**Integrating the Healthcare Enterprise**



**IHE Patient Care Coordination (PCC)**

**Technical Framework Supplement**

**CDA Document Summary Section**

**(CDADSS)**

**Revision x.x – Draft in Preparation for Public Comment (*or* Trial Implementation)**

Date: December 15, 2017

Author: PCC Technical Committee

Email: pcc@ihe.net

**Please verify you have the most recent version of this document.** See [here](http://ihe.net/Technical_Frameworks/) for Trial Implementation and Final Text versions and [here](http://ihe.net/Public_Comment/) for Public Comment versions.

<Instructions to authors are encapsulated in angled brackets as “< … >” and denoted with italicized text. These instructions should be deleted entirely prior to publication.>

<Use of capitalization: Please follow standard English grammar rules-only proper nouns and names are upper case. For example, “Modality Actor” is upper case, but “an actor which fulfills the role of a modality” is lower case. Do not use upper case to emphasize a word/topic. Examples:

<Note: Before creating a draft supplement, please review the editing conventions, which include information such as section, table and diagram numbering and how to use Microsoft Word tools, at <http://wiki.ihe.net/index.php?title=Writing_Technical_Frameworks_and_Supplements>. This guidance is especially useful for first time authors.>

<This supplement template is intended for developing new profiles or making significant changes to profiles, such as adding formal options. Simple changes to existing supplements or profiles should be made using the Change Proposal (CP) process. See the Technical Framework Development section at <http://wiki.ihe.net/index.php?title=Process#Technical_Framework_Development> for more guidance on supplements vs. CPs.>

<All of the sections in this document are required. Sections may not be deleted. The outline numbering is intended to be consistent across profiles and across domains, so do not adjust the outline numbering. If there is no relevant content for a section, simply state “Section not applicable”, but leave the numbering intact. Sub-sections may be added for clarity.>

*<This supplement template includes templates for Volumes 1 (Profiles), 2 (Transactions), 3 (Content Modules), and 4 (National Extensions).>*

*<Volumes 1, 2, and/or 3 are developed together for Public Comment and Trial Implementation submission. Volume 4, National Extensions, is typically developed at a later point in time, usually at Trial Implementation or later. Templates for all four volumes are included in this document for the sake of completeness. If you are beginning a new profile, you are strongly discouraged from using National Extensions and should instead focus on optional data sets or other alternatives. For more information, see* [*http://wiki.ihe.net/index.php?title=National\_Extensions\_Process*](http://wiki.ihe.net/index.php?title=National_Extensions_Process)*.>*

**Foreword**

This is a supplement to the IHE <Domain Name> Technical Framework <VX.X>. Each supplement undergoes a process of public comment and trial implementation before being incorporated into the volumes of the Technical Frameworks.

*<For Public Comment:>* This supplement is published on <Month XX, 201x> for Public Comment. Comments are invited and can be submitted at <http://www.ihe.net/Public_Comment/#domainname>. In order to be considered in development of the Trial Implementation version of the supplement, comments must be received by <Month XX, 201X>.

*<For Trial Implementation:>* This supplement is published on <Month XX, 201X> 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 <Domain Name> Technical Framework. Comments are invited and can be submitted at <http://www.ihe.net/Public_Comment/#domainname>.

This supplement describes changes to the existing technical framework documents.

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

Amend section X.X by the following:

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

General information about IHE can be found at [www.ihe.net](http://www.ihe.net/).

Information about the IHE <Domain Name> domain can be found at [ihe.net/IHE\_Domains](file:///D:\Google%20Drive\01_IHE\AppData\Roaming\Microsoft\Word\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://ihe.net/IHE\_Process](http://ihe.net/IHE_Process/) and [http://ihe.net/Profiles](http://ihe.net/Profiles/).

The current version of the IHE <Domain name>Technical Framework can be found at [http://ihe.net/Technical\_Frameworks](http://ihe.net/Technical_Frameworks/).

*<Comments may be submitted on IHE Technical Framework templates any time at* [*http://ihe.net/Templates\_Public\_Comments*](http://ihe.net/Templates_Public_Comments/)*. Please enter comments/issues as soon as they are found. Do not wait until a future review cycle is announced.>*

CONTENTS

[Introduction to this Supplement 8](#_Toc500238740)

[Open Issues and Questions 8](#_Toc500238741)

[Closed Issues 9](#_Toc500238742)

[General Introduction and Shared Appendices 10](#_Toc500238743)

[Appendix A – Actor Summary Definitions 10](#_Toc500238744)

[Appendix B – Transaction Summary Definitions 10](#_Toc500238745)

[Appendix D – Glossary 11](#_Toc500238746)

[Volume 1 – Profiles 12](#_Toc500238747)

[<*Copyright Licenses>* 12](#_Toc500238748)

[<*Domain-specific additions>* 12](#_Toc500238749)

[X <Profile Name (Acronym)> Profile 13](#_Toc500238750)

[X.1 <Profile Acronym> Actors, Transactions, and Content Modules 13](#_Toc500238751)

[X.1.1 Actor Descriptions and Actor Profile Requirements 16](#_Toc500238752)

[X.1.1.1 <Actor A> 17](#_Toc500238753)

[X.1.1.2 <Actor B> 17](#_Toc500238754)

[X.2 <Profile Acronym> Actor Options 17](#_Toc500238755)

[X.2.1 <Option Name> 18](#_Toc500238756)

[X.3 <Profile Acronym> Required Actor Groupings 19](#_Toc500238757)

[X.4 <Profile Acronym> Overview 22](#_Toc500238758)

[X.4.1 Concepts 22](#_Toc500238759)

[X.4.2 Use Cases 22](#_Toc500238760)

[X.4.2.1 Use Case #1: <simple name> 22](#_Toc500238761)

[X.4.2.1.1 <simple name> Use Case Description 22](#_Toc500238762)

[X.4.2.1.2 <simple name> Process Flow 23](#_Toc500238763)

[X.5 <Profile Acronym> Security Considerations 25](#_Toc500238764)

[X.6 <Profile Acronym> Cross Profile Considerations 25](#_Toc500238765)

[Appendices 27](#_Toc500238766)

[Appendix A – <Appendix Title> 28](#_Toc500238767)

[A.1 <Title> 28](#_Toc500238768)

[A.1.1 <Title> 28](#_Toc500238769)

[Appendix B – <Appendix Title> 29](#_Toc500238770)

[B.1 <Title> 29](#_Toc500238771)

[B.1.1 <Title> 29](#_Toc500238772)

[Volume 2 – Transactions 30](#_Toc500238773)

[3.Y <Transaction Name [Domain Acronym-#]> 30](#_Toc500238774)

[3.Y.1 Scope 30](#_Toc500238775)

[3.Y.2 Actor Roles 30](#_Toc500238776)

[3.Y.3 Referenced Standards 31](#_Toc500238777)

[3.Y.4 Interaction Diagram 31](#_Toc500238778)

[3.Y.4.1 <Message 1 Name> 32](#_Toc500238779)

[3.Y.4.1.1 Trigger Events 32](#_Toc500238780)

[3.Y.4.1.2 Message Semantics 32](#_Toc500238781)

[3.Y.4.1.3 Expected Actions 32](#_Toc500238782)

[3.Y.4.2 <Message 2 Name> 32](#_Toc500238783)

[3.Y.4.2.1 Trigger Events 33](#_Toc500238784)

[3.Y.4.2.2 Message Semantics 33](#_Toc500238785)

[3.Y.4.2.3 Expected Actions 33](#_Toc500238786)

[3.Y.5 Protocol Requirements 33](#_Toc500238787)

[3.Y.6 Security Considerations 33](#_Toc500238788)

[3.Y.6.1 Security Audit Considerations 33](#_Toc500238789)

[3.Y.6.(z) <Actor> Specific Security Considerations 34](#_Toc500238790)

[Appendices 35](#_Toc500238791)

[Appendix A – <Appendix Title> 36](#_Toc500238792)

[A.1 <Title> 36](#_Toc500238793)

[A.1.1 <Title> 36](#_Toc500238794)

[Appendix B – <Appendix Title> 37](#_Toc500238795)

[B.1 <Title> 37](#_Toc500238796)

[B.1.1 <Title> 37](#_Toc500238797)

[Volume 2 Namespace Additions 38](#_Toc500238798)

[Volume 3 – Content Modules 39](#_Toc500238799)

[5 IHE Namespaces, Concept Domains and Vocabularies 40](#_Toc500238800)

[5.1 IHE Namespaces 40](#_Toc500238801)

[5.2 IHE Concept Domains 40](#_Toc500238802)

[5.3 IHE Format Codes and Vocabularies 41](#_Toc500238803)

[5.3.1 IHE Format Codes 41](#_Toc500238804)

[5.3.2 IHEActCode Vocabulary 41](#_Toc500238805)

[5.3.3 IHERoleCode Vocabulary 42](#_Toc500238806)

[6 Content Modules 43](#_Toc500238807)

[6.3.1 CDA Document Content Modules 43](#_Toc500238808)

[6.3.1.D <Content Module Name (Acronym)> Document Content Module 44](#_Toc500238809)

[6.3.1.D.1 Format Code 44](#_Toc500238810)

[6.3.1.D.2 Parent Template 44](#_Toc500238811)

[6.3.1.D.3 Referenced Standards 44](#_Toc500238812)

[6.3.1.D.4 Data Element Requirement Mappings to CDA 45](#_Toc500238813)

[6.3.1.D.5 <Content Module Name (Acronym, if applicable)> Document Content Module Specification 46](#_Toc500238814)

[6.3.1.D.5.1 <Header Element or Section Name> <Vocabulary Constraint or Condition> 48](#_Toc500238815)

[6.3.1.D.5.2 <Header Element or Section Name> <Vocabulary Constraint or Condition> 48](#_Toc500238816)

[6.3.1.D.5.3 <Header Element or Section Name> <Vocabulary Constraint or Condition> 48](#_Toc500238817)

[6.3.1.D.5.4 <Header Element or Section Name> <Vocabulary Constraint or Condition> 49](#_Toc500238818)

[6.3.1.D.5.5 <Template Title name> <Vocabulary Constraint or Condition> 51](#_Toc500238819)

[6.3.1.D.5.6 <Template Title name> <Vocabulary Constraint or Condition> 51](#_Toc500238820)

[6.3.1.D.6 <Document and Acronym Name> Conformance and Example 52](#_Toc500238821)

[6.3.2 CDA Header Content Modules 53](#_Toc500238822)

[6.3.2.H <Header Element Module Name> Header Content Module 53](#_Toc500238823)

[6.3.2.H.1 <Description Name> <e.g., Responsible Party> <Specification Document *or* Vocabulary Constraint> 54](#_Toc500238824)

[6.3.2.H.2 <Description Name> <Specification Document OR Vocabulary Constraint> 54](#_Toc500238825)

[6.3.2.H.3 <Description Name> <Specification Document OR Vocabulary Constraint> 54](#_Toc500238826)

[6.3.3 CDA Section Content Modules 56](#_Toc500238827)

[6.3.3.10.S <Section Module Name> - Section Content Module 56](#_Toc500238828)

[6.3.3.10.S.1 <Data Element or Section Name> <Condition, Specification Document, or Vocabulary Constraint> 57](#_Toc500238829)

[6.3.3.10.S.2 <Data Element or Section Name> <Condition, Specification Document, or Vocabulary Constraint> 57](#_Toc500238830)

[6.3.3.10.S.3 <Data Element or Section Name> <Condition, Specification Document, or Vocabulary Constraint> 58](#_Toc500238831)

