

Anatomy of a Standard

HL7v3 and the Clinical Document Architecture

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Acknowledgements

- The first section draws on:
 - HL7v3 Guide, part of HL7v3 Normative 2010
 - HL7v3 Primer by Andrew Hinchley
 - Book sold by HL7 UK
- Slides so marked in the CDA section are from Liora Alschuler & Bob Dolin
- MIM CDA diagram is from NHS CFH MIM 7.2
- All extracts from HL7 standards are copyright HL7 International

Contents

- HL7v3 from RIM to XML - A quick tour
 - HL7v3 information models
 - RIM, D-MIM and R-MIM, and data types
 - From RIM to reality: building a simple example model from RIM-based classes
- Clinical Document Architecture

HL7v3 - A quick tour

HL7v3 information models

- Reference Information Model (RIM)
- Domain Message Information Model (D-MIM)
- Refined Message Information Model (R-MIM)
- Datatypes

Reference Information Model (RIM)

- A static model of health and health care information intended to support interoperability...
- ...that provides an underlying relatively simple yet comprehensive model for the data content of all HL7 messages
- The RIM is a class-based model that can be expressed in UML 2
 - HL7's own diagrams and tools are usually used for model development
 - HL7v3 models predate UML 2
 - Specialist tools provide better support than standard UML for the HL7v3 modelling style

Domain Message Information Model (D-MIM)

- A D-MIM is a specialization of the RIM that models the subject matter of a domain (a particular area of interest in healthcare)

Examples:

- The Clinical Statement Pattern D-MIM is used as a common pattern for clinical information
 - Basis for clinical information in CDA
- The Pharmacy D-MIM provides a top-level model that ensures consistency of common concepts across specific messages relating to drugs and medication

Refined Message Information Model (R-MIM)

- A subset or refinement of a D-MIM that expresses the information content for a particular message or closely related set of messages
- R-MIMs are the starting point for semi-automated derivation of data representations to use “on the wire”
 - The XML Implementation Technology Specification (XML ITS) is the most commonly used data representation

