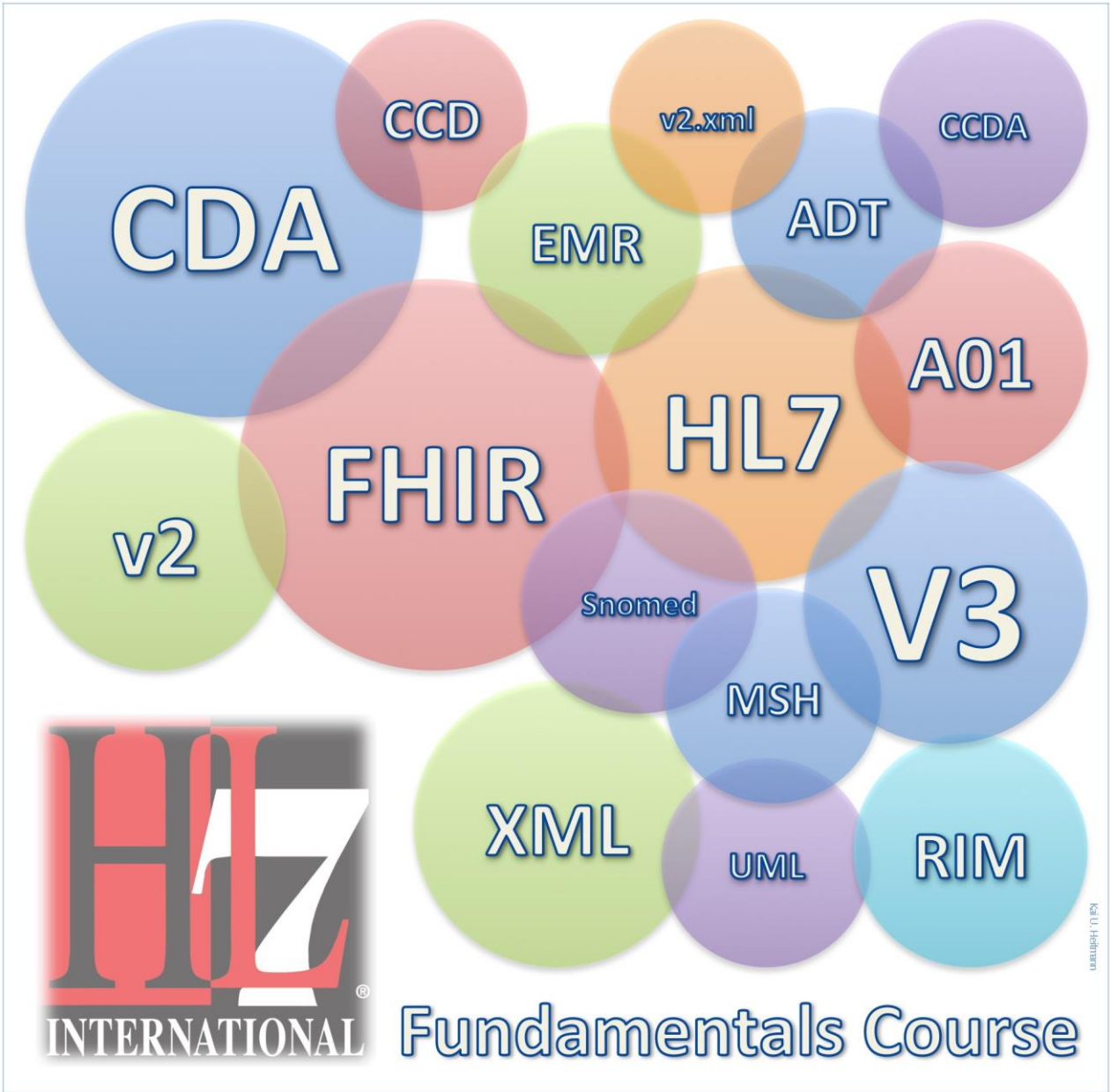


CDA Module, Unit 3:

CDA R2 Implementation Guides

Reading Material

Table of Contents

Unit Content and Learning Objectives

Through this unit we will explore the need for CDA R2 Implementation Guides (IG), review what a CDA R2 IG covers and look at some example guides.

Note: In the content of this Unit, we will use the terms CDA and CDA R2 as having the same meaning.
You should be aware that there was a previous CDA R1 (Release 1) specification. So whenever we refer to "CDA" we are specifically talking about CDA R2 (Release 2).

1. Why do we need CDA R2 Implementation Guides?

The CDA R2 specification is **generic** and **adaptable,** and due to this flexibility and level of abstraction, the fact that a given document is **conformant** to the CDA R2 standard **does not** necessarily imply it **satisfies a given requirement**.

The '**given requirements**' in question are diverse and depend on the community of use and the scope and business rules of a specific implementation or large-scale rollout.

Most (if not all) examples have their own scope and business rules, for example:

- Shared electronic health record in British Columbia, Canada
- Laboratory Report Exchange in Sao Paulo, Brazil
- Exchange of Radiology Reports and Images for the State of California, USA
- Electronic Prescription in the Netherlands

An implementation guide constrains the CDA R2 specification to ensure that the exchanged CDA R2 instances are aligned with the business requirements of a given interoperability scenario.

However, a CDA R2 instance received through any electronic exchange can at least be **rendered in any web browser without losing context** about the act (who participated / when it occurred / where it done / what was done / why it was done) and **without losing the narrative content**.

CDA implementation guides also allow us to define ADDITIONAL constraints, such as:

- What **kind of documents** can be exchanged and **when**?
- Which **institutions** are expected to be exchanging documents and about which specific **patient domain** (this is called the 'affinity domain')?
- Which are the **mandatory and optional sections** of the exchanged documents?
- How should we format the **narrative text for each section** (e.g. table, lists, etc.)?
- Which **coded information** and/or **controlled vocabularies** should the sections contain ICD-9 diagnostic codes, ACR codes, LOINC laboratory test codes, SNOMED CT clinical findings, etc.
- Which **standardized RIM-based structures** should be used for each entry?