[6.3.3.10.S Medical History - Cardiac Section 11329-0 58](#_Toc500238832)

[6.3.4 CDA Entry Content Modules 60](#_Toc500238833)

[6.3.4.E <Entry Content Module Name> Entry Content Module 61](#_Toc500238834)

[6.3.4.E.1 Simple Observation (wall motion) Vocabulary Constraints 62](#_Toc500238835)

[6.3.4.E.2 Simple Observation (wall morphology) Constraints 62](#_Toc500238836)

[<e.g.,6.3.4.E Result Observation - Cardiac 63](#_Toc500238837)

[6.4 Section not applicable 65](#_Toc500238838)

[6.5 <Domain Acronym> Value Sets and Concept Domains 66](#_Toc500238839)

[6.5.x <Value Set Name/Concept Domain Name> <oid> 66](#_Toc500238840)

[<e.g.,6.5.1 Drug Classes Used in Cardiac Procedure 1.3.6.1.4.1.19376.1.4.1.5.15 66](#_Toc500238841)

[6.5.1 UV\_CardiacProcedureDrugClasses 67](#_Toc500238842)

[Appendices 68](#_Toc500238843)

[Appendix A – <Appendix Title> 69](#_Toc500238844)

[A.1 <Title> 69](#_Toc500238845)

[A.1.1 <Title> 69](#_Toc500238846)

[Appendix B – <Appendix Title> 70](#_Toc500238847)

[B.1 <Title> 70](#_Toc500238848)

[B.1.1 <Title> 70](#_Toc500238849)

[Volume 4 – National Extensions 71](#_Toc500238850)

[4 National Extensions 71](#_Toc500238851)

[4.I National Extensions for <Country Name or IHE Organization> 71](#_Toc500238852)

[4.I.1 Comment Submission 71](#_Toc500238853)

[4.I.2 <Profile Name> <(Profile Acronym)> 71](#_Toc500238854)

[4.I.2.1<Profile Acronym> Value Set Binding for <Country Name or IHE Organization> Realm Concept Domains 71](#_Toc500238855)

[4.I.2.1 <Profile Acronym> Value Set Binding for US Realm Concept Domains 72](#_Toc500238856)

[4.I.2.1.1 US\_CardiacProcedureDrugClasses (1.3.6.1.4.1.19376.1.4.1.5.15) 72](#_Toc500238857)

[4.I.2.2<Profile Acronym> <Type of Change> 72](#_Toc500238858)

[4.I+1 National Extensions for <Country Name or IHE Organization> 72](#_Toc500238859)

[Appendices 73](#_Toc500238860)

[Appendix A – <Appendix Title> 74](#_Toc500238861)

[A.1 <Title> 74](#_Toc500238862)

[A.1.1 <Title> 74](#_Toc500238863)

[Appendix B – <Appendix Title> 75](#_Toc500238864)

[B.1 <Title> 75](#_Toc500238865)

[B.1.1 <Title> 75](#_Toc500238866)

# Introduction to this Supplement

<Provide a brief overview of the volumes/sections of the Technical Framework that get changed/ added by this supplement. Provide 200 words or less describing this supplement.>

Current CDA content profiles do not capture specific summary information about a document. Nor does it capture summary information about content in varying section(s) that is needed to be communicated to the reader (e.g. provider and/or patient) in a concise way. This profile will provide a way to communicate precise information about a document or section(s) in a useful way.

## Open Issues and Questions

<List the open issues/questions that need to be addressed. These are particularly useful for highlighting problematic issues and/or specifically soliciting public comments.>

## Closed Issues

<List the closed issues/questions with their resolutions. These are particularly useful for recording the rationale for closed issues to forestall unnecessary rehashing in the future and/or to make it easier to identify when a closed issue should be re-opened due to new information.>

# General Introduction and Shared Appendices

Update the following appendices to the General Introduction as indicated below. Note that these are **not** appendices to Volume 1.

# Appendix A – Actor Summary Definitions

Add the following actors to the IHE Technical Frameworks General Introduction Appendix A:

No new actor definition

# Appendix B – Transaction Summary Definitions

Add the following transactions to the IHE Technical Frameworks General Introduction Appendix B:

No new transactions

# Appendix D – Glossary

Add the following **new** glossary terms to the IHE Technical Frameworks General Introduction Appendix D.

| Glossary Term | Definition |
| --- | --- |
|  |  |
|  |  |
|  |  |
|  |  |

Volume 1 – Profiles

## Copyright Licenses

Add the following to the IHE Technical Frameworks General Introduction Copyright section:

Not applicable

## Domain-specific additions

None

Add new Section #

*<Reserve a subsequent section number in the current domain Technical Framework Volume 1 (DOM TF-1). Replace the letter “X” with that section heading number. This number should not change when this supplement is added to the Final Text Technical Framework. In this manner, references should be able to be maintained going forward.>*

# X CDA Document Summary Section Profile (CDADSS)

<Provide an end-user friendly overview of what the profile does for them. Keep it brief (a paragraph or two, up to a page). If extensive detail is needed, it should be included in Section X.4- Use Cases.>

CDA Document Summary Section is a content profile that defines means of providing a concise summary about a document or summary of content in a document based on user expectations.Depending on use case, a Document Summary Section can be added to a document, summarizing pertinent information populated by some of the data in the various sections to create a composite, single Summary section. A summary section can also be used for the author of the document to describe pertinent information about the document. The Summary Section can be rendered by the receiver of the document for viewing. When possible (i.e. contains discrete entries) can be imported by the user if desired.

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

This section defines the actors, transactions, and/or content modules in this profile. General definitions of actors are given in the Technical Frameworks General Introduction Appendix A at [http://www.ihe.net/Technical\_Frameworks](http://www.ihe.net/Technical_Frameworks/) .

Figure X.1-1 shows the actors involved in the Summary Section Integration Profile and the relevant transactions between them.



Figure X.1-1: CDADSS Actor Diagram

Table X.1-1 lists the transactions for each actor directly involved in the Summary Section Profile. In order to claim support of this Integration Profile, an implementation must perform the required transactions (labeled “R”). Transactions labeled “O” are optional. A complete list of options defined by this Profile and that implementations may choose to support is listed in Volume 1, Section X.2.

Table X.1-1: Summary Section Integration Profile - Actors and Transactions

|  |  |  |  |
| --- | --- | --- | --- |
| Actors | Transactions | Optionality | Section in TF |
| Content Creator | Share Content [PCC-1] | R | PCC TF-2:3.1 |
| Content Consumer | Share Content [PCC-1] | R | PCC TF-2:3.1 |

Table X.1-2 lists the content module(s) defined in the CDADSS 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”).

<Note that this table number has to change if this profile describes both transactions and content modules (or there will be two tables entitled X.1-1).>

<Note that the abbreviation in the column “Reference” the letter “D” will be incremented for every content module document defined in this profile (e.g., For example D1, D2).>

<In general, one supplement template will only contain one required content module document, but the example here shows multiple with one optional, just for illustration purposes.>

Table X.1-2 CDADSS – Actors and Content Modules

| Actors | Content Modules | Optionality | Reference |
| --- | --- | --- | --- |
| Content Creator | Synopsis Section  Template ID | O | PCC TF-3: 6.3.1.S |
|  | Notes Section  Template ID | O | C-CDA notes section |
| Care Plan Summary Section  Template ID | O | PCC TF-3: 6.3.3.S |
| ?? Section  Template ID | O | PCC TF-3: 6.3.1.S |
| ?? Section  Template ID | O | PCC TF-3: 6.3.1.S |
| ?? Section  Template ID | O | PCC TF-3: 6.3.1.S |
| ?? Section  Template ID | O | PCC TF-3: 6.3.1.S |
| Content Consumer | Synopsis Section  Template ID | O | PCC TF-3: 6.3.1.S |
| Notes Section  Template ID | O | PCC TF-3: 6.3.1.S |
| Care Plan Summary Section  Template ID | O | PCC TF-3: 6.3.1.S |
| ?? Section  Template ID | O | PCC TF-3: 6.3.1.S |
| ?? Section  Template ID | O | PCC TF-3: 6.3.1.S |
| ?? Section  Template ID | O | PCC TF-3: 6.3.1.S |
| ?? Section  Template ID | O | PCC TF-3: 6.3.1.S |

Note 1: *<For example, a note could describe that one of two possible transactions could be supported by an actor or other variations.*

*For example - Note 1: Either Content Module 2 or Content Module 3 shall be implemented for the Content Creator or Content Consumer.*

*For example- Note 1: At least one of Content Module 2, Content Module 3, or Content Module 4 shall be implemented for Content Consumer.>*

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

Most requirements are documented in PCC TF-2 Transactions. This section documents any additional requirements on profile’s actors.

#### X.1.1.1 Content Creator

The Content Creator in this profile is similar to content creators defined in other IHE profiles. It has one requirement, which is that it must be able to create content, for example, synopsis section, notes section, care plan summary section, etc as defined in this profile. This actor should support the Summary Section Content Option.

1. The Content Creator SHALL create a document with at least one summary section.
2. The Content Creator MAY create content conforming to a profile supporting a Medical Summary as defined in PCC TF-2:6.3.1.2 Medical Summary.
3. The Content Creator MAY create content conforming to a profile supporting a Consolidated CDA Implementation Guide Document.

#### X.1.1.2 Content Consumer

The Content Consumer in this profile is similar to content consumers defined in other IHE profiles. This actor should support the Summary Section Content Option.

1. The Content Consumer SHALL render at least one summary section.
2. The Content Consumer MAY implement a content profile supporting a Medical Summary as defined in PCC TF-2:6.3.1.2 Medical Summary.
3. The Content Consumer MAY implement a content profile supporting documents as defined by C-CDA Implementation Guide

### X.1.2 Content Modules

Table X.1.2-1 lists the content module(s) defined in the Summary Section 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.1.2-1: Summary Section Content Modules

| Content Modules | Optionality | Template ID |
| --- | --- | --- |
| Synopsis Section | O | IHE Card template ID |
| Notes Section | O | C-CDA Notes Section template ID |
| Care Plan Nesting Section | O – note 1 | New template ID |
| ?? Section | O | New template ID |
| ?? Section | O | New template ID |
| ?? Section | O | New template ID |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |

Note 1 – Summary sections generated virtually from the existing sections in the document.

## X.2 CDADSS Actor Options

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

Table X.2-1: CDADSS – Actors and Options

| Actor | Option Name | Reference |
| --- | --- | --- |
| Content Creator | Summary Section ContentOption | PCC TF- |
| Content Consumer | View | PCC TF-2:3.1.1 |
| Summary Section ContentView Option – Note 1 | PCC TF --- |
| Summary Section ContentImport Option – Note 2 | PCC TF- |

Note 1: Render Summary Section Content generated virtually from the existing sections in the document.

Note 2: Import Summary Section Content if discrete entry is provided.

*<Add a sub-section below for every new option defined in Table X.2-1.>*

### X.2.1 Summary Section Content Option

A Content Creator supporting the Summary Section Content Option must include Summary Section Content (see Section 6.x.x.S) in the document created.

### X.2.2 Summary Section Content View Option

A Content Consumer supporting the Summary Section Content View Option must render the Summary Section Content (see Section 6.x.x.S) generated virtually from the existing sections in the document as applicable.

### X.2.3 Summary Section Content Import Option

A Content Consumer supporting the Summary Section Content Import Option may import the Summary Section Content (see Section 6.x.x.S) if content contains entries.