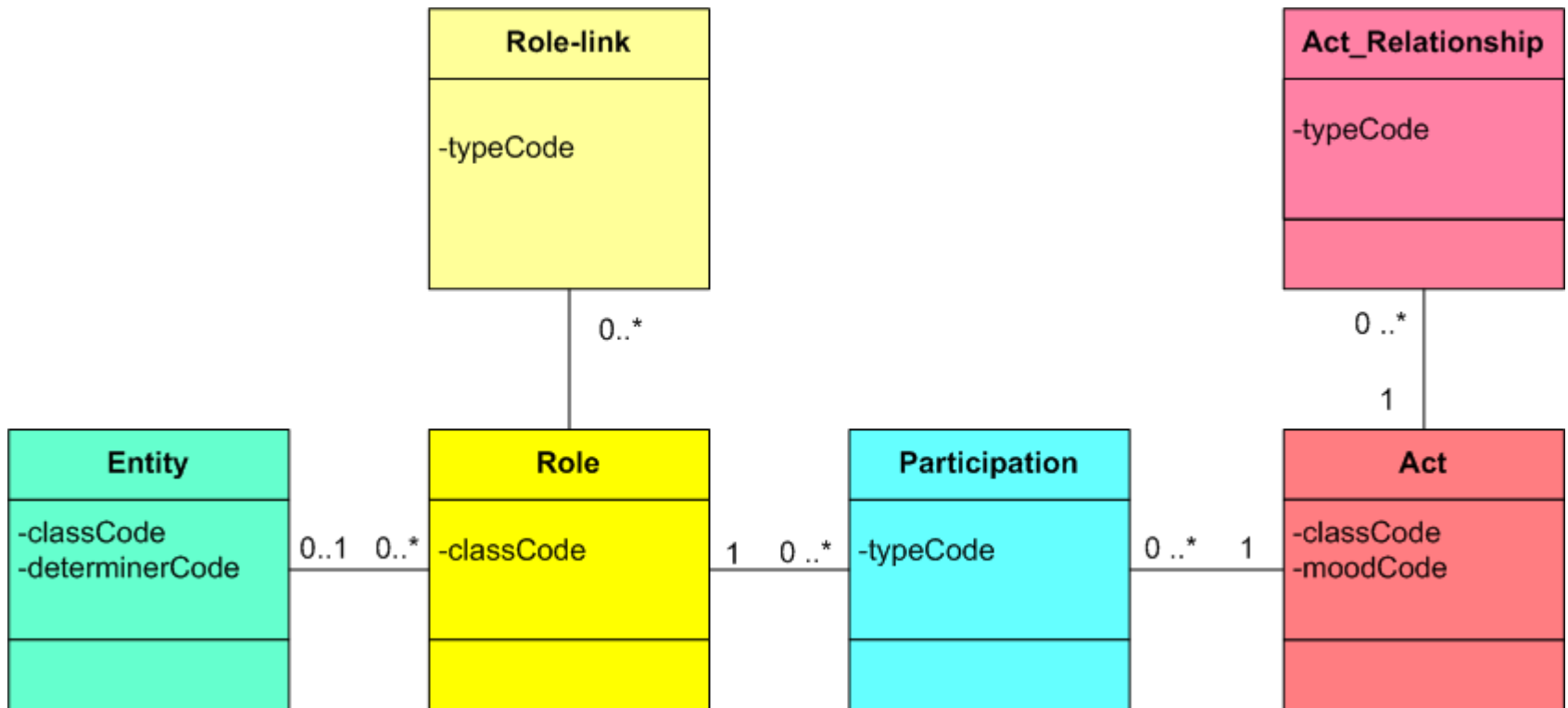
HL7v3 modelling style

- Elaboration of D-MIMs and R-MIMs brings out the intrinsic complexity and detail of health information
- A RIM class may appear many times in different specializations in one D-MIM or R-MIM
 - “Clones”
- Methodical use of class attributes to express structural relationships and dependencies
- Several modes of inheritance of characteristics “down” the structure of a model (“context conduction”)
- Association classes (in UML terms) are heavily used, and often carry substantive attributes of the domain being modelled

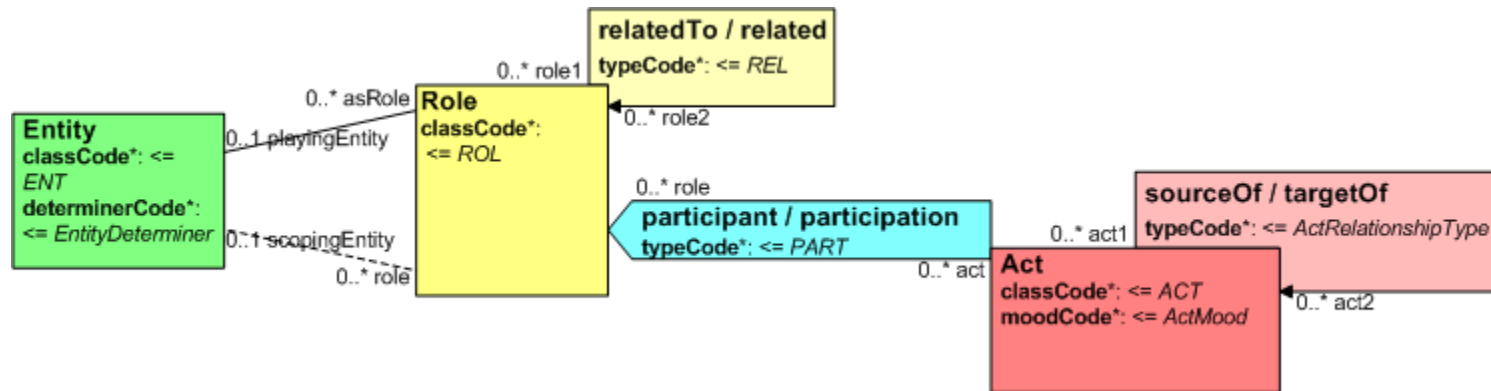
HL7v3 Datatypes

- Defines the repertoire of value types for attributes of classes in the RIM (and hence in D-MIMs and R-MIMs)
- The Datatype of an attribute determines the structural format of data carried in the attribute and the allowed values
 - Some Datatypes are quite complex objects, others are simple values
- Data representation of coded values
 - Usage of clinical terminology goes beyond representation of coded values in the Datatypes, with specific guidance for particular terminologies such as SNOMED CT
- Note: HL7v3 Datatypes cannot be fully validated using XML schema validation on their XML representation