Once you have a CDA R2 document, making it compliant with a specific implementation guide is typically only an additional step forward, as we can see in Figure 1 below:

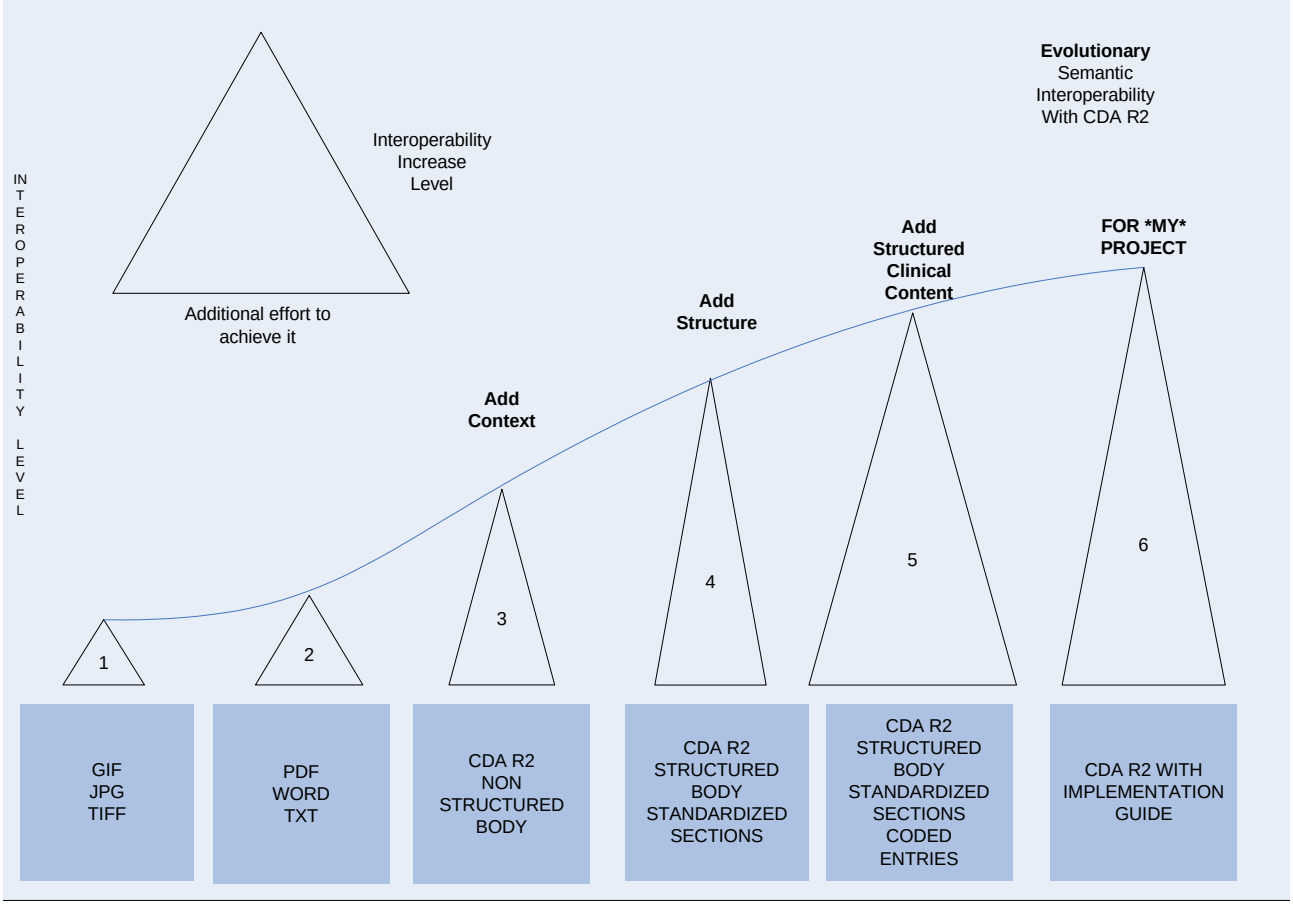


Figure 1: CDA R2 Evolutionary Semantic Interoperability

2. CDA R2 Implementation Guide Contents

A CDA R2 Implementation Guide (IG) should cover the following:

1. Scope and Requirements ('scope' and 'business rules')
2. Textual expression of constraints
3. Processable expression of constraints
4. References to standards and templates used (HL7 or other)
5. CDA R2 full instance and/or fragment examples
6. External and internal vocabularies used/allowed
7. Use of registries (OIDs)
8. Specific extensions

Let's look at some details and examples of each of these sections of a CDA R2 IG.

Scope and Requirements

This section should briefly define the scope and the business requirements for the CDA R2 instances needed to be exchanged (i.e. kind of documents, acts being documented, high-level business definitions, etc.)

Here are three examples:

Example 1 - fragment excerpted from HL7 Standard for CDA Release 2 Consultation Notes Levels 1, 2 and 3 (U.S. Realm):

> This standard specifies constraints on CDA R2 for Consultation Notes. It re-uses section and entry-level templates created for CCD and for the History and Physical DSTU.
>
> For the purpose of this implementation guide, a consultation visit is defined by the evaluation and management billing guidelines for a consultation established by the Centers for Medicare and Medicaid Services (CMS). According to those guidelines, a Consultation Note must be generated as a result of a physician or non-physician practitioner's (NPP) request for an opinion or advice from another physician or NPP. Consultations must involve face-to-face time with the patient.
>
> A Consultation Note must be provided to the referring physician and must include the history of present illness, physical examination, and decision-making component (assessment and plan).

Example 2 - Fragment excerpted from AIS0005 Laboratory Results Attachment:

> Additional Information Specifications (AIS) are used to convey information associated with a specific business purpose. AIS's are used to convey clinical and non-clinical additional information to support other health care transactions, such as the X12 837 claims and the X12 278 Health Care Services Review.
>
> This Laboratory Results Attachment is used to convey information about the results of examinations of blood, tissue and body fluids.
>
> When this attachment is used for a HIPAA transaction, please refer to the "definition" sub-section of the Claims Attachment Final Rule in the Federal Register for the HIPAA regulated standard definition of Laboratory Results.

Example 3 - fragment excerpted from IHE IG for Emergency Department Encounter Summary (EDES):

> Emergency Department Encounter Summary (EDES) is a summary of the patient's current health status and a summary of care rendered in the ED between arrival and ED departure. The EDES is not (yet) intended to replace the ED Chart as a complete, legal document of care, but is intended as a collection of medical summaries with focused scope that can be used to fulfill a number of collaborative transfers of care. The Emergency Department Encounter Summary may include links to diagnostic tests performed during the ED encounter, as well as documentation of an initial Emergency Department Referral (a 2006 IHE work product), prehospital (EMS) records (IHE roadmap 2008), and the consultations of other providers.