## X.3 CDADSS Required Actor Groupings

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

| CDADSS Actor | Actor(s) to be grouped with | Reference | Content Bindings Reference |
| --- | --- | --- | --- |
| Content Creator | None | -- | -- |
| Content Consumer | None | -- | -- |

## X.4 CDADSS Overview

*<Volume 2 documents each transaction/content module in isolation. This section shows how the transactions/content modules of the profile are combined to address the use cases.>*

*<Use cases are informative, not normative, and “SHALL” language is not allowed in use cases.>*

### X.4.1 Concepts

<If needed, this section provides an overview of the concepts that provide necessary background for understanding the profile. If not needed, state “Not applicable.” For an example of why/how this section may be needed, please see ITI Cross Enterprise Workflow (XDW).>

<It may be useful in this section but is not necessary, to provide a short list of the use cases described below and explain why they are different.>

### X.4.2 Use Cases

#### X.4.2.1 Use Case #1: <simple name>

<One or two sentence simple description of this particular use case.>

<Note that Section X.4.2.1 repeats in its entirety for additional use cases (replicate as Section X.4.2.2, X.4.2.3, etc.).>

##### X.4.2.1.1 <simple name> Use Case Description

<Describe the key use cases addressed by the profile. Limit to a maximum of one page of text or consider an appendix.>

##### X.4.2.1.2 <simple name> Process Flow

<Diagram and describe the process flow(s) covered by this profile in order to satisfy the use cases. Demonstrate how the profile transactions are combined/sequenced. To provide context and demonstrate how the profile interacts with other profiles, feel free to include transactions and events that are “external” to this profile (using appropriate notation.)

The set of process flows will typically be exemplary, not exhaustive (i.e., it will address all the use cases, but will not show all possible combinations of actors, or all possible sequencing of transactions).

If there are detailed behavioral rules that apply to a specific process flow or multiple process flows, an appendix may be added as needed.>

<The roles at the top of the swimlane diagram should correspond to actor names, include the profile acronym:actor name if referencing an actor from a different profile.>

<Modify the following “Swimlane Diagram”.>

Transaction-A [A]

Actor D/Actor E

Actor A/Actor B

Actor B/Actor C

Internal action 1

Internal action 2

Transaction-B [B]

Transaction-C [C]

Transaction\_2 [2]

Transaction\_3 [3]

Transaction-1 [1]

Transaction-D [D]

Transaction-2 [2]

Figure X.4.2.2-1: Basic Process Flow in <Profile Acronym> Profile

<If process flow “swimlane” diagrams require additional explanation to clarify conditional flows, or flow variations need to be described where alternate systems may be playing different actor roles, document those conditional flows here.>

<Delete the material below if this is a workflow or transport profile. Delete the material above if this profile is a content module only profile.>

**Pre-conditions**:

<Very briefly (typically one sentence) describe the conditions or timing when this content module would be used.>

**Main Flow**:

<Typically in an enumerated list, describe the clinical workflow when, where, and how this content module would be used.>

**Post-conditions:**

<Very briefly (typically one sentence) describe the state of the clinical scenario after this content module has been created including examples of potential next steps.>

## X.5 CDADSS Security Considerations

See ITI TF-2.x Appendix Z.8 “Mobile Security Considerations”

## X.6 CDADSS Cross Profile Considerations

<This section is informative, not normative. It is intended to put this profile in context with other profiles. Any required groupings should have already been described above. Brief descriptions can go directly into this section; lengthy descriptions should go into an appendix. Examples of this material include ITI Cross Community Access (XCA) Grouping Rules (Section 18.2.3), the Radiology associated profiles listed at wiki.ihe.net, or ITI Volume 1 Appendix E “Cross Profile Considerations”, and the “See Also” sections Radiology Profile descriptions on the wiki such as <http://wiki.ihe.net/index.php/Scheduled_Workflow#See_Also>. If this section is left blank, add “Not applicable.” >

*<Consider using a format such as the following:>*

<other profile acronym> - <other profile name>

A <other profile actor name> in <other profile name> might be grouped with a <this profile actor name> to <describe benefit/what is accomplished by grouping>.

Appendices

<Add appendices to Volume 1 for this profile here. Examples of an appendix include HITSP mapping to IHE Use Cases or long use case definitions.>

<If there are no Volume 1 appendices, enter “Not applicable” and delete the Appendix A and Appendix B placeholder sections.>

<Volume 1 appendices are informational only. No “SHALL” language is allowed in a Volume 1 Appendix.>

# Appendix A – <Appendix Title>

Appendix A text.

## A.1 <Title>

Appendix A.1 text.

### A.1.1 <Title>

Appendix A.1.1 text.

# Appendix B – <Appendix Title>

Appendix B text.

## B.1 <Title>

Appendix B.1 text.

### B.1.1 <Title>

Appendix B.1.1 text.

Volume 2 – Transactions

Add Section 3.Y

## 3.Y <Transaction Name [Domain Acronym-#]>

*<The “Y” in the heading should be the same as the # in the [Domain Acronym -#] title>*

### 3.Y.1 Scope

This transaction is used to *<…describe what is accomplished by using the transaction. Remember that by keeping transactions general/abstract, they can be re-used in a variety of profiles>*

### 3.Y.2 Actor Roles

<*Alternative 1*> Table 3.Y.2-1: Actor Roles

|  |  |
| --- | --- |
| **Actor:** | <Official actor name; list every actor in this transaction.> |
| **Role:** | <Very brief, one phrase, description of the role that this actor plays in this transaction.> |
| **Actor:** |  |
| **Role:** |  |
| **Actor:** |  |
| **Role:** |  |

*<The assignment and use of role names in transaction specifications has proved to be very effective/efficient in Radiology, especially when existing transactions are re-used by additional actors. Following is an alternative example of the Role section. Delete whichever form of the role section you choose not to use.>*

The roles in this transaction are defined in the following table and may be played by the actors shown here:

<*Alternative 2*>Table 3.Y.2-1 Actor Roles

|  |  |
| --- | --- |
| **Role:** | *<Role Name:><Only unique within this transaction. Typically one word. The Role Name is analogous to SCU or SCP in DICOM Services.>* |
| **Actor(s):** | The following actors may play the role of *<Role Name>*:  *<Actor Name>: <optionally, the situation where the actor would play this role if needed for clarity.>”* |
| **Role:** | *<e.g., Requestor:*  *Submits the relevant details and requests the creation of a new workitem.>* |
| **Actor(s):** | *<e.g., The following actors may play the role of Requestor:*  *Workitem Creator: when requesting workitems*  *Workitem Performer: when performing unscheduled workitems>* |
| **Role:** | *<e.g., Manager:*  *Creates and manages a Unified Procedure Step instance for the requested workitem.>* |
| **Actor(s):** | *<e.g., The following actors may play the role of Manager:*  *Workitem Manager: when receiving a new workitem for its worklist.>* |

Transaction text specifies behavior for each role. The behavior of specific actors may also be specified when it goes beyond that of the general role.

### 3.Y.3 Referenced Standards

* *<e.g., HL7 2.3.1 Chapters 2, 3>*
* *<e.g., DICOM 2008 PS 3.3: A.35.8 X-Ray Radiation Dose SR IOD>*
* *<e.g., applicable sub-sections in ITI TF-2x: Appendix Z on HL7 FHIR>*

### 3.Y.4 Interaction Diagram

<The interaction diagram shows the detailed standards-based message exchange that makes up the IHE transaction.>

Actor A

Message 1

Actor D

Message 2

#### 3.Y.4.1 <Message 1 Name>

<One or two sentence summary of what Message 1 accomplishes typically relating the message to the relevant standard. Avoid shall language in this upper level section. Do not duplicate the triggers, encoding, semantics, standards used, or expected actions. Those belong in the following sections.>

<Explicitly state if the multiplicity of an actor may be greater than one; i.e., if an actor (whether it is a client or server) can expect this message from a single source or multiple sources.>

##### 3.Y.4.1.1 Trigger Events

<Description of the real world events that cause the sender (Actor A) to send Message 1 (e.g., an operator or an automated function determines that a new workitem is needed).>

##### 3.Y.4.1.2 Message Semantics

<Detailed description of the meaning, structure and contents of the message, including any IHE specific clarifications of the message format, attributes, etc.>

<Start by describing the standard underlying the message and how the participating actors are mapped (e.g., “This message is a DICOM C-FIND Request. Actor A is the SCU. Actor D is the SCP.”).>

<Continue profiling the message by providing guidance or constraints on how the message parameters are populated, how the payload is encoded, how the message is structured and what the contents mean. These message semantics should both help the sender to construct the message and the receiver to interpret the message.>

##### 3.Y.4.1.3 Expected Actions

<Description of the actions expected to be taken as a result of sending or receiving this message.>

<Describe what the receiver is expected/required to do upon receiving this message. >

<Avoid re-iterating the transaction sequencing specified in the Profile Process Flows as expected actions internal to the transaction. Doing so prevents this transaction being re-used in other contexts.>

<Explicitly define any expected action based on the multiplicity of an actor(s), if applicable.>

#### 3.Y.4.2 <Message 2 Name>

<One or two sentence summary of what Message 2 accomplishes typically relating the message to the relevant standard. Avoid shall language in this upper level section. Do not duplicate the triggers, encoding, semantics, standards used, or expected actions. Those belong in the following sections.>

<Explicitly state if the multiplicity of an actor may be greater than one; i.e., if an actor (whether it is a client or server) can expect this message from a single source or multiple sources.>

<Repeat this section as necessary based on the number of messages in the interaction diagram.>

##### 3.Y.4.2.1 Trigger Events

<Description of the real world events that cause the sender (Actor A) to send Message 1(e.g., an operator or an automated function determines that a new workitem is needed).>

##### 3.Y.4.2.2 Message Semantics

<Detailed description of the meaning, structure and contents of the message, including any IHE specific clarifications of the message format, attributes, etc.>

<Start by describing the standard underlying the message and how the participating actors are mapped (e.g., “This message is a DICOM C-FIND Request. Actor A is the SCU. Actor D is the SCP.”).>

<Continue profiling the message by providing guidance or constraints on how the message parameters are populated, how the payload is encoded, how the message is structured and what the contents mean. These message semantics should both help the sender to construct the message and the receiver to interpret the message.>

##### 3.Y.4.2.3 Expected Actions

<Description of the actions expected to be taken as a result of sending or receiving this message.>

<Describe what the receiver is expected/required to do upon receiving this message. >

<Avoid re-iterating the transaction sequencing specified in the Profile Process Flows as expected actions internal to the transaction. Doing so prevents this transaction being re-used in other contexts.>

<Explicitly define any expected action based on the multiplicity of an actor(s), if applicable.>

### 3.Y.5 Protocol Requirements

<In this section, the selected protocol bindings of the transactions are explained in detail (like SOAP or HTTP bindings).For an example, see the QRPH DEX Profile or ITI TF-2b:3.34.5, 3.35.5. Indicate NA if not used.>

### 3.Y.6 Security Considerations

<Description of the transaction specific security consideration; such as use of security profiles.>

#### 3.Y.6.1 Security Audit Considerations

<This section should identify any specific ATNA security audit event that is associated with this transaction and requirements on the encoding of that audit event. >

##### 3.Y.6.(z) <Actor> Specific Security Considerations

<This section should specify any specific security considerations on an actor-by-actor basis.>

Appendices

<Detailed cross transaction relationships or mapping details are described in an appendix in Volume 2x. Volume 2 appendices may be informational or normative. Immediately after the title of a Volume 2 appendix, provide a very explicit statement defining whether this new appendix is informative or normative.

