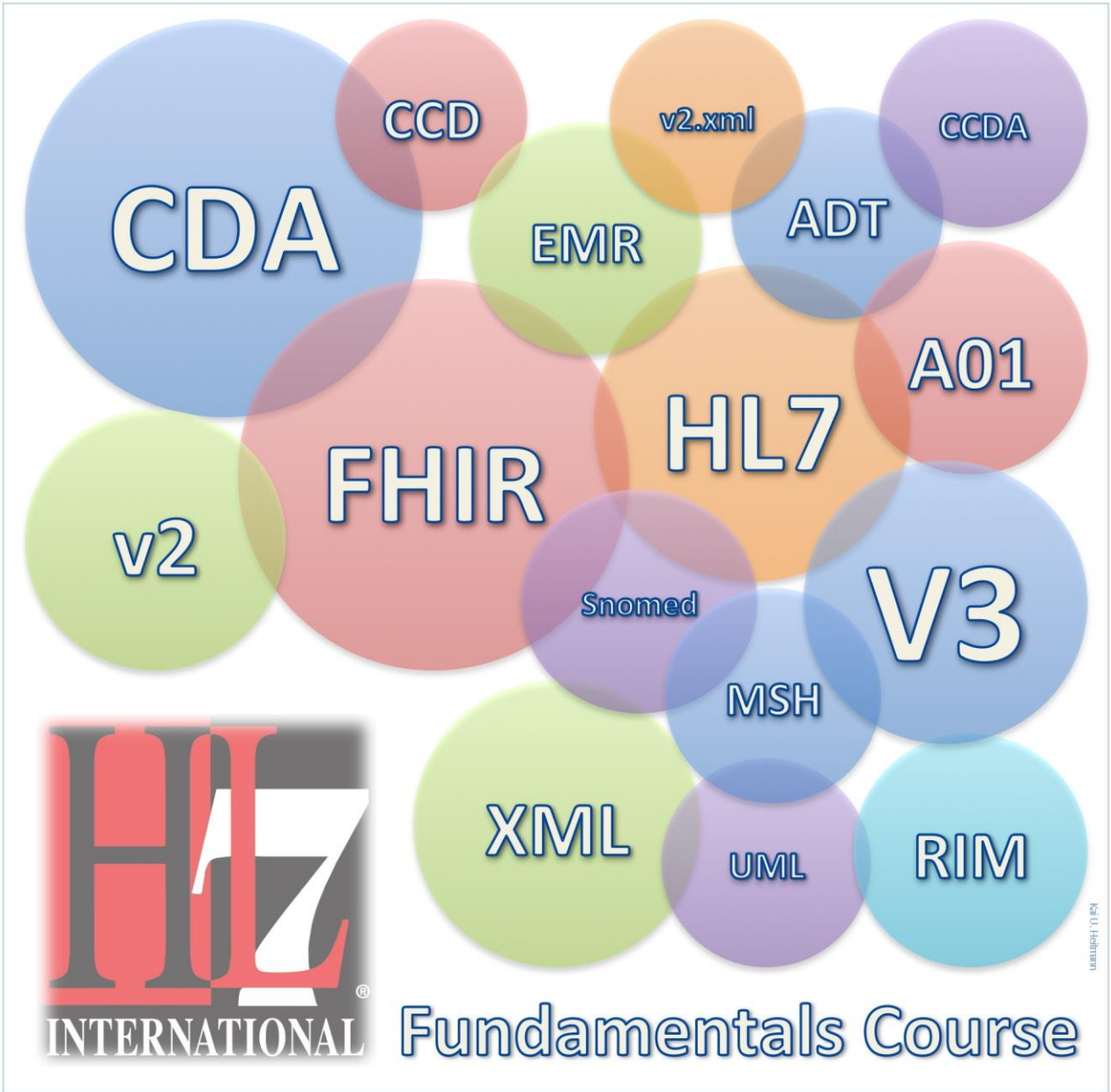


CDA Module, Unit 1:

Introduction to HL7 CDA

Reading Material

Table of Contents

Unit Content and Learning Objectives

In this Unit, we will present an overview of the Clinical Document Architecture (CDA) Release 2 (R2) standard, as well as several examples.

1. Introduction

CDA R2 is a HL7 standard that defines the structure of digital clinical documents, such as discharge letters, referrals, consultation notes and image or laboratory reports.

Specifically, we will go through:

- **Introduction:** A comparison between the message and document interoperability paradigm. What is the CDA? Where can the specifications be found? We discuss the scope, goals and key aspects (e.g. conformance levels) of the CDA standard.
- **Architecture:** Covers the document header; the use of structured and non-structured bodies, as well as structured and coded entries, and the relationship between CDA and the HL7 V3 RIM.
- **Exchange:** Means by which a document can be exchanged, e.g. using HL7 V2.x messages and HL7 V3 interactions.
- **Document validation:** Using the CDA XML Schema to validate clinical documents. The validation of templates as well as constraints documented in an implementation guides that use the Schematron language to test constraints.
- **Examples:** Finally, we will show you a clinical document example that contains all of the core parts of the CDA standard. Other CDA instances will be provided as well.

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).

2. When to use Messages? When to use Documents?

For a given information exchange scenario, one could ask the question whether it should be supported by the exchange of messages or by the exchange of documents. This section presents the key features of both interoperability paradigms.

Advantages of message exchange:

Messages allow us to transmit events as they occur - they allow us to capture and transmit the different states that each act goes through.

Messages require a closer relationship between systems than documents do, and the exchange of messages may not necessarily require human interaction.

Advantages of document exchange:

Documents are artifacts that providers use in day-to-day activities. Providers routinely exchange discharge reports, referrals, etc., although most do not follow a standardized electronic format. Documents in electronic format can easily be structured to be compatible with the existing paper forms, and allow free form narrative speech to be mixed with structured coded data. (It is estimated that of all the medical data, about 70% is not structured but is only available in the form of text).

Paper documents can be signed by the author as well as by a legally accountable person. In case of electronic documents, this can be achieved by means of digital signatures.

Documents typically carry "complete" information with just one document we can fully represent a medical encounter as a whole.

The exchange of documents requires that an application support the ability to send and/receive documents, as required by a document exchange scenario and typically defined in an implementation guide.

The table below contains a comparison between the message and document paradigm:

	Documents	Messaging
Life Cycle	Persistent by nature	Temporary - persistence only for logging and/audit purposes
Communication	Exchanged between humans	Exchanged between applications
Relationship with the Provider	They are authored by providers Providers are used to exchanging documents	The use of messages is not 'intuitive' for Providers
Legal aspects	Digital signatures associated with persistent documents are widely recognized by law	Can be signed electronically as well Given the "temporary" nature of messages, the usefulness of the associated signature is potentially short-lived
Source	Defined by historical consensus and usage	Ad-Hoc use cases defined for each specific domain
Context	Applies to the whole artifact	Application specific

The above table is presented here to give an idea of some of the potential differences between documents and messaging.

In reality, the need for the use of either messaging or documents will be based on the stakeholder's business requirements. The messaging and document paradigms are also quite often combined to support different parts of a data exchange scenario.

3. What is CDA?

Overview

CDA is an acronym for the HL7 "Clinical Document Architecture". CDA specifies the markup of XML documents and standardizes the document structure required to create clinical documents. The CDA semantics is based on the HL7 V3 reference information model (RIM), the HL7 V3 methodology and controlled or local vocabularies (such as SNOMED, LOINC, etc.)