RIM “backbone” classes



How RIM classes look in models

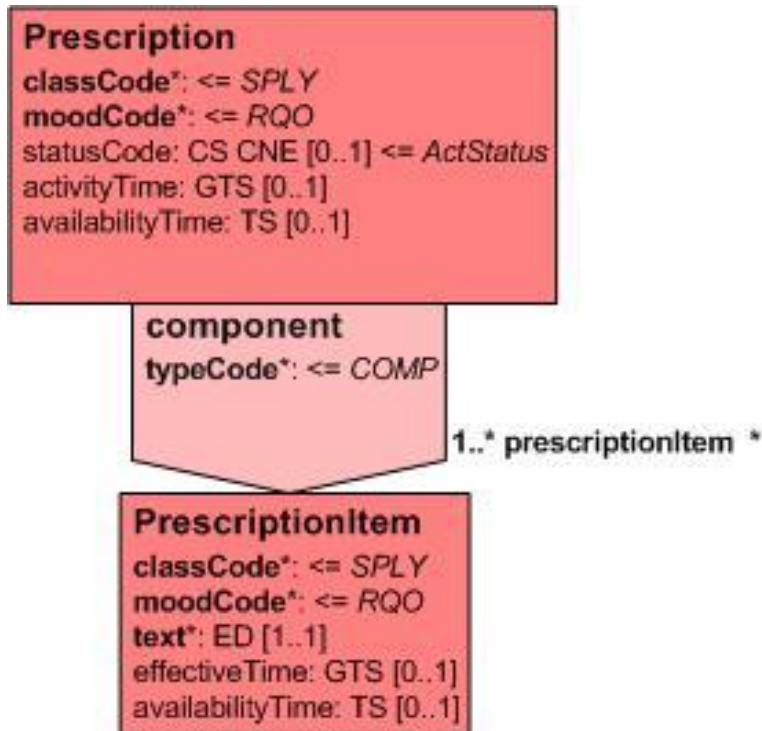


Building an example: Prescription

```
Prescription
classCode*: <= SPLY
moodCode*: <= RQO
statusCode: CS CNE [0..1] <= ActStatus
activityTime: GTS [0..1]
availabilityTime: TS [0..1]
```

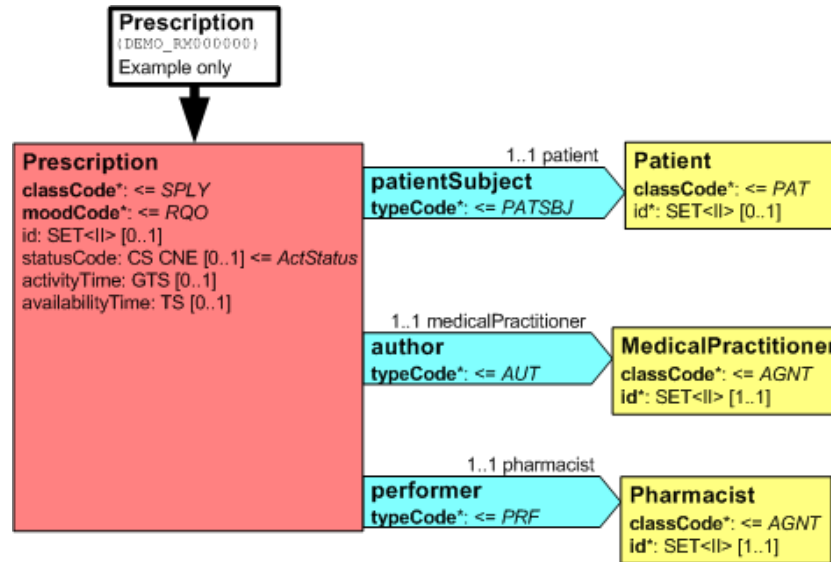
- A Prescription is a kind of Act.
- **classCode** is given as SPLY, in this case indicating supply of medication
- **moodCode** is given as RQO, that is, a request or order
- **statusCode** must be a member of the HL7 defined ActStatus vocabulary
- HL7v3 datatypes are given for the other attributes:
 - **activityTime** uses the General Timing Specification, that includes various ways to state extent of time including intervals and repetition
 - **availabilityTime** uses a datatype indicating a single point in time

Items belonging to a Prescription



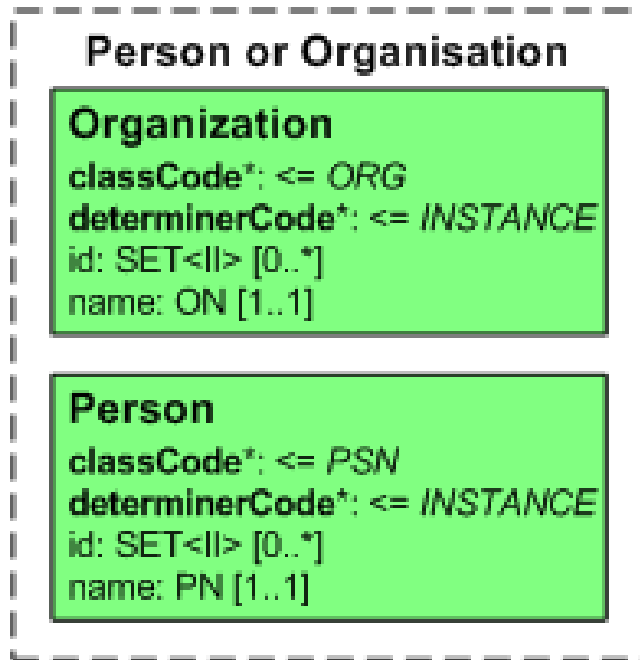
- **component** is an ActRelationship (association class)
 - typeCode is given as COMP, indicating this relationship is component-of
- **PrescriptionItem** is an Act
 - with its own **classCode** and **moodCode**
 - ...but no **statusCode**
 - **text** has datatype ED indicating embedded data
 - ...and finally its own **effectiveTime** and **availabilityTime**