If there are no Volume 2 appendices, enter “Not applicable” and delete the Appendix A and Appendix B placeholder sections.>

# Appendix A – <Appendix Title>

Appendix A text.

## A.1 <Title>

Appendix A.1 text.

### A.1.1 <Title>

Appendix A.1.1 text.

# Appendix B – <Appendix Title>

Appendix B text.

## B.1 <Title>

Appendix B.1 text.

### B.1.1 <Title>

Appendix B.1.1 text.

# Volume 2 Namespace Additions

<For Public Comment, please explicitly identify all new OIDs, UIDs, URNs, etc., defined specifically for this profile. These items should be collected from the sections above, and listed here as additions to the applicable domain OID Registry. This section will be deleted prior to inclusion into the Technical Framework as Final Text, but should be present for publication of Public Comment and Trial Implementation.>

At Trial Implementation publication, the domain technical committee **must** ensure that all new OIDs, UIDs, URNs, etc., defined specifically for this profile have been recorded in their OID Registry. This section will be deleted prior to inclusion into the Technical Framework Volumes as Final Text but should be present for publication of Public Comment and Trial Implementation.>

The <domain name> registry of OIDs is located at <link to your OID registry(ies)

Additions to the <Domain Name> OID Registry are:

Volume 3 – Content Modules

<The current version of the supplement template only addresses HL7 v3 CDA Content Modules. All CDA Content Modules will go in Section 6 of Volume 3 of each domain’s Technical Framework document. In the future, this supplement template may have additional sections for DICOM Content Modules (section 7 of Volume 3) and other types of Content Modules (section 8, etc., of Volume 3).

<Please note that prior to the release of the new template set, some domains may have defined CDA Content Modules in Volume 2 (e.g., PCC); however, going forward CDA Content Modules will be defined in Volume 3.>

# 5 IHE Namespaces, Concept Domains and Vocabularies

Add to Section 5 IHE Namespaces, Concept Domains and Vocabularies

## 5.1 IHE Namespaces

<**For Public Comment publication**, please explicitly identify all **new** OIDs, UIDs, URNs, etc., defined specifically for this profile. These items should be collected from the sections within this supplement and listed here as additions to the applicable domain OID Registry. The tables within this section will be deleted prior to inclusion into the Technical Framework as Final Text, but should be present for publication for Public Comment.>

<**For Trial Implementation publication**, the domain technical committee **must** ensure that all new OIDs, UIDs, URNs, etc., defined specifically for this profile (and listed here for public comment publication have now been recorded in their OID Registry. The tables within this section will be deleted prior to inclusion into the Technical Framework Volumes as Final Text but should be present for publication for Trial Implementation.>

<Ensure the domain’s registry of OIDs is linked to from the following wiki page. It may be another wiki page, a document on the ftp site, etc.>

The <domain name> registry of OIDs is located at <http://wiki.ihe.net/index.php/OID_Registration#IHE_Domain_Namespaces>

Additions to the <Domain Name> OID Registry are:

| codeSystem | codeSystemName | Description |
| --- | --- | --- |
| <oid or uid> | <code system name> | <short description or pointer to more detailed description> |
| <oid or uid> | <code system name> | <short description or pointer to more detailed description> |
| <oid or uid> | <code system name> | <short description or pointer to more detailed description> |

## 5.2 IHE Concept Domains

<Concept Domains are named categories of things that are used when it isn’t possible to bind to a specific set of codes. There are a number of reasons you might not be able to define and bind to a specific set of codes, one of the most common being that the codes set needs to vary depending on locale or context.>

For a listing of the <Domain Acronym> Concept Domains see <enter location of the domains Concept Domains or NA if none>

| conceptDomain | conceptDomainName | Description |
| --- | --- | --- |
| <oid or uid> | <code system name> | <short description or pointer to more detailed description> |
| <oid or uid> | <code system name> | <short description or pointer to more detailed description> |
| <oid or uid> | <code system name> | <short description or pointer to more detailed description> |

## 5.3 IHE Format Codes and Vocabularies

### 5.3.1 IHE Format Codes

List in the table below any **new** format codes to be added to the IHE Format Codes wiki page at <http://wiki.ihe.net/index.php/IHE_Format_Codes>. For public comment, the additions must be listed in the table below. The domain technical committee must ensure any new codes are also added to the wiki page prior to publication for trial implementation.

| Profile | Format Code | Media Type | Template ID |
| --- | --- | --- | --- |
| <Profile name (profile acronym)> | <urn:ihe: > |  | <oids> |
|  |  |  |  |
|  |  |  |  |

### 5.3.2 IHEActCode Vocabulary

List in the table below, any **new** additions to the IHEActCode Vocabulary wiki page at <http://wiki.ihe.net/index.php/IHEActCode_Vocabulary>. For public comment, the additions must be listed in the table below. The domain technical committee must ensure any new codes are also added to the wiki page prior to publication for trial implementation.

|  |  |
| --- | --- |
| Code | Description |
| <Code name> | <short one sentence description or reference to longer description (not preferred)> |
| <Code name> | <short one sentence description or reference to longer description (not preferred)> |
| <Code name> | <short one sentence description or reference to longer description (not preferred)> |

### 5.3.3 IHERoleCode Vocabulary

List in the table below any **new** additions to the IHERoleCode Vocabulary wiki page at <http://wiki.ihe.net/index.php/IHERoleCode_Vocabulary>. For public comment, the additions must be listed in the table below. The domain technical committee must ensure any new codes are also added to the wiki page prior to publication for trial implementation.

| Code | Description |
| --- | --- |
| <name of role> | <Short, one sentence description of role or reference to more info.> |
| <name of role> | <Short, one sentence description of role or reference to more info.> |
| <name of role> | <Short, one sentence description of role or reference to more info.> |

# 6 Content Modules

<Authors’ notes: This section of the supplement template is only for HL7 v3 CDA Content Module definitions. Please delete the entire section 6.3.1 if the Content Module is based on DICOM or another standard.

Please note that the template for DICOM or other types of content modules (other than CDA) has not yet been defined, although DICOM modules will eventually go into Volume 3 Section 7; yet another type of content module will go into Volume 3 Section 8, etc.>

### 6.3.1 CDA Document Content Modules

<Authors’ instructions: The understanding of content module grouping, options, and bindings are critical to CDA content modules. It is strongly recommended that the author review the IHE Technical Frameworks General Introduction section 10.3 and the Patient Care Coordination (PCC) Technical Framework Volume 2 sections 3 and 4 (PCC TF-2:3 and 4) prior to continuing. A critical understanding of CDA definitions for cardinality, optionality, coded terminology values, and CDA content module structure, as well as IHE CDA formatting conventions is also necessary. It is strongly recommended that the author is also conversant with the IHE Technical Frameworks General Introduction Appendix E “Conventions”.>

<This CDA Content Module template is divided into four parts:

D – Document –“D” will be replaced with a sub-section number when added to the Technical Framework

H – Header - “H” will be replaced with a sub-section number when added to the Technical Framework

S – Section - “S” will be replaced with a sub-section number when added to the Technical Framework

E – Entry - “E” will be replaced with a sub-section number when added to the Technical Framework

It is expected that the author will **replicate** each of these four parts as necessary within a supplement.>

**All examples should be deleted after the example has been read and understood.>**

Add to section 6.3.1.D Document Content Modules

<Authors’ Note: Replicate section 6.3.1.D for every CDA Document defined in this profile. Number as 6.3.1.**D1**, 6.3.1.**D2**, etc.>

#### 6.3.1.D <Content Module Name (Acronym)> Document Content Module

##### 6.3.1.D.1 Format Code

The XDSDocumentEntry format code for this content is **urn:ihe:dom:name:year**

<where **dom** is the domain abbreviation; **name** is an identifying profile, transaction, etc. name; and **year** is the year the profile is expected to reach trial implementation. For example, urn:ihe:card:imaging:2011>

##### 6.3.1.D.2 Parent Template

<The following text is common, so it is left here for consistency. If it is not relevant, then change the text to the accurate information, but retain the formatting convention. Be sure to include **all** parent templates.>

<e.g., This document is a specialization of the IHE PCC Medical Document template (OID = 1.3.6.1.4.1.19376.1.5.3.1.1.1).>

<e.g., Note: The Medical Document includes requirements for various header elements; name, addr and telecom elements for identified persons and organizations; and basic participations record target, author, and legal authenticator.>

<e.g., This document is a specialization of the HL7 Procedure Note template (OID = 2.16.840.1.113883.10.20.18.1).>

<e.g., Note: This document is not a specialization of the HL7 Basic Diagnostic Imaging Report template due to conflicts with two Procedure Note requirements (format of serviceEvent/effectiveTime, and title on DICOM Catalogue section). When and if these are resolved, an instance may also comply to the Diagnostic Imaging Report.>

##### 6.3.1.D.3 Referenced Standards

<Identify **all** standards referenced by **this** content module.>

All standards which are reference in this document are listed below with their common abbreviation, full title, and link to the standard.

Table 6.3.1.D.3-1: <Document Name> - Referenced Standards

| Abbreviation | Title | URL |
| --- | --- | --- |
| <abbreviated name of standard> | <full name of standard> | <link to standard> |
| <abbreviated name of standard> | <full name of standard> | <link to standard> |
| <e.g., CDA-PN> | <e.g., HL7 Implementation Guide for CDA Release 2: Procedure Note (Universal Realm) (DSTU)> | <e.g., http://www.hl7.org/documentcenter/public/standards/dstu/CDAR2\_IG\_PROCNOTE\_DSTU\_R1\_2010JUL.zip> |

##### 6.3.1.D.4 Data Element Requirement Mappings to CDA

This section identifies the mapping of data between referenced standards into the CDA implementation guide.

<Any required data mappings should be listed in this section (mark NA if not needed). Delete SAMPLE table before publishing.>

*<To complete Table 6.3.1.D.4-1, the author should add the referenced standards abbreviations in the first row/title bar. Add or delete columns and sub-rows as necessary. If this table is more than 8 to 10 rows long, consider putting this table into an appendix of this supplement. A brief sample follows.>*

SAMPLE

| ACC Key Data Element (KDECI) | CDA-DIR |
| --- | --- |
|  | DICOM Object Catalog (5) |
| Administrative  Facility (5)  Data Source (1)  Priority (1)  Accreditation (2)  Insurance (1) | CDA Header  General (10)  Document (19)  Participants (20)  Order (1)  Service Event (12)  Encounter (10) |
| Study Referral Data (2) | Request |
| History and Risk Factors  Vital Signs (4)  Labs (2)  Problems (14)  Chest Pain (5)  Family History (1)  Tobacco Use (1)  Risk Estimates (6) | History |

*>*

Table 6.3.1.D.4-1: < Document Name Acronym> - Data Element Requirement Mappings to CDA

| Clinical Data Element <source> | < this document acronym> |
| --- | --- |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |

<**Very important note:** From this point forward, the author may select one of two formats to represent the same data. The first format is a tabular format as was implemented in the Cardiology CIRC profile. The advantages to this format include that large amounts of data may be represented more concisely and that it is sometimes visually easier to determine if any information is missing. The second format is more similar to the current Consolidated CDA (C-CDA format). This format may be more verbose but may also be more recognizable to implementers familiar with other HL7 CDA Implementation Guides and may be easier for implementers to design and test with discrete conformance assertions.