CDA can be used in simple or complex ways: from a document with minimal content (e.g. some text) up to a completely codified document (e.g. with extensive use of clinical terminologies for document sections and coded entries).

The level of terminology and section coding is a key factor when it comes to CDA: the more we invest in codifying the information contained in the data, the better the reusability (and semantic understanding) of the data whenever the document is used, allowing for example better Clinical Decision System applications.

The document low in which CDA documents are exchanged is mostly based on document repositories in document registries. A document repository is an archive that contains documents, which can be queried for the documents that it contains. A document registry is a service in which documents are registered (using metadata) that can be stored in multiple (and distributed) document repositories. The document registry could just contain a pointer to another location where the document is stored. This could be a document repository used by a hospital, or could be a pointer to a central repository used by a national clinical record system, or could even contain a pointer to a data source where the patient has decided to store their own medical information.

The document registry could also have rules for accessing the information based on the user's defined policy (e.g. some form of role based access control), and indexes the documents by its type (e.g. discharge report, lab report, radiology report), patient identity, healthcare provider, encounter, and more contextual metadata.

The document flow based on the above applications is shown in Figure 1 below:

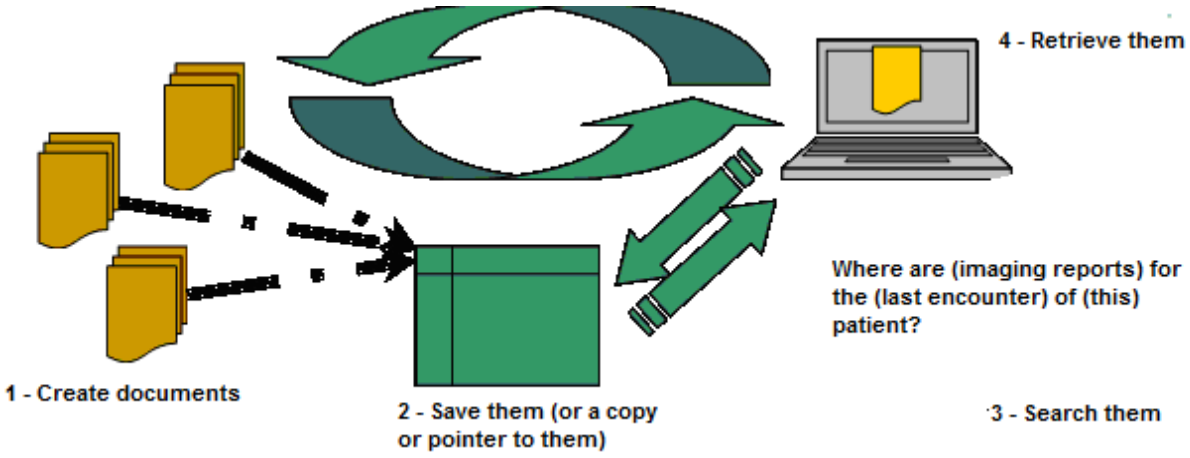


Figure 1: The CDA Document flow

4. A Brief History of CDA

The first meeting of the Special Interest Group (HL7 SIG) devoted to SGML took place in January 1997. A predecessor standard, the PRA (Patient Record Architecture) was created in 1998. CDA R1 became an HL7 and ANSI standard in 2000. CDA R2 became a HL7 and ANSI standard in 2005.

The HL7 Structured Documents (StructDoc) Work Group is responsible for both the creation and maintenance of the CDA standard.

CDA evolved through the years as the basis for document-based Electronic Health Records (EHR) worldwide. The flexibility of the CDA standard has allowed a large number of implementation guides (IG) to be created, each describing the use of the standard for a specific document type in a specific context.

Where can the CDA Specification be found?

The CDA specifications can be found in the normative HL7 editions inside of the Clinical Document family standard, here:

http://www.hl7.org/implement/standards/product_brief.cfm?product_id=7

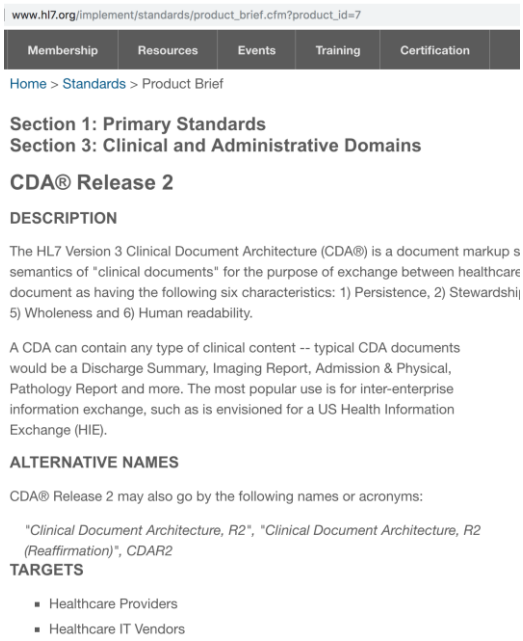


Figure 2: The HL7 CDA Product Family Page

New CDA R2 Releases

The HL7 Structured Documents Work Group is finishing the development of an incremental refresh of the specification known as CDA R2.1. It incorporates the CDA R2 errata, extensions previously defined and used by Implementation Guides, and changes to vocabulary. Expected publication date for this release is Q1-2019.

Implementation Guides Published by HL7 International

The product page above contains a link to the base standard and links to all the Implementation Guides (IGs) published by HL7 International.

Two IGs are the basis for most of the exchange in the US: CCD and C-CDA. We'll explore this guides through the next units.

Some of the IGs and their specific realm (for which specific country are they intended) are:

C-CDA Consolidated CDA (US)	Periodontal Attachments (US)	Long Term Post-Acute Summary
Report for Public Health Cancer Registry (US)	Medication Therapy Management (US)	Vital Records Death Reporting
Attachment Implementation Guide (US)	Personal Health Monitoring Report	Basic Imaging Reports
Report to Birth Defect Registries (US)	Trauma Registry Data Submission	Neonatal Care Reports
Clinical Oncology Treatment Plan and Summary (US)	CDA Framework for Questionnaires	Continuity of Care Document (CCD)
Emergency Medical Services -Patient Care Report – (US)	Genetic Testing Reports	International Patient Summary

We strongly recommend to look at some of the guides for a quick glimpse of the flexibility and power of the IGs.

Other Implementation Guides

HL7 Affiliates and other organizations all over the world publish CDA R2 based IGs.

A good place to start is IHE wiki about Patient Care Coordination : https://wiki.ihe.net/index.php/Patient_Care_Coordination

Key Features of CDA

Persistence: A clinical document continues to exist in an unaltered state, for a time-period defined by local and regulatory requirements. This is mandated by regulations (or organizational policies where there are no applicable regulations or they are less restrictive), not by the specific document format or life cycle of the document management application.

Stewardship: A clinical document is maintained by an organization entrusted with its care.

Potential for authentication: A clinical document is an assemblage of information that may be legally authenticated using digital signatures.

Context: A clinical document establishes the context for the details covered in the document content. The context covers; who is the patient, who created the document, other participants, the location of the event, the point of time of the encounter, etc.

Wholeness: A clinical document is more than just the sum of its individual sections. Each part is expected to be understood in the context of the whole document. Authentication of a clinical document applies to the whole and does not apply to portions of the document without the full context of the document.

Human readability: A clinical document is intended for provider-to-provider communication, and hence, must be human readable (i.e. CDA documents must be render-able using common web browsers without losing clinical meaning).