Textual Expression of Constraints

Constraints can be defined with varying levels of optionality.

A textual expression of these levels of constraints is written using these consistent 'keywords':

- If something is Required or **Mandatory**:
- **SHALL** (mandatory inclusion)
- **SHALL NOT** (mandatory exclusion)
- For Best Practice or **Non Mandatory** items**:**
- **SHOULD** (recommended inclusion)
- **SHOULD NOT** (recommended exclusion)
- For Acceptable or **Permitted** items
- **MAY** (acceptable inclusion)
- **NEED NOT** (acceptable exclusion)

CDA R2 constraints can be defined at different levels through the CDA R2 structure, and they can be numbered or labeled (for instance CONF-1, CONF-2, etc.) to allow referencing when tracing issues in a given instance.

In order to facilitate reading the guide, it is good to group all constraints about a given element in the same section.

Constraints on the Header

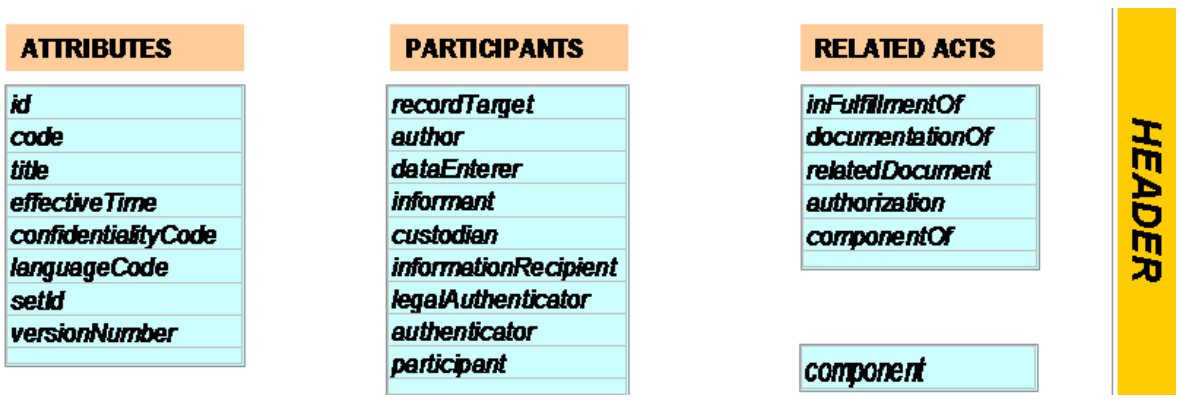


Figure 2: Constraints defined for the CDA R2 Header

Mandatory or suggested header elements: the constraint may indicate that some of the CDA R2 elements (other than the mandatory elements defined by the CDA specification) MUST be present.

Mandatory content or format in the elements: precisely describing the mandatory or optional contents of certain elements: address, phones, names, etc.

Specific use of identifiers or controlled vocabulary: prescribing the use of certain codes or code systems for sections, or the use of specific domain identifiers for persons or organizations.

Examples of mandatory or suggested header elements:

- "the **InFullfillmentOf** element **SHALL** be present, and include the id and code for the ordered service"
- "the **informationRecipient** element **SHOULD be present,** containing full contact information for the referring physicians for each laboratory order"
- "CCD **SHALL** contain one or more **ClinicalDocument /templateId** elements"
- "CCD SHALL contain exactly one ClinicalDocument /languageCode element"
- "CCD SHALL contain one or more ClinicalDocument /author/assignedAuthor/assignedPerson and/or ClinicalDocument/author/assignedAuthor/ representedOrganization"
- "Other references to the same entity (a person or organization) in the same or different role **NEED NOT** fully specify the actor information, provided they include the same entity identifier"
- "The guardian element should be present when the patient is a minor child"

Examples of constraints on content or format of header elements:

- "All elements containing addresses (element addr) for represented organizations **SHALL** contain: street name and number, city, state, postal code, and country."
- "Times specified in clinical documents **MAY** be specified with a precision in fractional seconds, and **MAY** contain a time zone offset."
- The **effectiveTime** element **SHOULD** contain both a low and a high element.

Here are some examples of specific use of vocabulary and identifiers:

- "The value for **ClinicalDocument/code SHALL** be 34133-9- Summarization of episode note from the 2.16.840.1.113883.6.1 LOINC coding system."

"The **inFulfillmentOf** element **SHALL** be present. They are the prior orders that are fulfilled (in whole or part) by the service events described in this document. For example, the prior order might be an order for a consult, and this consult note would be in fulfillment of that order. Since the order that is fulfilled would most likely be coming from another facility or organization, the root and extension for that organization and order **SHOULD** be used if it is known. However, the root of the ordering facility may not be known. In that case, the order **MAY** consist of the order number from the ordering facility as the extension and an OID that defines externally created order numbers as the root. In all cases, the original order SHOULD be used as the extension"

- "The root element for the **recordTarget/ providerOrganization/id** SHALL be "2.16.840.1.113883.10.99"."The LOINC code identifying the type of document as a (potentially) multidisciplinary laboratory report (presenting results from any specialties) is: 11502-2 from the LOINC codeSystem"

Constraints on the Body

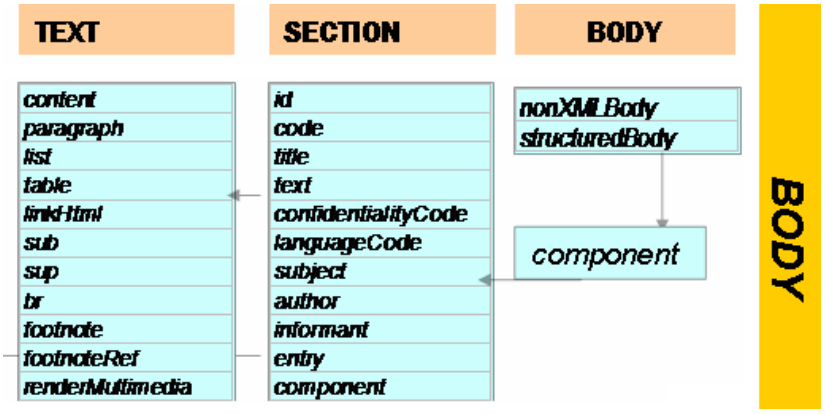


Figure 3: Constraints defined for the CDA R2 Body

Mandatory or recommended sections: the constraint may indicate that some of the sections are mandatory or recommended.