The format that you select must be consistent through this supplement (do not mix and match formats). The format changes are identified by ###Begin Tabular format ###End CDA Tabular format and ###Begin Discrete Conformance format ###End Discrete Conformance format. Delete all references to the format which was not selected between the hash marks. Also, a domain may decide on a single format for all new supplements within that domain.>

##### 6.3.1.D.5 <Content Module Name (Acronym, if applicable)> Document Content Module Specification

This section specifies the header, section, and entry content modules which comprise the <Content Module Name (Acronym)> Document Content Module, using the Template ID as the key identifier.

Sections that are used according to the definitions in other specifications are identified with the relevant specification document. Additional constraints on vocabulary value sets, not specifically constrained within the section template, are also identified.

<Authors’ note: A critical understanding of CDA definitions for cardinality, optionality, coded terminology values, and CDA content module structure, as well as IHE CDA formatting conventions is necessary. It is strongly recommended that the author is also conversant with the IHE Technical Frameworks General Introduction Appendix E “Conventions”. >

###Begin Tabular format - Document

Table 6.3.1.D.5-1 <Content Module Name (Acronym)> Document Content Module Specification

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Template Name | | <Template Name (Acronym, if applicable)> | | | |
| Template ID | | <oid/uid> | | | |
| Parent Template | | <Parent Template Name oid/uid [Domain Reference]>  <Parent Template Name oid/uid [Domain Reference]> <delete 2nd/additional parent template if not applicable>  <Enter NA if none> | | | |
| General Description | | <short textual description> | | | |
| Document Code | | <MAY or SHALL> be < code/oid/uid, Code System, “Value Set name”> | | | |
| Opt and Card | Condition | Header Element or Section Name | Template ID | Specification Document | Vocabulary Constraint |
| Header Elements | | | | | |
| x [?..?] |  | <Header Element name> | <oid> | <reference to section of TF or supplement document for details> | <reference to section of TF or supplement document for explanation, if applicable> |
| <e.g., R [0..1] |  | Order | 1.3.6.1.4.1.19376.1.4.1.3.2 | CARD TF-3 6.3.2.H> |  |
| <e.g., M [1..1] |  | Patient Demographics | 1.3.6.1.4.1.19376.1.4.1.3.3 | CARD TF-3 6.3.2.H | CARD TF-3 6.3.1.D.5.1> |
| Sections | | | | | |
| x [?..?] |  | <Section name> | <oid> | <reference to section of TF or supplement document for details> | <reference to section of TF or supplement document for explanation, if applicable> |
| <e.g., M [1..1] |  | Medications | 1.3.6.1.4.1.19376.1.5.3.1.3.19 | PCC TF-2 | CARD TF-3 6.3.1.D.5.2> |
| <e.g., R [1..1] |  | Coded Social History | 1.3.6.1.4.1.19376.1.5.3.1.3.16.1 | CARD TF-3 6.3.3.S | CARD TF-3 6.3.1.D.5.3> |
| <e.g., O [0..1] |  | Physical Examination | 2.16.840.1.113883.10.20.2.10 | CDA-PN> |  |
| <e.g., C [1..1] | CARD TF-3 6.3.1.D.5.4 | DICOM Object Catalog | 1.3.6.1.4.1.19376.1.4.1.2.15 | CDA-PN> |  |

<For each (1:1 correspondence) Vocabulary Constraint or Condition listed in the table above, create an additional section/reference below. Add the Header Element or Section Name and then select either “Vocabulary Constraint” or “Condition” and delete the other word.>

<Note that every Conditional element MUST have an explanatory paragraph referenced below.>

<It is required to use SHALL, SHOULD, or MAY in each definition as defined in Appendix E of the Technical Frameworks General Introduction.>

###### 6.3.1.D.5.1 <Header Element or Section Name> <Vocabulary Constraint or Condition>

<add vocabulary constraint or condition definition>

<remove example below prior to public comment:>

<e.g., The value for serviceEvent / code SHOULD be drawn from value set 1.3.6.1.4.1.19376.1.4.1.5.2 Cardiac Imaging Procedures.

OR

The value for serviceEvent/code SHOULD be drawn from the value set bound to the concept domain UV\_CardiacImagingProcedures.>

###### 6.3.1.D.5.2 <Header Element or Section Name> <Vocabulary Constraint or Condition>

<add vocabulary constraint or condition definition>

<remove example below prior to public comment:>

<e.g., Within the Medications section the Content Creator SHALL be able to create a Medications entry (templateID 1.3.6.1.4.1.19376.1.5.3.1.4.7 [PCC TF-2]) for each of the cardiac relevant medications identified in Value Set 1.3.6.1.4.1.19376.1.4.1.5.14 Cardiac Drug Classes, encoding the value in substanceAdministration/consumable/ManufacturedProduct/Material/code.

OR

Within the Medications section the Content Creator SHALL be able to create a Medications entry (templateID 1.3.6.1.4.1.19376.1.5.3.1.4.7 [PCC TF-2]) for each of the cardiac relevant medications identified in the value set bound to the concept domain UV\_CardiacRelevantMedications, encoding the value in substanceAdministration/consumable/ManufacturedProduct/Material/code.

>

###### 6.3.1.D.5.3 <Header Element or Section Name> <Vocabulary Constraint or Condition>

<add vocabulary constraint or condition definition>

<remove example below prior to public comment:>

<e.g., Within the Allergies and Other Adverse Reactions section the Content Creator SHALL be able to create an Allergies and Intolerances Concern Entry (templateID 1.3.6.1.4.1.19376.1.5.3.1.4.5.3 [PCC TF-2]) for each of the cardiac imaging agent classes identified in Value Set 1.3.6.1.4.1.19376.1.4.1.5.10 Contrast Agents Classes for Adverse Reactions, encoding the value in observation/participant/participantRole/playingEntity/code.

OR

Within the Allergies and Other Adverse Reactions section the Content Creator SHALL be able to create an Allergies and Intolerances Concern Entry (templateID 1.3.6.1.4.1.19376.1.5.3.1.4.5.3 [PCC TF-2]) for each of the cardiac imaging agent classes identified in value set bound to the concept domain UV ContrastAgentsClasses, encoding the value in observation/participant/participantRole/playingEntity/code.

>

###### 6.3.1.D.5.4 <Header Element or Section Name> <Vocabulary Constraint or Condition>

<add vocabulary constraint or condition definition>

<remove example below prior to public comment:>

<e.g., A DICOM Object Catalog Section SHALL be present if other document sections contain references to DICOM SOP Instances (images, structured report measurements, or other information objects), and MAY be present otherwise.>

**###End Tabular Format - Document**

**###Begin Discrete Conformance Format - Document**

*<Delete the example information contained in the material below (from Cardiology CRC)>*

<e.g., The complete set of body constraints, including those from C-CDA section/entry definitions are:

1. SHALL contain exactly one [1..1] **component** (CONF:9588).
   1. A Cath Report Content **SHALL** have a structuredBody (CONF:9589-CRC).
      1. A Cath Report Content **SHALL** conform to CDA Level 3 (structuredBody containing sections that contain a narrative block and coded entries). In this template (templateId 2.16.840.1.113883.10.20.22.1.6), coded entries are optional. (CONF:9590-CRC).
   2. The component/structuredBody SHALL conform to the section constraints below (CONF:9595-CRC).
      1. Each section SHALL have a title and the title SHALL not be empty (CONF:9937).>

<The following table shows relationships among the templates in the body of a Cath Report Content document.>

Table 6.3.1.D.5-1 <Content Module Name (Acronym)> Document Content Module Specification

| Template Title | Opt and Card | Condition | Template Type | templateId | Vocabulary  Constraints |
| --- | --- | --- | --- | --- | --- |
|  |  |  |  |  |  |
| Delete this row and the example information in the rows below. | | | | | |
| <e.g., Cath Report Content | R[1..1] |  | document | 1.3.6.1.4.1.19376.1.4.1.1.2 | 6.3.1.D.5.1 |
| Document Summary-Cardiac Section | O[0..1] |  | Section | 1.3.6.1.4.1.19376.1.4.1.2.16 |  |
| Medical History - Cardiac Section | R[1..1] |  | Section | 1.3.6.1.4.1.19376.1.4.1.2.17 |  |
| Procedure Activity Observation | O[0..\*] |  | Entry | 2.16.840.1.113883.10.20.22.4.13 |  |
| Procedure Activity Procedure | O[0..\*] |  | Entry | 2.16.840.1.113883.10.20.22.4.14 |  |
| Problem Observation - Cardiac | O[0..\*] |  | Entry | 2.16.840.1.113883.10.20.22.4.4 |  |
| Age Observation | O[0..1] |  | Entry | 2.16.840.1.113883.10.20.22.4.31 |  |
| Health Status Observation | O[0..1] | 6.3.1.D.5.2 | Entry | 2.16.840.1.113883.10.20.22.4.5 |  |
| Problem Status | O[0..1] |  | Entry | 2.16.840.1.113883.10.20.22.4.6 |  |
| Severity Observation | O[0..1] |  | Entry | 2.16.840.1.113883.10.20.22.4.8 |  |
| Allergies Section | R[1..1] |  | Section | 2.16.840.1.113883.10.20.22.2.6 |  |
| Allergy Problem Act | O[0..\*] |  | Entry | 2.16.840.1.113883.10.20.22.4.30 |  |
| Allergy Observation | R[1..\*] |  | Entry | 2.16.840.1.113883.10.20.22.4.7 |  |
| Allergy Status Observation | O[0..1] |  | Entry | 2.16.840.1.113883.10.20.22.4.28 |  |
| Reaction Observation | O[0..1] |  | Entry | 2.16.840.1.113883.10.20.22.4.9 |  |
| Severity Observation | O[0..1] |  | Entry | 2.16.840.1.113883.10.20.22.4.8 |  |
| Family History – Cardiac Section | O[0..1] |  | Section | 1.3.6.1.4.1.19376.1.4.1.2.18 |  |
| Problem Observation - Cardiac | O[0..\*] |  | Entry | 2.16.840.1.113883.10.20.22.4.4 |  |
| Social History Section | O[0..1] |  | Section | 2.16.840.1.113883.10.20.22.2.17 |  |
| Physical Exam Section | R[1..1] |  | Section | 2.16.840.1.113883.10.20.2.10 |  |
| Vital Signs | R[1..1] |  | Section | 2.16.840.1.113883.10.20.22.2.4.1 |  |
| Vital Signs Organizer | R[1..\*] |  | Entry | 2.16.840.1.113883.10.20.22.4.26 |  |
| Vital Sign Observation | R[2..\*] |  | Entry | 2.16.840.1.113883.10.20.22.4.27> |  |

<For each (1:1 correspondence) Vocabulary Constraint or Condition listed in the table above, create an additional section/reference below. Add the Header Element or Section Name and then select either “Vocabulary Constraint” or “Condition” and delete the other word.>

<Note that every Conditional element MUST have an explanatory paragraph referenced below.>

<It is required to use SHALL, SHOULD, or MAY in each definition as defined in Appendix E of the Technical Frameworks General Introduction.>

###### 6.3.1.D.5.5 <Template Title name> <Vocabulary Constraint or Condition>

<add vocabulary constraint or condition definition>

<remove example below prior to public comment:>

<e.g., The value for serviceEvent / code SHOULD be drawn from value set 1.3.6.1.4.1.19376.1.4.1.5.2 Cardiac Imaging Procedures.