Scope of the CDA Document Content

The content of the clinical document is defined by the RIM and not by the CDA. CDA only standardizes the structure and semantics required to represent clinical documents.

Messaging: The specification of messaging for use with CDA is outside the scope of CDA R2. It only suggests how to package a CDA instance within an HL7 V2.x or V3 message.

Document management: CDA does not specify how to create or manage documents, only their markup in readiness for exchange with another provider/. Document management, such as creation tools/, versioning, archiving, etc. depends on the context of the clinical document system environment and is out of scope (from the CDA specification).

CDA Scenarios and Use Cases

Some example scenarios for exchange of CDA R2 documents between healthcare organizations include:

- Between **providers**: for continuity of care documents (referrals, clinical summaries, discharge letters, telemedicine, etc.) and reporting (ancillary services)
- Between **providers and payers**: for e-claims and financial services.
- Between **providers and EHR Systems**: for clinical documents to be stored on electronic healthcare record systems
- Between **payers/providers and Public Health Care**: for risk analysis and secondary use

A CDA document can be used to represent a number of clinical document types: discharge reports, consultation notes, lab result reports, radiology reports, etc. Any signed document that contains clinical information about a patient can be represented in CDA.

The main use cases for CDA include:

Access, Portability and Document Exchange

- Search and locate a document by patient, provider, place or location, applicable dates - access to the information by using metadata or context information
- Stored and managed in document repositories

Integration

- Transcription systems (for radiology or clinical practices)
- Electronic Health Records - document based electronic healthcare records

Reuse of Information

- To generate reports and aid decision support functions.
- Extraction of data - this is the advantage of having all the documents following the same structure.

Goals of the CDA

- Give priority to patient care documentation.
- Allowing for cost-effective implementations across as many healthcare applications as possible.
- Enable exchange between users of different levels of technological development: from a single provider practice, to large multisite hospitals.
- Promoting the longevity of information based on this architecture (beyond the change of applications, platforms and operating systems over time).
- Enable a wide range of post-exchange processing applications.
- Promote exchange with independence from exchange mechanisms.
- Enable rapid CDA creation from a consistent design model.
- Enable regulators to support their own requirements consistent with the CDA specification.

Structure

- CDA is based on (but not limited to) XML markup. It also uses the V3 data-types and RIM semantics. Some classes were added to the RIM in order to support CDA R2.

Legibility / Rendering

- There is a deterministic way of rendering the contents of a CDA document for human display.
- It must be possible to render all CDA documents using common web browsers and a generic XML style sheet (e.g. the one provided by HL7).
- It should also possible to render a document with specific style-sheets if there is a need for alternative/presentation of the clinical context.
- Human legibility requirements only apply to the textual contents (narratives) and not to the content created for automated processing (eg coded entries).

Security and Confidentiality

- Applications that send and receive CDA documents are responsible for dealing with security and confidentiality aspects of documents.
- CDA provides information about the confidentiality of the information to assist applications with the handling of sensitive information.
- The confidentiality level can be applied to the entire document or can be limited to one or more sections of the document.

Extensibility

- Local extensions can be included in a CDA document in a XML namespace that differs from the default CDA XML namespace.
- The local extensions cannot change the meaning of the standard CDA elements and ignoring all local extensions should not cause any issues or risks when it comes to rendering or processing of a document.
- If there are requirements that cannot be met by the CDA R2 standard, you are encouraged to bring it forward to the HL7 Structdoc committee for inclusion in a future release of the CDA standard.

Conformance

- An XML instance is CDA conformant if it validates against the CDA R2 Schema - which ignores local extensions declared in different XML namespaces and vocabulary extensions/.
- A valid CDA document must also adhere to the requirements of human legibility: the originally authenticated content must be rendered properly to the receiver.
- A CDA receiver must be able to render the document using a generic XML style-sheet for CDA. The processing of body entries is not a conformance requirement. The validation against templates is not a conformance requirement.
- The sender must put all legally authenticated content in narrative blocks. A document that contains coded entries and does not contain the corresponding narrative text is not a valid CDA document.
- A local implementation guide may specify context-specific requirements with regard to the structure of the document, e.g. the use of mandatory sections or mandatory coded entries.

5. The CDA R2 Structure

Every CDA R2 document has a header and a body. The header and body are structured using XML as defined by the CDA specification. The body may also contain external attachments.

Root Element and Namespaces

The root element for CDA R2 instances is <ClinicalDocument>.

The default CDA XML Namespace is "urn:hl7-org:v3" and the "v3" Namespace Prefix is commonly used (when not default).

The CDA Vocabulary XML Namespace is "urn:hl7-org:v3/voc" and the "voc" Namespace Prefix is commonly used.

Header

The CDA header, which is required, contains the contextual information about the clinical document. This information is used to identify and classify the document. It contains the identification of the document, the document author, authentication information, the identification of the encounter, the identification of the patient, etc.

The header is specified in the CDA Header model, which is expressed as an R-MIM created using the HL7 Development Framework (HDF).

Figure 3 lists the main elements in the CDA Header (mandatory elements are listed in **bold**):

Element Name	Description
typeId	Indicates that the structure of the document is CDA R2. The attributes must be root="2.16.840.1.113883.1.3" and extension= "POCD_HD000040"
templateId	Allows for the identification of templates that specify additional constraints above and beyond the base CDA R2 structure
id	Document identifier (root and extension). A unique identifier for this document instance. The identifier is normally generated by the document creator.
code	Document type code. The recommended coding system is LOINC; extensions are allowed - see the additional reading material.
title	Document title - will be rendered by the browser as the title of the document.
effectiveTime	Date of document creation; date on which the author finalized the document.

Element Name	Description
confidentialityCode	The HL7 Confidentiality code coding system contains the following codes: N-Normal R-Restricted V-Very restricted (Other coding systems may be used)
languageCode	Language Code as defined by RFC3066.

Figure 3: The main CDA Header elements

Version Control elements in the CDA R2 header:

Element Name	Description
setId	The Identifier for a set of related documents. The original document and replacement document versions all share one and the same setId - but they all have a different/document identifier (the Id attribute as present in the header)
versionNumber	Contains the version number of this instance/of the document within a set of related documents. For additional information see the description of *Other Participants: relatedDocument:* it is used to link a later version of a document to a previous version of a document

Figure 4: The version control elements in the CDA Header

Note: These elements are not mandatory, but you should include them if you are sending a new version of a document that has been published before.

Participation elements in the CDA R2 header:

Element Name	N	Description
recordTarget	1..N	Identifies the patient that the document belongs to. This element identifies the patient and may also include their demographic information. The cardinality is 1..N, which means that theoretically a document could be associated with multiple patient records. This will only occur in exceptional cases.
Author	1-N	The document author. The person that composed/the contents of the document. The author could be any relevant party, for example: a nurse, a physician, a resident, an assistant, the patient themselves. The role of the author can also be recorded in functionCode or (more commonly) the AssignedAuthor.code attribute.
dataEnterer	0-1	The Person that has entered the information into the document (i.e.: the person responsible for the transcription).