Mandatory content or format for the narrative text in the sections: precisely describing the mandatory or optional specific format for some sections: using tables, lists, paragraph or any other narrative text construct.

Examples of Mandatory or Recommended Sections:

Example 4 - fragment excerpted from HL7/ACR's "Implementation Guide for CDA Release 2 - Diagnostic Imaging Report":

> Required Sections
> A Diagnostic Imaging Report SHALL contain sections that provide the following information:
> Findings - LOINC 18782-3
> ...
> Conditionally-Required Sections
> A Diagnostic Imaging Report SHALL contain the following sections if their respective requirement conditions are met:
> DICOM Object Catalog - DCM 121181

Example 5 - fragment excerpted from HL7's "Implementation Guide for CDA Release 2 - Consultation Notes Levels 1, 2 and 3 (U.S. Realm)":

> A Consult Note SHALL contain exactly one Physical Examination section

Example 6 - fragment excerpted from HL7's "Implementation Guide for CDA Release 2 - Consultation Notes Levels 1, 2 and 3 (U.S. Realm)":

> A Consultation Note SHALL contain exactly one and SHALL NOT contain more than one Past Medical History section. The Past Medical History section SHALL contain a narrative block, and SHOULD contain clinical statements.

Example 7 - fragment excerpted from HL7/ASTM's "CCD":

> CCD SHOULD contain exactly one and SHALL NOT contain more than one Problems section (templateId 2.16.840.1.113883.10.20.1.11). The Problems section SHALL contain a narrative block, and SHOULD contain clinical statements..

Some examples of Mandatory content or format for the narrative text in the sections:

Example 8 - fragment excerpted from HL7's "Implementation Guide for CDA Release 2 - Consultation Notes Levels 1, 2 and 3 (U.S. Realm)":

> "**section / title SHOULD** be valued with a case-insensitive, language-insensitive text string containing "alert" and / or "allergies and adverse reactions."

Example 9 - fragment excerpted from IHE's "IHE Laboratory Technical Framework 2006-2007":

> The narrative block contains:
> - Zero or more initial paragraph delivering contextual information on the battery: Pertinent information. Reason for ordering this battery. Information related to the specimen (specimen observation, specimen collection procedure, specimen target site). Method used by the battery (if it is common to all the tests belonging to it). 905 Name and phone of the verifier of the results, with date of validation...etc
> - a **MANDATORY** table with the test results belonging to the battery. The following columns **MAY** be used:
> o Name of analyte.
> o Method
> o Unit
> o Current observation with the date/time of specimen collection as header. This column is emphasized with Bold styleCode.
> o Reference to footnote comments (footnoteRef if any comments accompany some of the observations)
> o Reference range
> o Criteria for reference range

Constraints Defined for the CDA R2 Entries

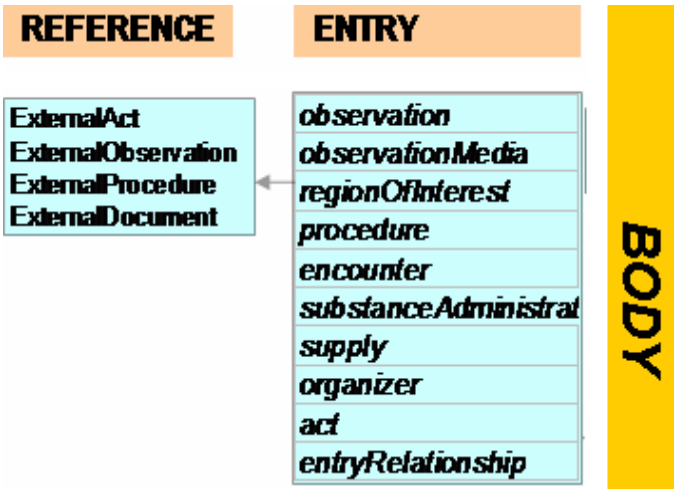


Figure 4: Constraints defined for the CDA R2 Entries

Mandatory or recommended coded entries: the CDA IG can mandate the use of some coded entries to represent in a computable manner some of the narrative text.

Mandatory or recommended content, structure and/or vocabulary for coded entries: allowing the definition of the specific RIM structure and controlled HL7 (or external) vocabulary required for proper processing of the entries.

Examples of Mandatory or Recommended Coded Entries:

Example 10 - fragment excerpted from HL7/ACR's "Implementation Guide for CDA Release 2 - Diagnostic Imaging Report":

> Coded Elements: Text entries may be present, and if present, shall contain the same text content as the Section.text. A Text entry is required if the findings in the section text are represented as inferred from report observations. If a text entry is present, the entry SHALL have the same text content as the Section.text. The entry's observation.text element SHOULD avoid replication of the text content by including it as a <reference> to tagged <content> in the Section.text.

Example 11 - fragment excerpted from HL7/ACR's "Implementation Guide for CDA Release 2 - Diagnostic Imaging Report":

> Report Observations: Report Observations may be present as Entries, enclosed in <entry> ... </entry> or as supporting observations in Text or Code entries, enclosed in <entryRelationship

Example 12 - fragment excerpted from HL7/ASTM's CCD:

