupData>
                <ItemGroupData ItemGroupOID="PROCEDURE">
1425              <ItemData ItemOID="MHTERM" Value="Total hip replacement, left"/>
```

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```
                  <ItemData ItemOID="MHONG" Value="RESOLVED"/>
                  <!--??? what to do about an effectiveTime of center ???-->
                </ItemGroupData>
              </FormData>
1430          <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"/>
1435            </ItemGroupData>
                <ItemGroupData ItemGroupOID="CM">
                  <ItemData ItemOID="CMTRT" Value="Clopidogrel"/>
                  <!--need table to translate HL7 frequency, e.g., 6h to BID-->
                </ItemGroupData>
1440          <ItemGroupData ItemGroupOID="CM">
                  <ItemData ItemOID="CMTRT" Value="Metoprolol"/>
                  <!--need table to translate HL7 frequency, e.g., 6h to BID-->
                </ItemGroupData>
                <ItemGroupData ItemGroupOID="CM">
1445              <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">
1450              <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>
1455          </FormData>
              <FormData FormOID="VSFORM">
                <ItemGroupData ItemGroupOID="VS">
                  <ItemData ItemOID="VSDTC" Value="1999-11-14"/>
                  <ItemData ItemOID="VSTEST" Value="Body height"/>
1460              <ItemData ItemOID="VSORRES" Value="177"/>
                  <ItemData ItemOID="VSORRESU" Value="cm"/>
                  <ItemData ItemOID="VSTEST" Value="Body weight"/>
                  <ItemData ItemOID="VSORRES" Value="86"/>
                  <ItemData ItemOID="VSORRESU" Value="kg"/>
1465              <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"/>
1470              <ItemData ItemOID="VSORRESU" Value="mm[Hg]"/>
                </ItemGroupData>
                <ItemGroupData ItemGroupOID="VS">
                  <ItemData ItemOID="VSDTC" Value="2000-04-07"/>
                  <ItemData ItemOID="VSTEST" Value="Body height"/>
1475              <ItemData ItemOID="VSORRES" Value="177"/>
                  <ItemData ItemOID="VSORRESU" Value="cm"/>
                  <ItemData ItemOID="VSTEST" Value="Body weight"/>
```

```
                     <ItemData ItemOID="VSORRES" Value="88"/>
                     <ItemData ItemOID="VSORRESU" Value="kg"/>
1480                 <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"/>
1485                 <ItemData ItemOID="VSORRESU" Value="mm[Hg]"/>
                   </ItemGroupData>
                 </FormData>
                 <FormData FormOID="AEForm">
                  <ItemGroupData ItemGroupOID="AE">
1490               <ItemData ItemOID="AETERM" Value="Penicillin"/>
                  </ItemGroupData>
                  <ItemGroupData ItemGroupOID="AE">
                    <ItemData ItemOID="AETERM" Value="Aspirin"/>
                  </ItemGroupData>
1495              <ItemGroupData ItemGroupOID="AE">
                    <ItemData ItemOID="AETERM" Value="Codeine"/>
                  </ItemGroupData>
                 </FormData>
               </StudyEventData>
1500        </SubjectData>
          </ClinicalData>
        </ODM>
```