Element Name	N	Description
Informant	0-N	The source of the information, for instance, a person that communicates the patient's symptoms if the patient is unable to communicate.
Custodian	1	The organization that has stewardship over the original document. The custodian is mandatory. This Is especially helpful if: Receivers only persist some, but not all documents; or documents are only persisted for a limited amount of time. The primary responsibility of archiving a persistent master copy of the document lies with the custodian. The CDA document is a transformation (e.g. a scanned version) of an original document. The stewardship of the original document lies with the custodian.
informationRecipient	0-N	Parties that have a need (or will be requested) to receive the information contained within the document.
legalAuthenticator	0-1	A Person who has legally authenticated the document. This implies a statement related to the accuracy and completeness of the document.
authenticator	0-N	Persons that confirm the accuracy and completeness of the document, but who don't have privileges to legally authenticate the document.
participant	0-N	Other participants - see below

Figure 5: The Participation Elements in the CDA Header

Other Participants

The CDA header contains information about several other ancillary participants, for example: the admitting physician, the attending physician, the referring physician. The **participant** element can be used to convey information about these participants (identification, names, represented organization, code and dates of participation).

Other elements in the header (acts related to the document):

Element Name	N	Description
inFullfilmentOf/	0-1	Identifies the order/that was the reason for the creation of this document instance. The Order activity contains an **id** (the identification of the order), a **code** (the kind of order, e.g. "CT Abdomen") and **priority**.

Element Name	N	Description
documentation-Of/serviceEvent	0-1	Identifies the medical activity that is documented by the document instance. This element provides additional detail related to the medical activity when compared to the value of **ClinicalDocument.code**. The serviceEvent activity contains an identification of the act (the **id** of the act should be different from the identification of the document), **code** (to identify the type of serviceEvent), **effectiveTime** (time of the serviceEvent) and **performer** (the person engaged in executing the serviceEvent)
relatedDocument	0-1	Identifies the document that this document instance replaces, augments (appends) or transforms. The kind of relationship (RPLC, APPND, XFRM) is expressed in the **typeCode** attribute.
componen-tOf/EncompassingEncounter	0-1	Identifies the encounter encompassing the act that produced the document. Contains the identification, a code, the location, responsible organization and the responsible physicians.

Figure 6: Other Elements in the main CDA Header

Body

The body of a CDA document has a generic structure that can be used to represent the structure of any document type to express any clinical content.

The body could simply consist of plain text, or it can be any other format (e.g. HTML, RTF, PDF, TIFF). The only requirement is that the format can be rendered by a software application and read by a human reader.

A CDA body can take one of two forms:

1. It can be unstructured. An *unstructured body* could contain any binary object.
2. It can be structured. The CDA specification contains a description of the allowable XML structures. A *structured body* has two kinds of content: human readable and coded parts.

Unstructured Body

If a document has an unstructured body, it will have a <**nonXMLBody>** element. An unstructured body contains any content, for example, a base64 encoded document (PDF, HTML, Word, etc.) or plain text but it must not contain XML markup. The mediaType attribute will indicate the type of content to be processed.

Structured Body

If a document has a structured body, it will have a <**structuredBody>** element.

A structured body may include an arbitrary number of **sections** as **component**s. Sections may have a **title**, a **code** (to classify the section content type) and **text** elements. Complex document structures may use sections as components of other sections.

The human readable part of a section consists of the **title** and **text.** These are the parts that have to be presented to a human reader (typically using a style-sheet) and the parts that a legal authenticator will be held responsible for.

The narrative text can be structured using a set of elements that approximates HTML or XHTML. Some of the elements are listed in Figure 7:

Element	Intended Use
paragraph	Divides the section into paragraphs
list	Includes a list of sorted/items
table	Includes a table
caption	Includes a caption for a table
linkHTML	Includes an external hyperlink
content	Divides the text into separate blocks to allow special formatting instructions (bold, italics, etc.) or for the referencing of software processable parts related to a part of the text (see *entries* below)
revise (delete/)	Expresses that some content was deleted or inserted in a new version of a document
sub, sup	Indicates superscript or subscript
Br	Includes blank paragraphs or line breaks
renderMultiMedia	Includes an image or other multimedia object that is part of the narrative block

Figure 7: The Narrative Text Elements

Entries

Entries are RIM-based structures used to convey software-processable information in CDA documents within a structured body.

Entries are based on the concept of "Clinical Statements", a RIM-based structure that allows for the coding of activities (e.g. Observation, Procedure, Organizer, Supply, Encounter, SubstanceAdministration) and the relationships between the activities. Entries can be optionally included in the narrative text, allowing for software processing and reuse of (parts of) the information.

A description of the kinds of entries can be found in Figure 8 below:

Entry Type	Intended Use
Encounter	Identifies a patient encounter related to a particular item/of clinical data
Observation	Contains information related to an observation (e.g. a laboratory, radiology observation) or diagnoses
ObservationMedia	Contains a multi-media observation (e.g. image)
Organizer	Used to organize sets of clinical data into collections, sets or lists
Procedure	Contains information related to a procedure (e.g. surgery)

Entry Type	Intended Use
RegionOfInterest	Identifies what part(s) of a multi-media observation are of clinical relevance in a specific context (e.g. region of an X-Ray image showing a lymphoma)
SubstanceAdministration	Contains information related to a substance administration activity. (e.g. prescription and administration data related to pharmaceutical products)
Supply	Contains information about the (logistical) supply activity (e.g. a packet of medication, a set of crutches)
Act	Contains information about generic/clinical activities (not modeled by one of the more specialized activities shown above)

Figure 8: The Participation Elements in the CDA Header

6. The CDA R2 Structure at-a-Glance

This section contains a description of the context of a CDA documents, as well as the sequence in which they appear in an instance.

These figures do not replace the CDA R-MIM or the Excel view of that R-MIM, but they are easier to read (reading directions: just follow the arrows and go from top to bottom in each box):