OR

The value for serviceEvent / code SHOULD be drawn from the value set bound to the concept domain UV\_CardiacImagingProcedures

>

###### 6.3.1.D.5.6 <Template Title name> <Vocabulary Constraint or Condition>

<add vocabulary constraint or condition definition>

<remove example below prior to public comment:>

<e.g., Within the Medications section the Content Creator SHALL be able to create a Medications entry (templateID 1.3.6.1.4.1.19376.1.5.3.1.4.7 [PCC TF-2]) for each of the cardiac relevant medications identified in Value Set 1.3.6.1.4.1.19376.1.4.1.5.14 Cardiac Drug Classes, encoding the value in substanceAdministration/consumable/ManufacturedProduct/Material/code.

OR

Within the Medications section the Content Creator SHALL be able to create a Medications entry (templateID 1.3.6.1.4.1.19376.1.5.3.1.4.7 [PCC TF-2]) for each of the cardiac relevant medications identified in the value set bound to the concept domain UV\_CardiagDrugClasses, encoding the value in substanceAdministration/consumable/ManufacturedProduct/Material/code.

>

**###End Discrete Conformance Format - Document**

##### 6.3.1.D.6 <Document and Acronym Name> Conformance and Example

<This section is the same, independent of whether the tabular or discrete conformance formats were chosen.>

<Describe the conformance of this document in terms of inheritance from other templates. Use the OIDs of those templates for clarity. A complete example of this document MUST be placed on the IHE ftp server as part of the Public Comment process of a Content Module supplement at ftp://ftp.ihe.net/TF\_Implementation\_Material/. The file naming convention for these files should be <Domain Acronym>\_<Profile Acronym>\_CDA-sample\_<version number>.xml where version number is the version number of the profile>.

CDA Release 2.0 documents that conform to the requirements of this document content module shall indicate their conformance by the inclusion of the <templateId> XML elements in the header of the document.

A CDA Document may conform to more than one template. This content module inherits from the *<template name(s) and template ID(s)>* <e.g., CDA-PN, 2.16.840.1.113883.10.20.18.1, and the PCC TF Medical Document, 1.3.6.1.4.1.19376.1.5.3.1.1.1, content modules> and so must conform to the requirements of those templates as well this document specification, *<templateName and templateID>* <e.g., Cardiac Imaging Report template, 1.3.6.1.4.1.19376.1.4.1.1.1>.

A complete example of the <Content Module Name and Acronym> Document Content Module is available on the IHE ftp server at: <indicate location here>.

Note that this is an example and is meant to be informative and not normative. This example shows the <templateId (OIDs)> elements for all of the specified templates.

Add to section 6.3.2 Header Content Modules

### 6.3.2 CDA Header Content Modules

#### 6.3.2.H <Header Element Module Name> Header Content Module

<Authors’ Note: Replicate section 6.3.2.H for each Header Content Module defined in this profile. Number as 6.3.2.H**1**, 6.3.2.H**2**, etc.>

**###Begin Tabular Format - Header**

<Either the Parent Template OR the Header Element may constrain this Header Element, not both. One should be “N/A”.>

<The values in the column “Participations and Act Relationships” must come from the defined terms in the CDA schema. See the IHE Technical Frameworks General Introduction, Appendix E: CDA Conventions.>

Table 6.3.2.H-1 <Content Module Name (Acronym)> Header

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Template Name | | <Template Name> | | | | |
| Template ID | | <oid> | | | | |
| Parent Template | | <Name and oid of parent template or NA> | | | | |
| Header Element | | <CDA Header Elements participant or componentOf or NA>  e.g., componentOf / encompassingEncounter | | | | |
| General Description | | <short textual description. Short paragraph at most.> | | | | |
| Opt and Card | Participation/ Act Relationship | Description | Template | Specification Document | Vocabulary Con-straint |
| x [?..?] | <select from defined part /act relationship terms; App E> | <Header Content description name> | <oid> | <document reference, if applicable> | <Vocab constraint, if applicable> |
|  |  |  |  |  |  |
| <e.g., R [1..1] | RESP | Responsible Party |  | CARD TF-3: 6.3.2.H.1> |  |
| <e.g., R [1..1] | LOC | Health Care Facility |  | CARD TF-3: 6.3.2.H.2> |  |
| <e.g., O [0..1] | REF | Referring Provider |  | CARD TF-3: 6.3.2.H.3> |  |
| <e.g., C [0..1] | ATND | Physician of Record | 2.16.840.1.113883.10.20.6.2.2 | CDA-DIR | CARD TF-3: 6.3.2.H.4> |

*<For each Vocabulary Constraint or Specification Document listed in the table above, create an additional section/reference below. Add the Description Name and then select either “Vocabulary Constraint” or “Spec Document” and delete the other word.>*

*<It is required to use SHALL, SHOULD, or MAY in each definition as defined in Appendix E of the Technical Frameworks General Introduction.>*

*<Also note that the Specification Document link can be a link to an outside document/reference. Do not replicate (cut and paste) sections of other documents into this document since they could become out of sync.>*

##### 6.3.2.H.1 <Description Name> <e.g., Responsible Party> <Specification Document *or* Vocabulary Constraint>

<Describe constraints or other info. This specification may include more information on conditions or cardinality, additions elements, data mappings, or data types, or other information.>

<Delete the example below prior to publishing for Public Comment.>

<e.g., The responsible party element represents only the party responsible for the encounter, not necessarily the entire episode of care.>

<e.g., The responsibleParty element MAY be present. If present, responsibleParty/ assignedEntity SHALL have at least one assignedPerson or representedOrganization element present.>

<e.g., Note: This is identical to CDA-DIR CONF-DIR-67>

<e.g., responsibleParty assignedEntity id SHALL be present with the responsible physician’s identifier.>

<e.g., assignedEntity code SHOULD be present with the responsible physician’s specialty.>

<e.g., assignedEntity MAY include an accreditation element from the **urn:ihe:card** namespace to provide physician accreditation status.>

<e.g., The accreditation element SHALL use the character string (ST) data type.

The accreditation element SHALL appear after the defined elements of the Role class, and before any scoper or player entity elements.>

<e.g., assignedEntity assignedPerson name SHALL be present with the responsible physician’s name.>

##### 6.3.2.H.2 <Description Name> <Specification Document OR Vocabulary Constraint>

##### 6.3.2.H.3 <Description Name> <Specification Document OR Vocabulary Constraint>

**###End Tabular Format – Header**

**###Begin Discrete Conformance Format – Header**

The header for the <*Document Name*> document shall support the following header constraints as noted in this section. Note that this content profile is realm agnostic. These header constraints are based on the C-CDA header constraints but all references to US Realm specific types have been removed.

<An example is provided to demonstrate the desired consistent use and format. Delete this example prior to publication for Public Comment. The statement must be numbered, begin with SHALL/SHOULD/MAY, identify the cardinality using [n..n], the name of the element, and a subitem which describes the value or source of the information.>

<e.g.,

1. SHALL contain exactly one [1..1] **typeId** (CONF:5361).
   1. This typeId SHALL contain exactly one [1..1] **@root**="2.16.840.1.113883.1.3" (CONF:5250).
   2. This typeId SHALL contain exactly one [1..1] **@extension**="POCD\_HD000040" (CONF:5251).
2. SHALL contain exactly one [1..1] **templateId** (CONF:5252) such that it
   1. SHALL contain exactly one [1..1] @root="1.3.6.1.4.1.19376.1.4.1.1.2" for the Cath Report Content document template (CONF:CRC-xxx).
3. SHALL contain exactly one [1..1] **id** (CONF:5363).
   1. This id **SHALL** be a globally unique identifier for the document (CONF:9991).
4. SHALL contain exactly one or two [1..2] **code** (CONF:5253-CRC).
   1. SHALL be selected from ValueSet ProcedureNoteDocumentTypeCodes 2.16.840.1.113883.11.20.6.1 DYNAMIC (CONF:8497). Either or both of the following codes should be included:

|  |  |  |  |
| --- | --- | --- | --- |
| Value Set: ProcedureNoteDocumentTypeCodes 2.16.840.1.113883.11.20.6.1 DYNAMIC  Code System: LOINC 2.16.840.1.113883.6.1 | | | |
| LOINC Code | Type of Service ‘Component’ | Setting ‘System’ | Specialty/Training/Professional Level ‘Method\_Type’ |
| 18745-0 | Study report | Heart | Cardiac catheterization |
| 34896-1 | Interventional procedure note | {Setting} | Cardiology |

1. SHALL contain exactly one [1..1] **title** (CONF:5254).
   1. Can either be a locally defined name or the display name corresponding to clinicalDocument/code (CONF:5255).>

**###End Discrete Conformance Format – Header**

### 6.3.3 CDA Section Content Modules

Add to section 6.3.3.10 Section Content Modules

< Authors’ Note: Replicate section 6.3.3.10.S for each Section Content Module defined in this profile. Number as 6.3.3.10.S**1**, 6.3.3.10.S**2**, etc.>

<Authors’ notes: Section naming instructions: If a section is a specialization of an existing section, begin the name with the original section name. For example, if Cardiology is creating a specialization of the “Medical History Section”, the new section should be named “Medical History Section – Cardiac” and not “Cardiac Medical History Section”.>

**###Begin Tabular Format - Section**

<Delete examples in rows of table below prior to Public Comment.>

#### 6.3.3.10.S <Section Module Name> - Section Content Module

Table 6.3.3.10.S-1 <Section Module Name> Section

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Template Name | | <exact same Section Module name listed above> | | | |
| Template ID | | <oid> | | | |
| Parent Template | | <Parent Template Name oid/uid [Domain - Reference] or NA> | | | |
| General Description | | <brief textual description, one paragraph> | | | |
| Section Code | | <Code, Code Scheme, “Section Code Name”> | | | |
| Author | | <If inherited from encompassing content module use “current recordTarget”, unless otherwise specified. Role and entity must be specified if not inherited. > | | | |
| Informant | | <If inherited from encompassing content module use “current recordTarget”, unless otherwise specified.> | | | |
| Subject | | <If inherited from encompassing content module use “current recordTarget”, unless otherwise specified.> | | | |
| Opt and Card | Condition | Data Element or Section Name | Template ID | Specification Document | Vocabulary  Constraint |
| Subsections | | | | | |
| x [?..?] | <ref or link to cond section below, if applicable> | <name of subsection> | <oid> | <reference or link to specification document location, if applicable> | <reference or link to vocab constraint, if applicable> |
| <e.g., O [0..1] |  | Active Problems | 1.3.6.1.4.1.19376.1.5.3.1.3.6 | PCC TF-3> |  |
| <e.g., O [0..1] |  | History of Present Illness | 1.3.6.1.4.1.19376.1.5.3.1.3.4 | PCC TF-3> |  |
| <e.g., O [0..1] |  | History of Past Illness | 2.16.840.1.113883.10.20.2.9 | CDA-PN> |  |
| Entries | | | | | |
| x [?..?] | <ref or link to cond section below, if applicable> | <name of entry> | <oid> | <reference or link to specification document location, if applicable> | <reference or link to vocab constraint, if applicable> |
| <e.g., C [1..\*] | CARD TF-3 6.3.3.x.S.1 | Problem Concern Entry | 1.3.6.1.4.1.19376.1.5.3.1.4.5.2 | PCC TF-3> |  |
| <e.g., C [1..1] |  | Diabetes Problem Entry | 1.3.6.1.4.1.19376.1.4.1.4.1 | CARD TF-3 6.3.3.1> |  |
| <e.g., C [1..1] |  | Angina Problem Entry | 1.3.6.1.4.1.19376.1.4.1.4.2 | CARD TF-3 6.3.3.1> |  |
| <e.g., C [1..\*] | CARD TF-3 6.3.3.x.S.1 | Simple Observation | 1.3.6.1.4.1.19376.1.5.3.1.4.13 | PCC TF-3 | CARD TF-3 6.3.3.x.S.2> |

##### 6.3.3.10.S.1 <Data Element or Section Name> <Condition, Specification Document, or Vocabulary Constraint>

<Describe constraints; refer to other Specification Document, condition, or other info. This specification may include more information on conditions or cardinality, additions elements, data mappings, or data types, or other information.>

<Delete the example below prior to publishing for Public Comment.>

<e.g., The Medical History Section SHALL contain at least one Problem Concern Entry or at least one Simple Observation.