> CCD-CONF-238: A social history observation (templateId 2.16.840.1.113883.10.20.1.33) SHALL be represented with Observation.
>
> CCD-CONF-239: The value for "Observation / @classCode" in a social history observation SHALL be "OBS" 2.16.840.1.113883.5.6 ActClass STATIC.
>
> CCD-CONF-240: The value for "Observation / @moodCode" in a social history observation SHALL be "EVN" 2.16.840.1.113883.5.1001 ActMood STATIC.
>
> CCD-CONF-241: A social history observation SHALL contain at least one Observation / id.
>
> CCD-CONF-242: A social history observation SHALL include exactly one Observation / statusCode.
>
> CCD-CONF-243: The value for "Observation / statusCode" in a social history observation SHALL be "completed" 2.16.840.1.113883.5.14 ActStatus STATIC.
>
> CCD-CONF-244: The value for "Observation / code" in a social history observation SHOULD be selected from LOINC (codeSystem 2.16.840.1.113883.6.1) or SNOMED CT (codeSystem 2.16.840.1.113883.6.96), or MAY be selected from ValueSet 2.16.840.1.113883.1.11.20.18 SocialHistoryTypeCode STATIC 20061017.
>
> CCD-CONF-245: Observation / value can be any datatype. Where Observation / value is a physical quantity, the unit of measure SHALL be expressed using a valid Unified Code for Units of Measure (UCUM) expression.
>
> CCD-CONF-246: A social history observation SHALL contain one or more sources of information, as defined in section 5.2 Source.
>
> CCD-CONF-247: A social history observation MAY contain exactly one social history status *observation.
>
> CCD-CONF-248: A social history status observation (templateId 2.16.840.1.113883.10.20.1.56) SHALL be a conformant status observation (templateId 2.16.840.1.113883.10.20.1.57) (as defined in section 5.1 "Type" and "Status" values).
>
> CCD-CONF-249: The value for "Observation / value" in a social history status observation SHALL be selected from ValueSet 2.16.840.1.113883.1.11.20.17 SocialHistoryStatusCode STATIC 20061017.

3. Computable Expression of Constraints

The textual expression of the constraints are complemented with system computable expressions of the same constraints in order to validate **conformance** of a given XML instance to a CDA R2 IG.

For each of the constraints that is system computable (or processable), it is good practice to include the xPath expression to the actual element(s) involved, and a minimal and/or full XML example.

CDA R2 constraints can be defined at different levels through the CDA R2 structure, and they can be numbered or labeled (for instance CONF-1, CONF-2, etc.) to allow referencing when tracing issues in a given instance.

Usually, first level of validation is achieved using the CDA Schema. If the document passes, then we can generally assume it's a valid CDA R2 document.

However, this is not always the case, as discussed in this whitepaper:
www.ringholm.de/docs/03020_en_HL7_CDA_common_issues_error.htm

Once the CDA R2 instance is XML Schema valid, additional validation can be performed through a set of rules built using Schematron (or other similar rule-based systems). More details about Schematron can be found in the additional reading material of the XML unit of the Introductory Module of this Course. For almost every narrative restriction we can build a Schematron assertion (if the constraint can be expressed using an xPath).

Assertions are grouped into RULES, which bring context (i.e. an xPath expression pointing to a specific element or group of elements) to the group of assertions.

An example of this can be found in the CCD IG rules. The **textual** expression for the group of constraints is as follows:

A result observation (templateId 2.16.840.1.113883.10.20.1.31) SHALL be represented with Observation.
The value for "Observation / moodCode" in a result observation SHALL be "EVN"
2.16.840.1.113883.5.1001 ActMood STATIC.
A result observation SHALL contain at least one Observation / id.
A result observation SHALL contain exactly one Observation / statusCode.
A result observation SHALL contain exactly one Observation / code.
A result observation SHALL contain exactly one Observation / value.

The **computable** expression for this group of constraints is as follows:

```
<rule
 context='*[cda:templateId/@root="2.16.840.1.113883.10.20.1.31"]'>
 <assert test="self::cda:observation">A result observation must be
      represented with the observation.</assert>
 <assert test="@moodCode='EVN'">The value for "Observation /
      moodCode" in a result observation SHALL be EVN. </assert>
 <assert test="cda:id">A result observation SHALL contain at least
      one Observation / id.</assert>
 <assert test="count(cda:statusCode)=1">A result observation SHALL
      contain exactly one Observation / statusCode.</assert>
```

```
  <assert test="count(cda:code)=1">A result observation SHALL contain
       exactly one Observation / code.</assert>
  <assert test="count(cda:value)=1">A result observation SHALL contain
       exactly one Observation / value</assert>
</rule>
```

Note 1: We say that schematron rules are computable because there is software to transform sets of schematron rules (called patterns) into a single XSLT. So the process to validate a CDA R2 instance XML is as easy as rendering the XML file with the resulting XSLT "rules". This process will result in a list of additional assertions being applied to our CDA R2 instance - to ensure these elements are conformant to our implementation guide.

Note 2: You may have noticed that we haven't mentioned one element yet during this unit: ***templateId****. This element will be covered later.*

4. References to Standards and Templates Used (HL7 or other)

Overview

The CDA Implementation Guide should include a reference to all standards and/or external templates used.

Example - Fragment of IHE-LAB IG:

1.3 References

- "Clinical Document Architecture Release 2" CDA R2 (from HL7 V3 normative edition)
- HL7 V3 "Laboratory" Domain (from May 2006 Ballot)
- HL7 V3 "Specimen" Domain (from May 2006 Ballot)
- XDS Integration Profile in IHE Infrastructure Technical Framework: The laboratory report is produced by a Content Creator Actor, shared in a Document Repository and registered in a Document Registry for further access by Content Consumer Actors.
- NAV Integration Profile in IHE Infrastructure Technical Framework: At time of registration in the Document Registry, the laboratory report may be notified by the Notification Sender coupled with Content Creator to a Notification Receiver coupled with Content Consumer.
- XDR (Cross-Enterprise Document Reliable Interchange), supplement 2006 of the IHE Infrastructure Technical Framework. A laboratory report may be interchanged by email, using the XDR profile.
- XDM (Cross-Enterprise Document Media Interchange), supplement 2006 of the IHE Infrastructure Technical Framework. A laboratory report may be interchanged using a CD, a USB key, using the XDM profile.
- PCC (Patient Care Continuity) Technical Framework
- LSWF Integration Profile in IHE Laboratory Technical Framework: The Content Creator Actor issuing the laboratory report may be coupled with either an Order Filler Actor (in

CDA R2 Full Instance and/or Fragment Examples

For examples, it is considered good practice to:

- include a CDA R2 instance conformant with your CDA R2 IG, with all elements populated representing a COMPLETE EXAMPLE.
- include a CDA R2 instance compliant with the CDA R2 IG, with all MANDATORY elements populated. This is a MINIMUM CONFORMANT EXAMPLE.
- include fragments of all elements of interest along with the expression of the textual constraints.

External and Internal Vocabularies Used/Allowed

For vocabularies, it is considered good practice to:

- Include as an Appendix, tables with all the vocabularies (value sets and code systems) used by the CDA IG.

- Include references to all external vocabularies used by the CDA IG.
- Include validation of the vocabularies used (only if possible using Schematron rules, etc.)