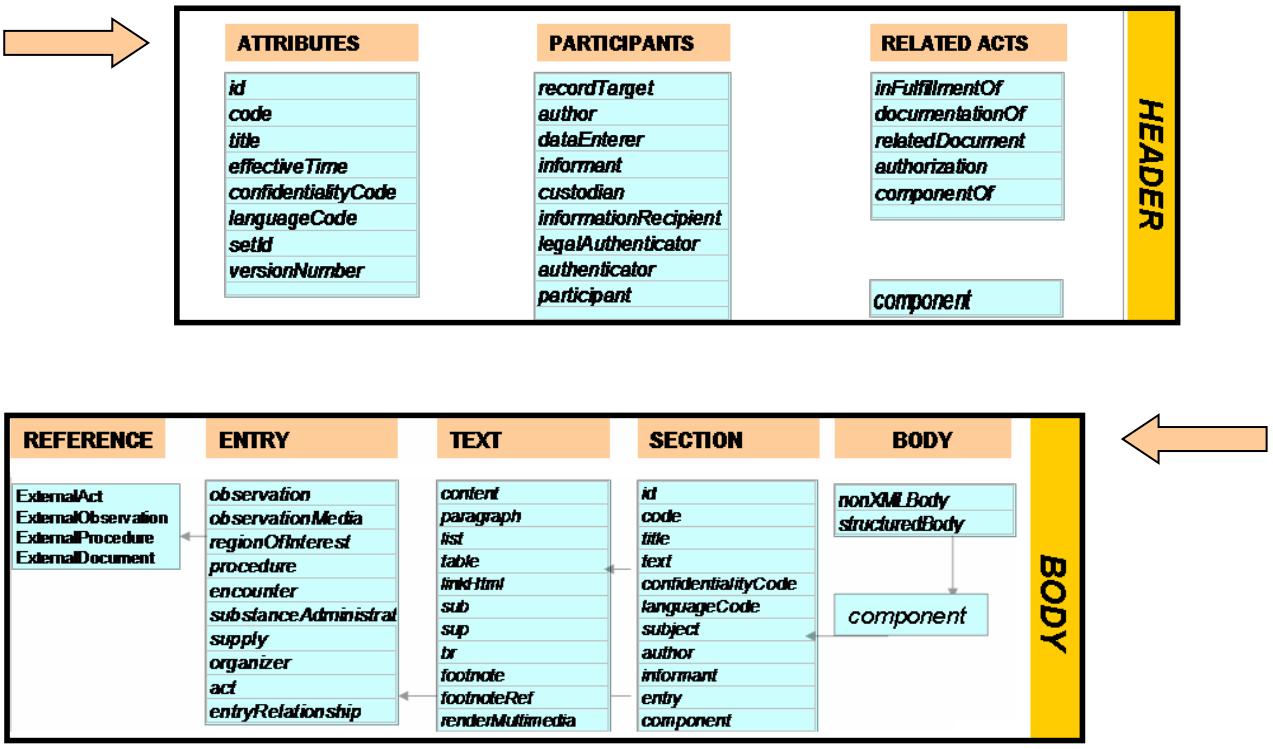


Figure 9: The CDA R2 Structure at-a-Glance

7. The HL7 v3 CDA Domain

The Clinical Document Architecture is based on the HL7 Reference Information Model (RIM)[1]. The HL7 development Framework has been used to create an R-MIM for clinical documents. CDA and messages share the same development framework, and both are based on the HL7 v3 RIM and HL7 v3 data types.

The CDA R-MIM is used to generate an Excel view of the model, as well as XML Schemas (used for document creation and document validation).

As shown in the Figure below, the R-MIM CDA model can be divided in four areas: the header, the body, entries and external references:

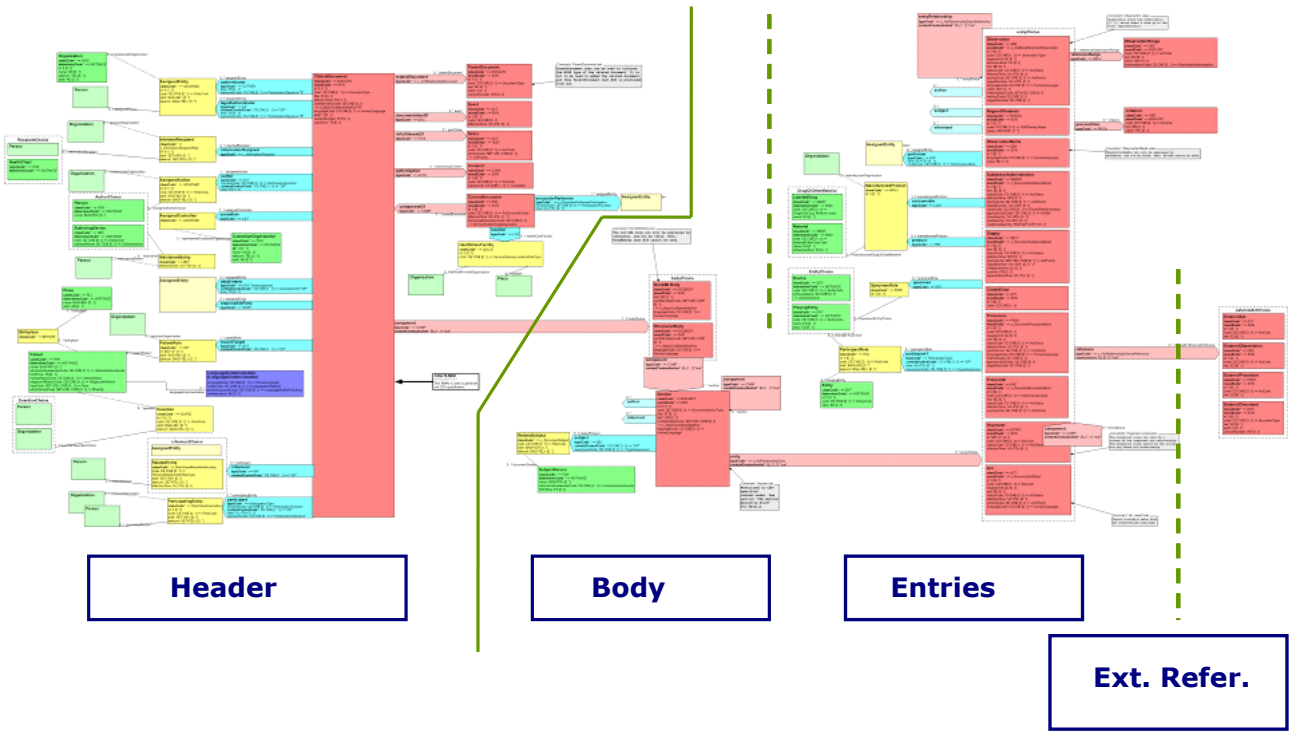


Figure 10: The CDA R-MIM Model

[1] For more information in the HL7 RIM, see the optional "V3 RIM" Unit of this Course!

8. Exchange of CDA XML Instances

The CDA specification does not define how or when documents should be transmitted. It only defines the *structure* of clinical documents.

Some options for the exchange of documents are Web Services, RPC, IPC, basic file-exchange mechanisms based on FTP, e-mail, etc.

From the perspective of a V2.x or V3 message, a CDA document can be thought of as a multimedia object that can be exchanged as a Multipurpose Internet Mail Extensions (MIME, RFC 2046) package, encoded as an encapsulated data type (ED).

Transmitting CDA using HL7 V2.x

In V2.x, CDA documents are to be exchanged in the OBX segment, in any message that can exchange documents (such as MDM). Within the OBX segment, the MIME package is placed in OBX.5 (Field 00573 Observation value), encoded as a V2.x encapsulated data type. The value of OBX.2 (Field 00570 Value Type) should be set to "ED".

The value of OBX.3 should be the same as ClinicalDocument.code.

Transmitting CDA using HL7 V3

In V3, CDA documents can be exchanged in any message that can exchange documents (such as the HL7 V3 Medical Records messages). The Act.text RIM attribute contains the MIME package, encoded as an encapsulated data type.

9. Validation of CDA Document Instances

XML Schemas

The CDA Release 2 standard contains a number of XML schemas that jointly define the structure of CDA documents.

The schemas include:

- CDA.xsd - contains the definition of the root element only
- POCD_MT000040.xsd - contains the definition for all the header and body and the entries (derived directly from the R-MIM)
- NarrativeBlock.xsd - markup for the narrative block elements
- datatypes.xsd and datatypes-base.xsd - XML ITS for the data-types of HL7 V3
- voc.xsd - vocabulary for HL7 V3
- The CDA Schemas as published in the HL7 V3 Normative Editions

Levels of Validation

CDA is all about *adding structure to* text at various levels to meet specific requirements. CDA instances may vary in the amount of software-processable information versus plain text information it provides.

There are a number of levels at which CDA documents can be validated:

Level 1: instances have to validate against the unconstrained CDA specification. That is, only the minimal requirements must be meet.

Level 2: instances have to validate with section-level templates applied. For example, e.g. an implementation guide (for one specific document type from one specific country) may specify what the *mandatory sections* are (in terms of section code, the section title or both). The implementation guide could mandate that all document instances MUST contain a section for PHYSICAL EXAMINATION (LOINC CODE 22122).

Level 3: instances have to validate with entry-level (and optionally section-level) templates applied. For example, e.g. an implementation guide may specify what the *mandatory entries* are (in terms of act code, or vocabularies). Usually implementation guides are expressed through a combination of:

- A formal description defining the mandatory and optional elements of the document structure, vocabulary and data type constraints) and
- One or more Schematron files or style-sheets allowing for software validation of a document instance.