Note: Problems MAY be recorded directly in the Medical History Section, or in one or more subsections such as Active Problems, History of Present Illness, or History of Past Illness.>

##### 6.3.3.10.S.2 <Data Element or Section Name> <Condition, Specification Document, or Vocabulary Constraint>

<Describe constraints, refer to other Specification Document, condition, or other info. This specification may include more information on conditions or cardinality, additions elements, data mappings, or data types, or other information.>

<Delete the example below prior to publishing for Public Comment.>

<e.g., A Content Creator SHALL be able to include a Problem Concern Entry for each of the conditions identified in Value Set [1.3.6.1.4.1.19376.1.4.1.5.4 Cardiac Problems/Concerns](#_1.3.6.1.4.1.19376.1.4.1.5.4__Cardia), encoding the value in act/entryRelationship/observation/code.

A Problem Concern Entry for {73211009, SNOMED CT, diabetes} SHALL use the specialized Diabetes Problem Entry (OID = 1.3.6.1.4.1.19376.1.4.1.4.1).

A Problem Concern Entry for {194828000, SNOMED CT, angina} SHALL use the specialized Angina Problem Entry (OID = 1.3.6.1.4.1.19376.1.4.1.4.2).

OR

A Content Creator SHALL be able to include a Problem Concern Entry for each of the conditions identified in the Concept Domain UV\_CardiacProblems (See section X.X for the description/list of concepts in this domain), encoding the value in act/entryRelationship/observation/code.

A Problem Concern Entry for “diabetes” SHALL use the specialized Diabetes Problem Entry (OID = 1.3.6.1.4.1.19376.1.4.1.4.1).

A Problem Concern Entry for “angina” SHALL use the specialized Angina Problem Entry (OID = 1.3.6.1.4.1.19376.1.4.1.4.2).

>

##### 6.3.3.10.S.3 <Data Element or Section Name> <Condition, Specification Document, or Vocabulary Constraint>

**###End Tabular Format – Section**

**###Begin Discrete Conformance Format – Section**

<An example is provided to demonstrate the desired consistent use and format. Delete this example prior to publication for Public Comment. The statements must be numbered, begin with SHALL/SHOULD/MAY identify the cardinality using [n..n], the name of the element, and a subitem which described the value or source of the information.>

<e.g.,

#### 6.3.3.10.S Medical History - Cardiac Section 11329-0

[section: templateId 1.3.6.1.4.1.19376.1.4.1.2.17(open)]

[section: templateId 2.16.840.1.113883.10.20.22.2.39(open)]

The Medical History section describes all aspects of the medical history of the patient even if not pertinent to the current procedure, and may include chief complaint, past medical history, social history, family history, surgical or procedure history, medication history, and other history information. The history may be limited to information pertinent to the current procedure or may be more comprehensive. The history may be reported as a collection of random clinical statements or it may be reported categorically. Entries for History of Past Illness and History of Present Illness have been consolidated into this section. Social and Family History are discussed in their own sections. For this Cath Report Content profile, this section may also contain history about specific relevant problems as problem observations.

In the event that the patient was transferred from another facility where there was a problem indication that the patient was determined to need a cath procedure, this will be noted as a problem observation in this medical history section as text in the narrative for now until there is a code representing this.

1. SHALL contain exactly two [2..2] templateId (CONF:8160) such that it
   1. SHALL contain exactly one [1..1] @root="1.3.6.1.4.1.19376.1.4.1.2.17" (CONF:10403-CRC).
   2. SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.22.2.39" (CONF:10403).
2. SHALL contain exactly one [1..1] code/@code="11329-0" Medical (General) History (CodeSystem: LOINC 2.16.840.1.113883.6.1) (CONF:8161).
3. SHALL contain exactly one [1..1] title (CONF:8162).
4. SHALL contain exactly one [1..1] text (CONF:8163).
5. MAY contain zero or more [0..\*] entry (CONF:CRC-xxx) such that it
   1. SHALL contain exactly one [1..1] Problem Observation - Cardiac (1.3.6.1.4.1.19376.1.4.1.4.9) (CONF:CRC-xxx).
6. MAY contain zero or more [0..\*] **entry** (CONF:CRC-xxx) such that it
   1. SHALL contain exactly one [1..1] **Procedure Activity Observation** (2.16.840.1.113883.10.20.22.4.13) (CONF:CRC-xxx).
7. MAY contain zero or more [0..\*] entry (CONF:CRC-xxx) such that it
   1. SHALL contain exactly one [1..1] Procedure Activity Procedure (2.16.840.1.113883.10.20.22.4.14) (CONF:CRC-xxx).

<section>

<templateId root="1.3.6.1.4.1.19376.1.4.1.2.17"/>

<templateId root="2.16.840.1.113883.10.20.22.2.39"/>

<code code="11329-0" codeSystem="2.16.840.1.113883.6.1"

codeSystemName="LOINC"

displayName="MEDICAL (GENERAL) HISTORY"/>

<title>MEDICAL (GENERAL) HISTORY</title>

<text>

<list listType="ordered">

<item>Patient has had a recent issue with chest pain that does not seem to be related to any particular cause.</item>

<item>Previous concerns of heart disease were actually related to other causes.</item>

<item>Patient had recent weight gain due to sedentary lifestyle and

new job.</item>

</list>

</text>

<entry>

<observation classCode=”OBS” moodCode=”EVN”>

<templateId root=”1.3.6.1.4.1.19376.1.4.1.9”/>

<id root=”xyz”/>

…

</observation>

</entry>

</entry>

<observation classCode="PROC" moodCode="EVN">

<templateId root="2.16.840.1.113883.10.20.22.4.14"/>

<!-- Procedure Activity Procedure template -->

...

</observation>

</entry>

</entry>

<observation classCode="OBS" moodCode="EVN">

<templateId root="2.16.840.1.113883.10.20.22.4.13"/>

<!-- Procedure Activity Observation template -->

...

</observation>

</entry>

</section>

Figure Example: Example Section example>

**###End Discrete Conformance Format - Section**

### 6.3.4 CDA Entry Content Modules

Add to section 6.3.4.E Entry Content Modules

#### 6.3.4.E <Entry Content Module Name> Entry Content Module

<Authors’ Note: Replicate section 6.3.4.E for each Entry Content Module defined in this profile. Number as 6.3.4.E**1**, 6.3.4.E**2**, etc.>

<If this entry has subsidiary/child entries, these entries are referenced in the table below. Create one row for each subsidiary/child entry.>

**### Begin Tabular Format - Entry**

Table 6.3.4.E-1 <Entry Module Name> Entry

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Template Name | | | | <Template name> | | | | | | |
| Template ID | | | | <oid> | | | | | | |
| Parent Template | | | | <Parent Template Name oid/uid [Domain - Reference]> or NA | | | | | | |
| General Description | | | | <brief textual description, one paragraph> | | | | | | |
| Class/Mood | | Code | | | | Data Type | Value | | | |
| <use one of defined Class/Mood see General Intro App E> | | <Code, code system, code meaning e.g., 18118-0, LOINC, “LV Wall Motion Segmental Findings”> | | | | <Applies only if the Class/ Mood is OBS/EVN. Enumerated in HL7 V3 Data Types R1.> | <If the Class/Mood is OBS/EVN, then this Value field is the constraint on Observation Value. Otherwise, this field should be “N/A”.> | | | |
| Opt and Card | entryRelationship | | Description | | Template ID | | | Specification Document | Vocabulary Constraint |
| <e.g., x [?..?]> |  | | Simple Observation | | oid | | | reference to document e.g., PCC-TF-3 | <reference/link to definition of constraint, often in next paragraph/ subsection e.g., CARD TF-3 6.3.3.4.9.10> |
| <e.g., C [1..\*] | COMP | | Simple Observation | | 1.3.6.1.4.1.19376.1.5.3.1.4.13 | | | PCC TF-2 | CARD TF-3 6.3.4.E.1 (Wall morphology)> |
| <e.g., O [0..1] | COMP | | Simple Observation | | 1.3.6.1.4.1.19376.1.5.3.1.4.13 | | | PCC TF-2 | CARD TF-3 6.3.4.E.2 (Viability)> |
| <e.g., O [0..1] | COMP | | observationMedia Entry | | 1.3.6.1.4.1.19376.1.4.1.4.7 | | | CARD TF-3 6.3.1.6> |  |

##### 6.3.4.E.1 Simple Observation (wall motion) Vocabulary Constraints

<Describe constraints, refer to other Specification Document, condition, or other info. This specification may include more information on conditions or cardinality, additions elements, data mappings, or data types, or other information.>

<Can be in a tabular format or textual description.>

<Delete the example below prior to publishing for Public Comment.>

<e.g., The conditional entries specified in this table SHALL be present based on the exam type as specified in the CDA Header in the documentationOf / serviceEvent / code element.>

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Opt and Card | Condition | observation/code | Data Type | Unit of Measure | Value Set/  Concept Domain |
| <e.g., C [1..\*] | <Identifies the predicate and the if the predicate evaluates as true, then indicate whether mandatory, required or optional  e.g., Required if “exam type” is “LVG” (left ventriculogram)>  R: LVG | 60797005, SNOMED CT, “Cardiac Wall Motion”  <”+” = May be post-coordinated with priorityCode, methodCode, targetSiteCode . See HL7 V3. Include a value directly or include a link to a value set, if applicable.>  e.g., + targetSiteCode from 1.2.840.10008.6.1.219 DICOM CID 3718 Myocardial Wall Segments in Projection | CD | n/a unless the Data Type is PQ or IVL<PQ> | <include link to value set, e.g., 1.3.6.1.4.1.19376.1.4.1.5.20 Wall motion  OR, include value directly as e.g.,  <The Observation Value may also have a post-coordinated interpretation such as:>  +interpretationCode  +negationInd > |
| <e.g., C [1..\*] | R: SPECT, TTE, TEE, CMR  O:CCTA | 60797005, SNOMED CT, “Cardiac Wall Motion”  + targetSiteCode from 1.2.840.10008.6.1.218 DICOM CID 3717 Myocardial Wall Segments | CD | n/a | UV\_WallMotion > |

##### 6.3.4.E.2 Simple Observation (wall morphology) Constraints

<Describe constraints; refer to other Specification Document, condition, or other info. This specification may include more information on conditions or cardinality, additions elements, data mappings, or data types, or other information.>

<Can be in a tabular format or textual description.>

<Delete the example below prior to publishing for Public Comment.>

<e.g., The conditional entries specified in this table SHALL be present based on the exam type as specified in the CDA Header in the documentationOf / serviceEvent / code element.>

| Opt and Card | Condition | observation/code | Data Type | Unit of Measure | Value Set/  Concept Domain |
| --- | --- | --- | --- | --- | --- |
| <e.g., C [1..\*] | R: Cath with LVG | 72724002, SNOMED CT, “Morphology findings”  + targetSiteCode from 1.2.840.10008.6.1.219 DICOM CID 3718 Myocardial Wall Segments in Projection | CD | n/a | 1.3.6.1.4.1.19376.1.4.1.5.19 Myocardium Assessments> |
| <e.g., C [1..\*] | R: SPECT, echo, CMR  O:CCTA | 72724002, SNOMED CT, “Morphology findings”  + targetSiteCode from 1.2.840.10008.6.1.218 DICOM CID 3717 Myocardial Wall Segments | CD | n/a | UV\_MyocardiumAssessments> |

<e.g., The observation/value MAY be a null flavor.>

<e.g., morphological assessment observation MAY have a subsidiary Severity observation (templateID 1.3.6.1.4.1.19376.1.5.3.1.4.1 [PCC TF-2]).>

**### End Tabular Format - Entry**

**### Begin Discrete Conformance Format – Entry**

<An example is provided to demonstrate the desired consistent use and format. Delete this example prior to publication for Public Comment. The statements must be numbered, begin with SHALL/SHOULD/MAY identify the cardinality using [n..n], the name of the element, and a subitem which described the value or source of the information.>

##### <e.g.,6.3.4.E Result Observation - Cardiac

[observation: templateId 1.3.6.1.4.1.19376.1.4.1.4.16 (open)]

A result observation is a clinical statement that a clinician has noted during the Cath Lab procedure. This entry is used to describe the specific procedure findings that were observed during the specific Cath Lab procedure.