Use of Registries (OIDs)

It is also good practice to include as an Appendix all registered OIDs used by the CDA IG (if possible).

Extensions

Should you need to define local element extensions (always in an XML namespace different from CDA R2's namespace) then include the local extension definition in your implementation guide.

Example - Definition of extensions in IHE-LAB IG:

10.4 statusCode of the documented serviceEvent in the header

This profile supports the sharing of both final and preliminary reports. To distinguish between the two, the `statusCode` element has been added to the `documentationOf/serviceEvent` element. A preliminary report documents a `serviceEvent` in the status "active" whereas as final report document a "completed" `serviceEvent`.

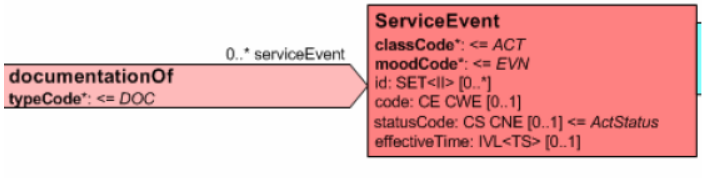


Figure 10-3: StatusCode added to serviceEvent in the header

Example of a preliminary laboratory report:

```
<ClinicalDocument xmlns="urn:hl7-org:v3"
        xmlns:lab="urn:oid:1.3.6.1.4.1.19376.1.3.2"
        xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance">
....
    <documentationOf>
        <serviceEvent>
            <lab:statusCode code="active">
            <effectiveTime value="200603210630"/>
            <performer>
                ...
```

5. The Use of Templates

Implementation Guides have a textual expression and a computable expression for constraints: a schematron or style-sheet.

However, creating these guides is intensive and to make this task easier and productive, we can use TEMPLATES.

What is a Template?

Templates allow us to define partial and reusable structures for document validation - and of course for document creation purposes. These structures can be included in several implementation guides. The Template is an identifier to a set of rules (ie XML Schema and/or Schematron etc) that must be applied to that XML section of the CDA document.

These definitions can be generated at the DOCUMENT LEVEL, HEADER ELEMENT LEVEL, SECTION LEVEL and ENTRY LEVEL for CDA R2.

How do we declare Conformance to a given Template at the Document Level?

We declare conformance at the document level by including the **templateId** element after the fixed **typeId** element in our CDA R2 instance.

For example, to declare conformance to the CCD IG, we would include the **templateId** element:

```
<ClinicalDocument xmlns='urn:hl7-org:v3'>
  <typeId extension='POCD_HD000040' root='2.16.840.1.113883.1.3'/>
  <templateId root='2.16.840.1.113883.10.20.1'/>
  ...
</ClinicalDocument>
```

How do we Declare Conformance to a given Template at the Header Element Level?

We declare conformance at any CDA R2 header element level by including the **templateId** element as the first child element of the header element.

For example, to declare conformance to a specific way of including patient names in a CDA R2 document (one given, one family and one suffix), we should include the **templateId** element inside the patient element:

```
<patient>
<templateId root="2.16.840.1.113883.2.19.12"/>

        <name>
          <given>Adam</given>
          <family>Everyman</family>
          <suffix>the 2nd</suffix>
        </name>
```

```
...
</patient>
```

How do we declare Conformance to a given Template at the Section Level?

We declare conformance at the section level by including the **templateId** element as the first child element of the section element.

For example, to declare conformance to the Vital Signs section defined by the EDES IHE Implementation Guide, we would include the **templateId** element inside the section element:

```
<component>
 <section>
  <templateId root='1.3.6.1.4.1.19376.1.5.3.1.3.25'/>
    <!-- Required Vital Signs Section content -->
 </section>
</component>
```

How do we declare Conformance to a given Template at the Entry Level?

We declare conformance at the entry level by including the **templateId** element as the first child element of the entry element.

```
<entry>
<observation>
  <templateId root='1.3.6.1.4.1.19376.1.5.3.1.1.10.4.1'/>
</observation>
</entry>
```

Creating templates will take effort in the first instance, but in subsequent CDA IG's the defined templates can be reused as they typically reuse the same patterns. CDA IGs can be developed using a collection of templates applied to a given scenario. Conformant CDA XML instances can be created by assembling the valid structures based on the defined templates.

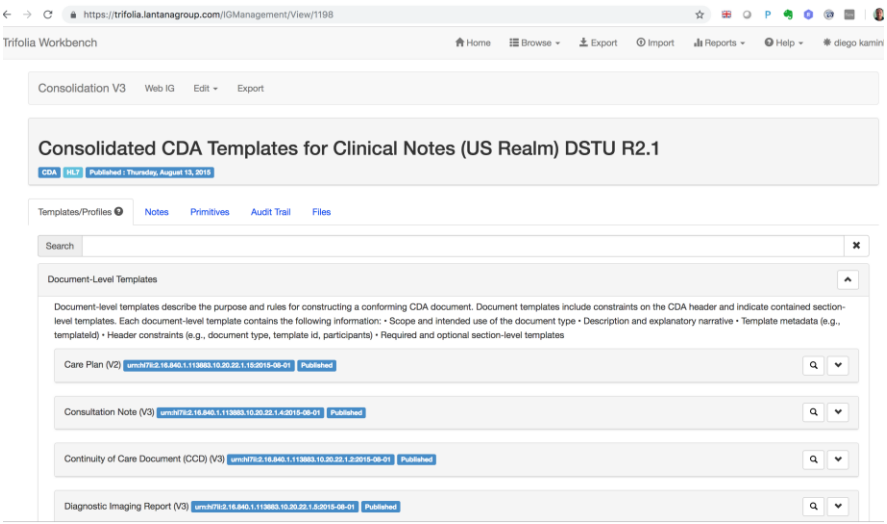
The use of templates allows developers and CDA IG developers to be more productive and increase consistency and the level of interoperability in their projects.

CDA R2 Template Editors

Manual creation of implementation guides and templates can be a daunting job. In the last years, at least two CDA R2 IG/template editor tools were created. Both tools allow you to specify constraints at all levels (document, section, template) and automatically create the documentation (PDF or Word) and the validator tools (schemas, schematron, etc.). They also allow maintenance of the vocabularies (value sets, code systems, etc.)