Validation Sites

Here are a few sites that can be used to validate CDA R2 instances online:

- https://www.lantanagroup.com/validator/
- http://hl7.org.ar/_nanocda/ [2]

These sites use the CDA XML Schema to validate instances.

[2] NanoCDA features a CDA R2 validation page, and a very small CDA repository, where you can upload, search and finally retrieve your CDA instances.

10. *Unit Summary and Conclusion*

We will see more CDA detail in the following example of header, body and entries of CDA R2 instances.

Additional Reading Material

Please study the CDA R2 specification (it is *relatively* small in size) and the below additional material:

The CDA Specification: www.hl7.org/implement/standards/product_brief.cfm?product_id=7

'Document versus Messaging' Whitepaper by Rene Spronk: www.ringholm.de/docs/04200_en.htm

The LOINC codes for documents: www.LOINC.org

The Detailed Clinical Model Project: http://wiki.hl7.org/index.php?title=Detailed_Clinical_Models

On the CDA R2 structure:

See this JAMIA paper by Robert H. Dolin et al: HL7 Clinical Document Architecture, Release 2: https://academic.oup.com/jamia/article-pdf/8/6/552/2337897/8-6-552.pdf

Additional CDA instance examples as well as implementation guides from multiple countries: www.ringholm.de/download/CDA_R2_examples.zip (~74 Mb)

Implementation Guides by IHE on the use of CDA R2 as a basis for a document-based EHR:
www.ihe.net/Technical_Framework/upload/IHE_PCC_TF_Vol_1_TI_2007_08_15.pdf
www.ihe.net/Technical_Framework/upload/IHE_PCC_TF_Vol_2_TI_2007_08_15.pdf

HL7 International offers certification testing related to the CDA R2 specification. For more details and conditions, see the www.hl7.org/implement/certification.cfm

Appendix A: CDA Document Example

In this section one complete CDA document instance will be shown and discussed. Feel free to use these examples as an aid in this unit's activities.

The additional reading material contains references to other instance examples.

Root Element

Root Element and Namespaces Declaration

```
<ClinicalDocument
xmlns="urn:hl7-org:v3"
xmlns:voc="urn:hl7-org:v3/voc"
xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd">
...
</ClinicalDocument>
```

CDA Header

typeId

```
<typeId root="2.16.840.1.113883.1.3" extension = "POCD_HD000040"/>
```

templateId

```
<templateId root="2.16.840.1.113883.19.10.1.1.9" extension="LAB"/>
```

id

```
<id root="2.16.840.1.113883.2.19.1.4.2" extension="I910969-1"/>
```

code

```
<code code="18733-6" codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC" display-
  Name="Ambulatory Visit Note"/>
```

title

```
<title>GHH RADIOLOGY REPORT</title>
```

effectiveTime

```
<effectiveTime value="20070420103000"/>
```

confidentialityCode

```
<confidentialityCode code="N" codeSystem="2.16.840.1.113883.5.25"/>
```

languageCode

```
<languageCode code="en-US"/>
```

setId

```
<setId root = "2.16.840.1.113883.19.1.4.3" extension="I910969-1"/>
```

versionNumber

```
<versionNumber value="1"/>
```

recordTarget

```
<recordTarget>
  <patientRole>
    <id extension="493829" root="2.16.840.1.113883.19.2"/>
    <patient>
   <name>
    <given>Adam</given>
    <family>Everyman</family>
    <suffix>the 2nd</suffix>
   </name>
      <administrativeGenderCode
    code="M" codeSystem="2.16.840.1.113883.5.1"/>
  <birthTime value="19250321"/>
    </patient>
    <providerOrganization>
   <id root="2.16.840.1.113883.19.2"/>
   <name>GHH Outpatient Clinic</name>
    </providerOrganization>
  </patientRole>
</recordTarget>
```

author

```
<author>
  <time value="20062805153000"/>
  <assignedAuthor>
      <id root="2.16.840.1.113883.19.1.3" extension="777777"/>
      <telecom value="tel:5555554002"></telecom>
      <assignedPerson>
          <name>
            <given>BILL</given>
            <given qualifier="IN">B</given>
            <family>BEAKER</family>
   </name>
      </assignedPerson>
      <representedOrganization>
      <id root="2.16.840.1.113883.19.11.2"/>
      <name>RELIABLE LABS, INC</name>
      </representedOrganization>
```

```
    </assignedAuthor>
</author>
```

dataEnterer

```
<dataEnterer>
  <time value="200702231330"/>
  <assignedEntity>
   <id root="2.16.840.1.113883.19.5" extension="323123"/>
   <assignedPerson>
     <name>
       <family>ENTER</family>
       <given>ELLEN</given>
       <given>E</given>
     </name>
   </assignedPerson>
   <representedOrganization>
    <id root="2.16.840.1.113883.19.4"/>
    <name>GHH LAB</name>
   </representedOrganization>
  </assignedEntity>
</dataEnterer>
```

informant

```
<informant>
  <relatedEntity classCode="NOK">
   <code code="MTH" codeSystem="2.16.840.1.113883.5.111"></code>
   <addr>
     <streetAddressLine>4444 HOME STREET</streetAddressLine>
     <city>ANN ARBOR</city>
     <state>MICHIGAN</state>
     <postalCode>99999</postalCode>
     <country>USA</country>
   </addr>
   <telecom value="tel:5555552006"></telecom>
   <effectiveTime value="200701201030"></effectiveTime>
   <relatedPerson>
    <name>
     <family>MUM</family>
     <given>MARTHA</given>
    </name>
   </relatedPerson>
  </relatedEntity>
</informant>
```

custodian

```
<custodian>
  <assignedCustodian>
   <representedCustodianOrganization>
```

```
  <id root="2.16.840.1.113883.19.11.2"/>
  <name>GHH CLINIC</name>
   </representedCustodianOrganization>
  </assignedCustodian>
</custodian>
```

informationRecipient

```
<informationRecipient>
     <intendedRecipient>
       <id root="2.16.840.1.113883.2.19.1.1.2" extension="4001"/>
       <telecom value="tel:5555551009"></telecom>
       <informationRecipient>
          <name>
            <family>SPECIALIZE</family>
            <given>SARA</given>
    </name>
       </informationRecipient>
       <receivedOrganization>
          <name>SPECIALISTS</name>
       </receivedOrganization>
     </intendedRecipient>
</informationRecipient>
```

legalAuthenticator

```
<legalAuthenticator>
  <time value="20000407130000+0500"/>
  <signatureCode code="S"/>
  <assignedEntity>
  <id nullFlavor="NI"/>
  <representedOrganization>
      <id root="2.16.840.1.113883.19.2.11.2"/>
      <name>GHH Clinic</name>
  </representedOrganization>
  </assignedEntity>
</legalAuthenticator>
```

authenticator

```
<authenticator>
     <time value="20060322221030"/>
     <signatureCode code="S"/>
     <assignedEntity>
       <id root="2.16.840.1.113883.19.10.1.1.2" extension="4121"/>
       <code code="BRS"
         codeSystem="2.16.840.1.113883.19.10.1.1.12"
       displayName="Responsable Lab Technician"/>
    <assignedPerson>
          <name>
           <family>BEAKER</family>
```

```
            <given>BILL</given>
          </name>
        </assignedPerson>
        <representedOrganization>
          <id root="2.16.840.1.113883.19.1.1.4" extension="365"/>
          <name>GHH LAB</name>
        </representedOrganization>
      </assignedEntity>
</authenticator>
```