The specific result observations are defined in 1.3.6.1.4.1.19376.1.4.1.5.38 Procedure Findings Constraints/ValueSet.

1. SHALL contain exactly one [1..1] @classCode="OBS" Observation (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6) (CONF:7130).
2. SHALL contain exactly one [1..1] @moodCode="EVN" Event (CodeSystem: ActMood 2.16.840.1.113883.5.1001) (CONF:7131).
3. SHALL contain exactly one [1..1] templateId (CONF:7136) such that it
   1. SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.22.4.2" (CONF:9138).
4. SHALL contain at least one [1..\*] id (CONF:7137).
   1. The first id represents this specific globally unique result observation.
   2. The second id represents the lesion ID which should be an assigned numeric code that identifies lesions within a specific targetSiteCode.This lesion ID is used to link lesion specific data in this Result Observation – Cardiac with Procedure Activity Procedure - Cardiac.
5. SHALL contain exactly one [1..1] code (CONF:7133).
   1. SHOULD be from LOINC (CodeSystem: 2.16.840.1.113883.6.1) or SNOMED CT (Value Set: 1.3.6.1.4.1.19376.1.4.1.5.38) (CONF:7166-CRC).
6. SHOULD contain zero or one [0..1] text (CONF:7138).
   1. The text, if present, SHOULD contain zero or one [0..1] reference/@value (CONF:7139).
      1. This reference/@value SHALL begin with a '#' and SHALL point to its corresponding narrative (using the approach defined in CDA Release 2, section 4.3.5.1) (CONF:9119).
7. SHALL contain exactly one [1..1] statusCode="completed" Completed (CodeSystem: ActStatus 2.16.840.1.113883.5.14) (CONF:7134).
8. SHALL contain exactly one [1..1] effectiveTime (CONF:7140).
   1. represents clinically effective time of the measurement, which may be when the measurement was performed (e.g., a BP measurement), or may be when sample was taken (and measured some time afterwards) (CONF:7141).
9. SHALL contain exactly one [1..1] value with @xsi:type="ANY" (CONF:7143).
10. SHOULD contain zero or more [0..\*] interpretationCode (CONF:7147).
11. MAY contain zero or one [0..1] methodCode (CONF:7148).
12. MAY contain zero or one [0..1] targetSiteCode (CONF:7153).
    1. The targetSiteCode, if present, SHALL contain exactly one [1..1] code where the @code SHALL be selected from ValueSet Body Site 1.3.6.1.4.1.19376.1.4.1.5.32 STATIC (CONF:CRC).
13. MAY contain zero or one [0..1] author (CONF:7149).
14. SHOULD contain zero or more [0..\*] referenceRange (CONF:7150).
    1. The referenceRange, if present, SHALL contain exactly one [1..1] observationRange (CONF:7151).
       1. This observationRange SHALL NOT contain [0..0] code (CONF:7152).
15. SHOULD contain zero or one [0..1] entryRelationship (CONF:CRC-xxx) such that it
    1. SHALL contain exactly one [1..1] @typeCode="SUBJ" Has subject (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002) (CONF:CRC-xxx).
    2. SHALL contain exactly one [1..1] @inversionInd="true" TRUE (CONF:CRC-xxx).
    3. SHALL contain exactly one [1..1] Severity Observation (2.16.840.1.113883.10.20.22.4.8) (CONF:CRC-xxx).

<observation classCode="OBS" moodCode="EVN">

<templateId root="1.3.6.1.4.1.19376.1.4.1.4.16"/>

<!-- Result Observation template -->

<id root="c6f88321-67ad-11db-bd13-0800200c9a66"/>

<!-- This second ID represents the lesion ID -->

<id root="107c2dc0-67a5-11db-bd13-0800200c9a66" extension="1"/>

<code code="233970002"

codeSystem="2.16.840.1.113883.6.96"

codeSystemName="SNOMED CT"

displayName="Post procedure stenosis"/>

<text><reference value="1"/></text>

<statusCode code="completed"/>

<effectiveTime value="19991114"/>

<targetSiteCode code="41879009" codeSystem="1.3.6.1.4.1.19376.1.4.1.5.32"

displayName="Distal RCA"/>

<value xsi:type="PQ" value="0" unit="%"/>

<interpretationCode code="N" codeSystem="2.16.840.1.113883.5.83"/>

</observation>

e.g., Figure 6.3.4.E-1: Result observation example >

**### End Discrete Conformance Format - Entry**

## 6.4 Section not applicable

Not applicable

<This heading is not currently used in a CDA document and remains here for section numbering integrity. Do not remove it or renumber sections following it. >

Add to Section 6.5 Value Sets

## 6.5 <Domain Acronym> Value Sets and Concept Domains

<Replicate the Value Set 6.5.x section as many times as needed for this supplement.>

<It is preferable to use tabular format. Add notes as needed. Be aware of potential national licensing issues of coding schemes.>

### 6.5.x <Value Set Name/Concept Domain Name> <oid>

<Add description or clarifications here if necessary.>

|  |  |
| --- | --- |
| Coding Scheme  Concept | <Coding Scheme Name> |
|  |  |
|  |  |
|  |  |
|  |  |

Note: <as necessary, applicable>

OR

|  |
| --- |
| <Concept Domain Name> |
|  |
|  |
|  |
|  |

<Delete the example below prior to publication for Public Comment.>

### <e.g.,6.5.1 Drug Classes Used in Cardiac Procedure 1.3.6.1.4.1.19376.1.4.1.5.15

| Coding Scheme  Concept | SNOMED CT | NDF-RT |
| --- | --- | --- |
| Calcium channel blockers | 48698004 | N0000029119 |
| Beta-blockers | 33252009 | N0000029118 |
| Nitrates | 31970009 | N0000007647 |
| Aminophylline | 55867006 | N0000146397 |

Note: As described in Section 6.1.2.4, the selection of the appropriate coding system for use may be based on local policy or national regulation.

OR

### 6.5.1 UV\_CardiacProcedureDrugClasses

This Concept Domain holds a list of Drug Classes used in Cardiac Procedures. The concepts in this domain must be bound to a value set at implementation.

|  |
| --- |
| Concept Name |
| Calcium channel blockers |
| Beta-blockers |
| Nitrates |
| Aminophylline |

>

Appendices

*<Add any applicable Volume 3 appendices below.*

*<If there are no Volume 3 appendices, enter “Not applicable” and delete the Appendix A and Appendix B placeholder sections.>*

# Appendix A – <Appendix Title>

Appendix A text.

## A.1 <Title>

Appendix A.1 text.

### A.1.1 <Title>

Appendix A.1.1 text.

# Appendix B – <Appendix Title>

Appendix B text.

## B.1 <Title>

Appendix B.1 text.

### B.1.1 <Title>

Appendix B.1.1 text.

Volume 4 – National Extensions

Add appropriate Country section

# 4 National Extensions

4.I National Extensions for <Country Name or IHE Organization>

<A template for Volume 4 is included in this document for completeness; however, National Extensions are typically developed after a profile has been published for Trial Implementation. If you are developing a new profile for Public Comment, it is recommended that this section be marked “Not Applicable”.>

<Avoid using this section if you can, this is “only if absolutely necessary”. Differences add cost to implementation and testing and can reduce interoperability. Review carefully to determine if the national use case truly requires a difference in the profile mechanisms rather than just differences in system configuration.>

< National Extensions can add requirements above and beyond IHE, but **not** relax requirements. This would prevent Connectathon results based on national testing being recognized elsewhere. For more information, see <http://wiki.ihe.net/index.php?title=National_Extensions_Process>.>

The format of this section is not strongly specified due to the varying nature of national extensions. For an example of National Extensions, see RAD TF 4.>

4.I.1 Comment Submission

This national extension document was authored under the sponsorship and supervision of <sponsor name>, who welcome comments on this document and the IHE <country> initiative. Comments should be directed to:

<Name, organization, title, email address>

4.I.2 <Profile Name> <(Profile Acronym)>

<Add info or tables>

4.I.2.1<Profile Acronym> Value Set Binding for <Country Name or IHE Organization> Realm Concept Domains

*<This section defines the actual value sets and code systems for any coded concepts that were described by concept domains in the main profile and binds the value set to the coded concepts.>*

*<Add info or tables>*

*<Delete the example below prior to publication for Public Comment.>*

*<e.g.,*

4.I.2.1 <Profile Acronym> Value Set Binding for US Realm Concept Domains

| UV Concept Domain | US Realm Vocabulary Binding or Single Code Binding | Value Set OID |
| --- | --- | --- |
| UV\_CardiacProcedureDrugClasses | US\_CardiacProcedureDrugClasses | 1.3.6.1.4.1.19376.1.4.1.5.15 |

#### 4.I.2.1.1 US\_CardiacProcedureDrugClasses (1.3.6.1.4.1.19376.1.4.1.5.15)

|  |  |  |
| --- | --- | --- |
| Coding Scheme  Concept | SNOMED CT | NDF-RT |
| Calcium channel blockers | 48698004 | N0000029119 |
| Beta-blockers | 33252009 | N0000029118 |
| Nitrates | 31970009 | N0000007647 |
| Aminophylline | 55867006 | N0000146397 |

>

4.I.2.2<Profile Acronym> <Type of Change>

<Add info or tables>

4.I+1 National Extensions for <Country Name or IHE Organization>

<Repeat (and increment) the section above as needed for additional National Extensions>

Appendices

*<Add any applicable Volume 4 appendices below>*

*<If there are no Volume 4 appendices, enter “Not applicable”* *and delete the Appendix A and Appendix B placeholder sections.>*

# Appendix A – <Appendix Title>

Appendix A text.

## A.1 <Title>

Appendix A.1 text.

### A.1.1 <Title>

Appendix A.1.1 text.

# Appendix B – <Appendix Title>

Appendix B text.

## B.1 <Title>

Appendix B.1 text.

### B.1.1 <Title>

Appendix B.1.1 text.