Trifolia – Created by Lantana – free to use for HL7 members

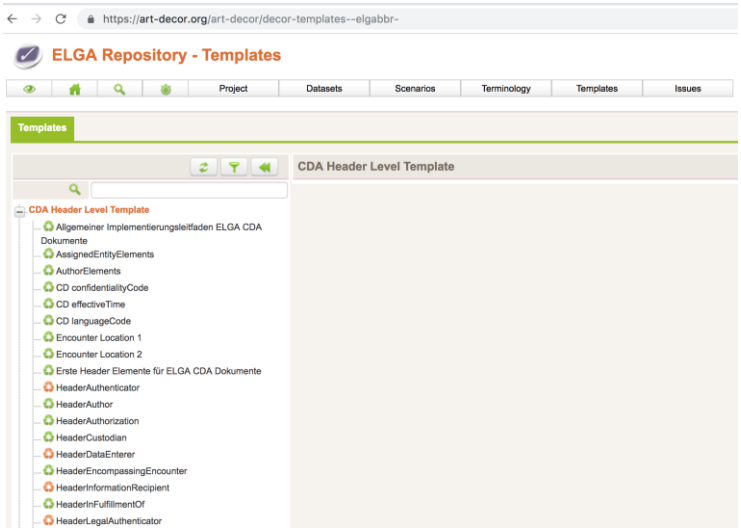
https://trifolia.lantanagroup.com/home



Art-Decor – Maintained by HL7 European affiliates – free to use

https://art-decor.org/art-decor/home

Used by several HL7 European affiliates (Austria, Poland, Germany, Netherlands) and IHE Europe to create and hold their IGs.



6. The C-CDA Implementation Guide (USA)

Introduction

The C-CDA Implementation Guide was developed and produced through the joint efforts of HL7, two Sub-Work Groups of the Office of the National Coordinator (ONC) Standards and Interoperability (S&I) Framework — Longitudinal Care Plan (LCP) and Long-Term Post-Acute Care (LTPAC) Transition) — and through the SMART C-CDA Collaborative hosted by ONC and Harvard Medical School. It provides a library of CDA templates for implementing a set of CDA documents.

This guides defined the format of exchange for sending, receiving and displaying documents for Continuity of Care purposes as required for providers to comply with some measures defined in the US Meaningful Use Stage 2/3 Program (For more details about this see https://www.cdc.gov/ehrmeaningfuluse/index.html)

The current version of the IG (2.1) can be found here: http://www.hl7.org/implement/standards/product_brief.cfm?product_id=492

The guide allows representation for exchange of these document types:

Care Plan including Home Health Plan of Care (HHPoC)
Consultation Note
Continuity of Care Document (CCD)
Diagnostic Imaging Reports (DIR)
Discharge Summary
History and Physical (H&P)
Operative Note
Procedure Note
Progress Note
Referral Note
Transfer Summary
Unstructured Document
Patient Generated Document (US Realm Header)

It's divided in two volumes (Introductory -63 pages- and Templates/Supporting Material -920 pages!-)

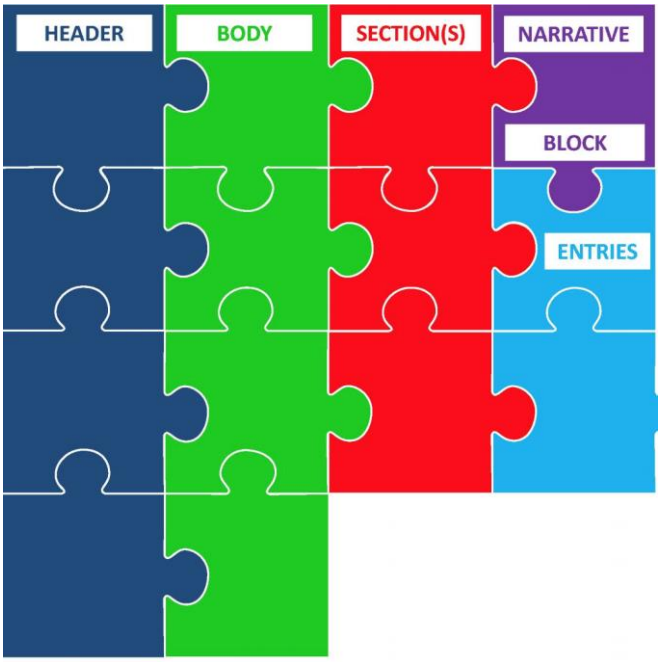
There is also a Companion Guide (101 pages) here: https://confluence.hl7.org/download/attachments/35718965/CDAR2_IG_CCDA_COMPANION_R1_INFORM_2017MAR.pdf?api=v2

The Companion Guide adds "good practice" rules and industry consensus for clarification of the guide contents.

The templates are defined at all levels:

- document header (which header elements and participants are required)
- document sections (which sections are optional or mandatory for each document type)
- entries (which entries are optional or mandatory for each section)

All template definitions in C-CDA are reusable, so each document type definition is built as a puzzle of templates at the document, section, and entry level. Each definition includes the required and optional elements, and a skeleton example in XML.



These 'recipe for documents' is comprised by

- Common rules for the header - Header Template
- Specific sections to include (optional or mandatory) depending on the document type – Document Type Template
- Templates for each section (how to build each section, which entries are required) – Section Template
- Templates for coded entries (how to build each coded entry) – Entry templates will be discussed in the next unit

Header Template

This template -US Realm Header (V3)- contains rules and constraints for the header.
These rules cover the header elements (id, code, title, effectiveTime, etc) and all participations (recordTarget, author, custodian, etc.) and related acts (inFulfillmentOf, documentationOf, authorization, etc) and apply to all the document types covered by the IG.
A partial rendering of this template can be seen below