Participant

The example shows a role with the REFB participation within the CDA Header:

```
<participant typeCode="REFB">
    <associatedEntity classCode="ASSIGNED">
      <id root="2.16.840.1.113883.19.10.1.1.2" extension="4001"/>
      <associatedPerson>
        <name>
          <family>CHOW</family>
          <given>CONNIE</given>
        </name>
      </associatedPerson>
      <scopingOrganization>
        <id root="2.16.840.1.113883.19.10.1" extension="102"/>
        <name>LONE TREE ISLAND SATELLITE CLINIC</name>
        <asOrganizationPartOf>
          <wholeOrganization>
            <id root="2.16.840.1.113883.19.10.1"/>
            <name>GOOD HEALTH HOSPITAL</name>
          </wholeOrganization>
        </asOrganizationPartOf>
      </scopingOrganization>
    </associatedEntity>
</participant>
```

InFullfillmentOf/Order

The CDA document was created as a result of one specific request (with the id as stated below and of type CHEM-9):

```
<inFulfillmentOf>
    <order>
      <id root="2.16.840.1.113883.19.1.2.3" extension="636236"/>
    <code code="160"
          codeSystemName="2.16.840.1.113883.19.10.1.2.3"
  displayName="CHEM-9"/>
    <priorityCode
  code="R" codeSystem="2.16.840.1.113883.5.7"
                codeSystemName="ActPriority"
  displayName="routine"/>
    </order>
```

```
</inFulfillmentOf>
```

documentatioOf/serviceEvent

The serviceEvent is a Primary Care Provision activity (PCPR) performed by Seth Stretcher between 1990 and 2000-04-07.

```
<documentationOf>
  <serviceEvent classCode="PCPR">
    <effectiveTime><low value="19320924"/><high value="20000407"/></effectiveTime>
    <performer typeCode="PRF">
      <functionCode code="PCP" codeSystem="2.16.840.1.113883.5.88"/>
      <time><low value="1990"/><high value='20000407'/></time>
      <assignedEntity>
  <id root="20cf14fb-b65c-4c8c-a54d-b0cca834c18c"/>
  <assignedPerson>
   <name><given>Stretcher</given><family>Seth</family></name>
  </assignedPerson>
  <representedOrganization>
  <id root="2.16.840.1.113883.19.5"/>
  <name>Good Health Clinic</name>
  </representedOrganization>
      </assignedEntity>
    </performer>
 </serviceEvent>
</documentationOf>
```

relatedDocument/parentDocument

If parentDocument has a value, then the setId and versionNumber attributes have to be populated as well.

```
...
<id extension="15120-3"   root="2.16.840.1.113883.2.10.1.2.2"/>
...
<setId extension="15120"   root="2.16.840.1.113883.19.1.2.1"/>
<versionNumber value="3">
...
<relatedDocument typeCode="RPLC">
 <parentDocument>
   <id    extension="15120-2"
      root="2.16.840.1.113883.19.10.1.2.2"/>
   <setId extension="15120"
  root="2.16.840.1.113883.19.10.1.2.1"/>
   <versionNumber value="2"/>
 </parentDocument>
</relatedDocument>
```

componentOf/encompassingEncounter

```
<componentOf>
     <encompassingEncounter>
       <id root="2.16.840.1.113883.19.10.1.1.8" extension="H0156280"/>
```

```
        <effectiveTime><low value="20040912"/></effectiveTime>
        <location>
          <healthCareFacility>
            <id root="2.16.840.1.113883.19.10.1.1.7" extension="205"/>
            <location>
              <name>GHH ROOM 234</name>
            </location>
          </healthCareFacility>
        </location>
      </encompassingEncounter>
</componentOf>
```

CDA Body

component (structured body)

A CDA structured body contains one or more component/section parts:

```
<component>
 <structuredBody>
  <component>
    <section>
  ...
    </section>
  </component>
 </structuredBody>
</component
```

component (non structured body)

```
<component>
  <nonXMLBody>
  <text mediaType="application/pdf" representation="B64">
          K7CXIe2be+/1DzXQP+RlbmRzdHJlYW0KZW5kb2JqCjYgMCBvY
            moKMjAxCmVuZG9iago0
          ...
          MgolJUVPRgo=
  </text>
  <nonXMLBody>
</component>
```

Structured Body

Section

The section below has the human readable description (Chief Complaint) as well as a level-2 code 29299-5 (Reason for visit) for processing.

```
...
  <section>
    <code  code="29299-5"
       codeSystemName="LOINC"
   codeSystem="2.16.840.1.113883.6.1"
       displayName="REASON FOR VISIT"/>
    <title>CHIEF COMPLAINT</title>
    <text>
  Arrived from the ICU - Anemia - Chest Pain
    </text>
  </section>
...
```

Narrative Block

Given that each type of the narrative text will display differently, each example below is accompanied by a display example.

content

```
<text>
 <content ID="REF1" styleCode="Bold">Personal</content>
 <content ID="REF2" styleCode="Italics">No known allergies</content>
 <content ID="REF3" styleCode="Underline">Type 2 Diabetes</content>
</text>
```

... is displayed as:

Personal
No known allergies
Type 2 Diabetes

linkHTML

```
<text>
   ...
  See information about Durogesic
  <linkHtml
   href=" http://en.wikipedia.org/wiki/Duragesic"  title="Durogesic">
   here
  </linkHtml>
  ...
```

```
</text>
```

… is displayed as:

See information about Durogesic here

sub, sup

```
<text>
  R<sub>1</sub> : Cease activity if in pain
  1<sup>st</sup>: Furosemida 40 mg PO w/breakfast
  ...
</text>
```

… is displayed as:

R_1: Cease activity if in pain 1^{st}: Furosemida 40 mg PO w/breakfast

paragraph, br

```
<text>
 <paragraph>
 <caption>CHOLESTEROL</caption>Strict control of risk factors.  Total Cholesterol must be below 200
  mg/dl.
 </paragraph><br/><br/>
 <paragraph>
  <caption>BLOOD GLUCOSE</caption>In case of diabetes keep HBA1C below 6.5
 </paragraph><br/><br/>
 <paragraph>
  <caption>BLOOD PRESSURE</caption>
  Keep Blood pressure below 130/85
 </paragraph><br/>
</text>
```

… is displayed as:

CHOLESTEROL: Strict control of risk factors. Total cholesterol must be below 200 mg/dl.

BLOOD GLUCOSE: In case of diabetes keep HBA1C below 6.5

BLOOD PRESSURE: Keep blood pressure below 130/85

footnote, footnoteRef

```
<text>
...
<table>
<tr> ...
<td><footnoteRef IDREF="N1"/>(1)</td>
...
</table>
<footnote ID="N1">
(1) Result controlled with a second run
</footnote>
</text>
```

... is displayed as:

ELECTROLYTES HCFA 98 AND VENOUS PH PANEL

Lytes

	Mar 21, 2006 07:10	Ann.	Reference range	Int.c.	Mar 12, 2006 08:15	Jan 01,
Na (mmol/L)	**140**		135 -145		141	
K (mmol/L)	**3.4**	(1)	3.5 - 5.0	L		3.3
Cl (mmol/L)	**99**		98 - 106			100

(1) Result controlled with a second run

list

```
<text>
 ...
 <list>
  <caption>OTHER DRUGS</caption>
  <item>Furosemida 40 mg, breakfast, PO </item>
  <item>AAS 100 mg dinner, PO</item>
  <item>Omeprazol 20 mg daily, PO</item>
 </list>
 ...
</text>
```

... is displayed as:

OTHER DRUGS

- Furosemida 40 mg, breakfast, PO
- AAS 100 mg dinner, PO
- Omeprazol 20 mg daily, PO

table

```
<text>
...
<table border="1"><thead align="center">
```

```
 <tr><th colspan="3" align="left">Electrophoretic fraction</th></tr>
 <tr><th/><th>Mar 21, 2006 07:10</th><th>Reference range</th></tr>
 </thead><tbody align="center">
 <tr><td>Total protein</td><td><content styleCode="Bold">72</content></td><td>64 - 80</td></tr>
 <tr><td>Albumin</td><td><content styleCode="Bold">40</content></td><td>38 - 50</td></tr>
 <tr><td>Alpha 1</td><td><content styleCode="Bold">4</content></td><td>3 - 5</td></tr>
 <tr><td>Alpha 2</td><td><content styleCode="Bold">5</content></td><td>3 - 7</td></tr>
 <tr><td>Beta</td><td><content styleCode="Bold">8</content></td><td>6 - 10</td></tr>
 <tr><td>Gamma</td><td><content styleCode="Bold">11</content></td><td>7 - 14</td></tr>
 </tbody>
</table>
...
<text>
```

… is displayed as:

Electrophoretic fraction

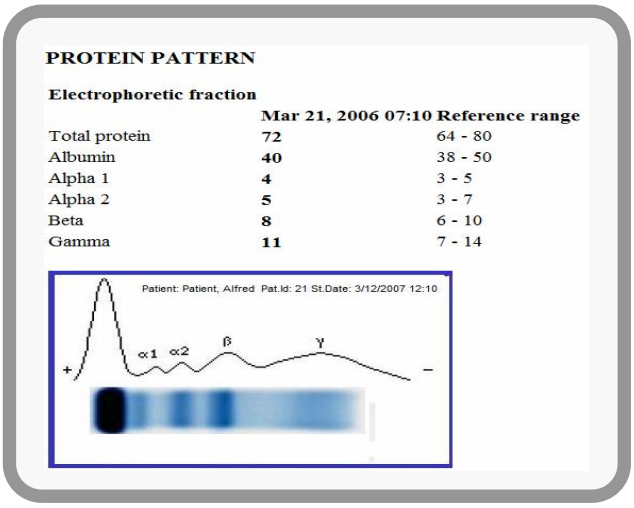
	Mar 21, 2006 07:10	Reference range
Total protein	**72**	64 - 80
Albumin	**40**	38 - 50
Alpha 1	**4**	3 - 5
Alpha 2	**5**	3 - 7
Beta	**8**	6 - 10
Gamma	**11**	7 - 14

renderMultimedia

The renderMultimedia element always has an associated Entry: in this case, it contains the URL of an image:

```
<text>
  ...
  <renderMultiMedia referencedObject="PROT">
  <caption>Electrophoresis Protein</caption>
  </renderMultiMedia>
</text>
<entry>
  <observationMedia classCode="OBS" moodCode="EVN" ID="PROT">
    <id root="2.16.840.1.113883.19.10.8.2"
  extension="PT200603120001"/>
    <value mediaType="image/jpeg">
  <reference value="PROTEINOGRAMA.JPG"/>
    </value>
  </observationMedia>
</entry>
```

… is displayed as:



PROTEIN PATTERN

Electrophoretic fraction

	Mar 21, 2006 07:10	Reference range
Total protein	72	64 - 80
Albumin	40	38 - 50
Alpha 1	4	3 - 5
Alpha 2	5	3 - 7
Beta	8	6 - 10
Gamma	11	7 - 14

Entries

observation

```
<section>
 <code code="369" codeSystem="2.16.840.1.113883.19.10.1.1.3"/>
 <text><content ID="a1">HEMATOCRIT : 39,0 % Ref.  Range: 37,0-47,0 Method:
     Automated Blood Counter</content>
 </text>
 <entry>
  <observation classCode="OBS" moodCode="EVN">
  <id root="2.16.840.1.113883.2.10.1.4.5" extension="E157300-466-1"/>
  <code code="369" codeSystem="2.16.840.1.113883.19.10.1.1.3"
    displayName="HEMATOCRIT">
   <originalText>
     <reference value="#a1"/>
  </originalText>
  </code>
  <statusCode code="completed"/>
  <effectiveTime value="20061106171200"/>
  <value unit="%" value="39.0" xsi:type="PQ"/>
  <referenceRange>
    <observationRange>
      <value xsi:type="IVL_PQ"><low unit="%" value="37.0"/></value>
    </observationRange>
  </referenceRange>
 <referenceRange>
   <observationRange>
     <value xsi:type="IVL_PQ">
       <high unit="%" value="47.0"/>
    </value>
   </observationRange>
  </referenceRange>
 </observation>
```

```
 </entry>
</section>
```

observationMedia

(See renderMultimedia example above)

procedure

```
<section>
  <code code="29554-3" codeSystem="2.16.840.1.113883.6.1"
            codeSystemName="LOINC"/>
 <title>In-office Procedures</title>
 <text>
  <list>
    <item>Suture removal, left forearm.</item>
 </list>
 </text>
 <entry>
  <procedure classCode="PROC" moodCode="EVN">
   <code code="30549001"
    codeSystem="2.16.840.1.113883.6.96" codeSystemName="SNOMED CT"
    displayName="Suture removal"/>
   <statusCode code="completed"/>
   <effectiveTime value="200004071430"/>
   <targetSiteCode code="66480008" codeSystem="2.16.840.1.113883.6.96"
    codeSystemName="SNOMED CT" displayName="Left forearm"/>
 </procedure>
 </entry>
</section>
```

encounter

```
<section>
 <code code="18776-5" codeSystem="2.16.840.1.113883.6.1"
                codeSystemName="LOINC"/>
 <title>Plan</title>
 <text>
<list><item>Control visit next week</item></list>
 </text>
 <entry>
  <encounter classCode="ENC" moodCode="RQO">
    <code code="185389009" codeSystem="2.16.840.1.113883.6.96"
    codeSystemName="SNOMED CT" displayName="Follow-up visit"/>
    <effectiveTime>
      <low value="20060412"/>
      <high value="20060417"/>
   </effectiveTime>
 </encounter>
 </entry>
</section>
```

substanceAdministration

```
...
<text>Prednisone  20mg PO daily from Mar 28, 2000 (Active)</text>
<entry typeCode="DRIV">
 <substanceAdministration classCode="SBADM" moodCode="EVN">
 <id root="cdbd5b03-6cde-11db-9fe1-0800200c9a66"/>
 <statusCode code="active"/>
 <effectiveTime xsi:type="IVL_TS">
    <low value="20000328"/>
 </effectiveTime>
 <effectiveTime xsi:type="PIVL_TS" operator="A">
   <period value="24" unit="h"/>
 </effectiveTime>
 <routeCode code="PO" codeSystem="2.16.840.1.113883.5.112"
     codeSystemName="RouteOfAdministration"/>
 <doseQuantity value="1"/>
 <consumable>
    <manufacturedProduct> <manufacturedMaterial>
  <code code="312615" codeSystem="2.16.840.1.113883.6.88"
    displayName="Prednisone 20 MG oral tablet">
   <originalText>Prednisone</originalText>
          </code>
   </manufacturedMaterial></manufacturedProduct>
  </consumable>
 </substanceAdministration>
</entry>
...
```