Table 3: US Realm Header (V3) Constraints Overview

XPath	Card.	Verb	Data Type	CONF #	Value
ClinicalDocument (identifier: urn:hl7ii:2.16.840.1.113883.10.20.22.1.1:2015-08-01)					
realmCode	1..1	SHALL		1198-16791	US
typeId	1..1	SHALL		1198-5361	
@root	1..1	SHALL		1198-5250	2.16.840.1.113883.1.3
@extension	1..1	SHALL		1198-5251	POCD_HD000040
templateId	1..1	SHALL		1198-5252	
@root	1..1	SHALL		1198-10036	2.16.840.1.113883.10.20.22.1.1
@extension	1..1	SHALL		1198-32503	2015-08-01
id	1..1	SHALL		1198-5363	
code	1..1	SHALL		1198-5253	
title	1..1	SHALL		1198-5254	
effectiveTime	1..1	SHALL		1198-5256	US Realm Date and Time (DTM,US FIELDED) (identifier: urn:oid:2.16.840.1.113883.10.20.22.5.4
confidentialityCode	1..1	SHALL		1198-5259	urn:oid:2.16.840.1.113883.1.11.16926 (HL7 BasicConfidentialityKind)
languageCode	1..1	SHALL		1198-5372	urn:oid:2.16.840.1.113883.1.11.11526 (Language)
setId	0..1	MAY		1198-5261	
versionNumber	0..1	MAY		1198-5264	
recordTarget	1..*	SHALL		1198-5266	
patientRole	1..1	SHALL		1198-5267	
id	1..*	SHALL		1198-5268	
addr	1..*	SHALL		1198-5271	US Realm Address (AD,US FIELDED) (identifier: urn:oid:2.16.840.1.113883.10.20.22.5.2

Document Type Template

The definition for each document type is a combination of mandatory and optional sections.

Example: Discharge Summary

Note: the (Vx) is the version of the template, below are the LOINC code for the document type and template id

Discharge Summary (V3) (Discharge Summarization Note) 18842-5 2.16.840.1.113883.10.20.22.1.8:2014-06-09	Allergies and Intolerances Section (entries optional) (V3) Hospital Course Section Discharge Diagnosis Section (V3) Plan of Treatment Section (V2)	Admission Diagnosis Section (V3) Admission Medications Section (entries optional) (V3) Chief Complaint and Reason for Visit Section** Chief Complaint Section** Discharge Diet Section (DEPRECATED) Discharge Medications Section (entries optional) (V3)*** Discharge Medications Section (entries required) (V3)*** Family History Section (V3) Functional Status Section (V2) History of Past Illness Section (V3) History of Present Illness Section Hospital Consultations Section Hospital Discharge Instructions Section Hospital Discharge Physical Section Hospital Discharge Studies Summary Section Immunizations Section (entries optional) (V3) Nutrition Section Problem Section (entries optional) (V3) Procedures Section (entries optional) (V2) Reason for Visit Section** Review of Systems Section Social History Section (V3) Vital Signs Section (entries optional) (V3)

Section Template

For each section, there is a definition of the mandatory ("SHALL") and optional elements ("SHOULD", "MAY"), and (when needed) the fixed values or value set (allowed codes for coded elements). It also includes a pointer to the required or optional coded entries.

Example: **Discharge Medications Section**

Note: See the 'act' xPath the link to an entry template called "Discharge Medication (V3)". We will discuss Entry templates in the next unit.

Table 92: Discharge Medications Section (entries optional) (V3) Constraints Overview

XPath	Card.	Verb	Data Type	CONF #	Value
section (identifier: urn:hl7ii:2.16.840.1.113883.10.20.22.2.11:2015-08-01)					
templateId	1..1	SHALL		1198-7816	
@root	1..1	SHALL		1198-10396	2.16.840.1.113883.10.20.22.2.11
@extension	1..1	SHALL		1198-32561	2015-08-01
code	1..1	SHALL		1198-15359	
@code	1..1	SHALL		1198-15360	urn:oid:2.16.840.1.113883.6.1 (LOINC) = 10183-2
@codeSystem	1..1	SHALL		1198-32480	urn:oid:2.16.840.1.113883.6.1 (LOINC) = 2.16.840.1.113883.6.1
translation	1..1	SHALL		1198-32854	
@code	1..1	SHALL		1198-32855	75311-1
@codeSystem	1..1	SHALL		1198-32856	urn:oid:2.16.840.1.113883.6.1 (LOINC) = 2.16.840.1.113883.6.1
title	1..1	SHALL		1198-7818	
text	1..1	SHALL		1198-7819	
entry	0..*	SHOULD		1198-7820	
act	1..1	SHALL		1198-15490	Discharge Medication (V3) (identifier: urn:hl7ii:2.16.840.1.113883.10.20.22.4.35:2016-03-01

1. **SHALL** contain exactly one [1..1] **templateId** (CONF:1198-7816) such that it
   a. **SHALL** contain exactly one [1..1] **@root**="2.16.840.1.113883.10.20.22.2.11" (CONF:1198-10396).
   b. **SHALL** contain exactly one [1..1] **@extension**="2015-08-01" (CONF:1198-32561).
2. **SHALL** contain exactly one [1..1] **code** (CONF:1198-15359).
   a. This code **SHALL** contain exactly one [1..1] **@code**="10183-2" Hospital Discharge medications (CodeSystem: LOINC urn:oid:2.16.840.1.113883.6.1 **STATIC**) (CONF:1198-15360).
   b. This code **SHALL** contain exactly one [1..1] **@codeSystem**="2.16.840.1.113883.6.1" (CodeSystem: LOINC urn:oid:2.16.840.1.113883.6.1) (CONF:1198-32480).

C-CDA Validators and Examples

You can use these validators to know if an XML instance someone sent you (or you created) is conformant to the C-CDA Implementation Guide

C-CDA Guideline Validation (HealthIT.gov site):

https://sitenv.org/sandbox-ccda/ccda-validator

Lantana Validator: Allows validation of simple CDA R2 and also some implementation guides.

https://www.lantanagroup.com/validator/

C-CDA Scorecard: promotes best practices in C-CDA implementation by assessing key aspects (called rules or rubrics) of the structured data found in individual documents.

https://sitenv.org/ccda-smart-scorecard/

A collection of C-CDA documents can be found here: https://github.com/jmandel/sample_ccdas

A curated gallery of C-CDA section examples can be found here: http://hl7-c-cda-examples.herokuapp.com/

Additional Reading Material

A number of CDA Implementation Guides are available from: www.hl7.org/implement/standards/product_section.cfm?section=5&ref=nav

IHE Technical Frameworks: www.ihe.net/Technical_Framework/index.cfm (not all of them use CDA R2, look specially for XD-LAB and PCC)

IHE CDA Templates: http://wiki.ihe.net/index.php?title=Category:CDA_Section_Templates

International Patient Summary Project (IPS): http://international-patient-summary.net/mediawiki/index.php?title=IPS_implementationguide_1

Unit Summary and Conclusion

In the following Unit, we will review the HL7 Clinical Statement and its relationship to the CDA R2 specification.