People involved in a Prescription



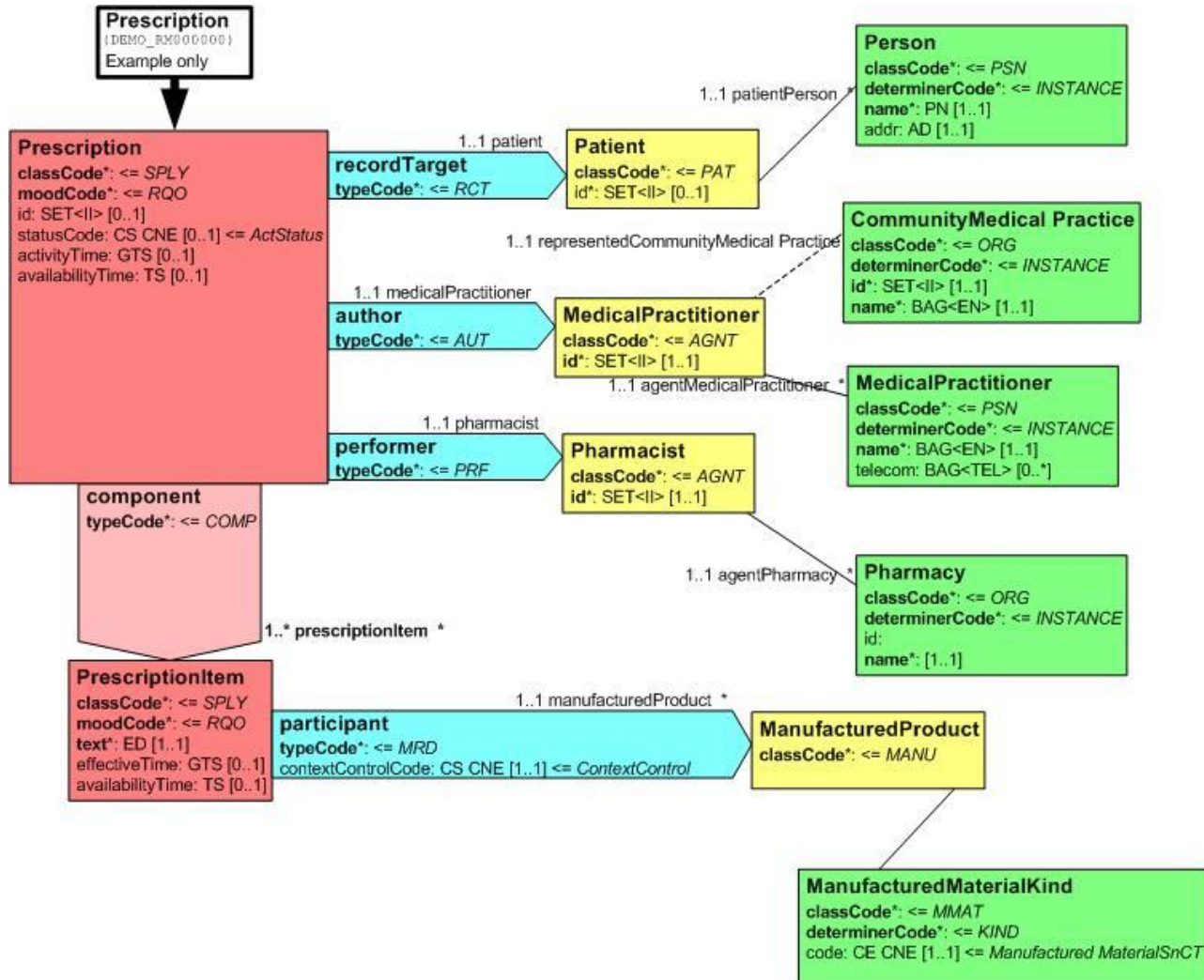
- Blue arrow-shaped classes are Participations
 - They indicate ways that people or things are involved in an Act
- Yellow boxes are Roles
 - They indicate which “hat” a person is wearing when they participate in the Act

People and Organizations



- **classCode** shows what kind of entity this is
 - In terms of an HL7 defined vocabulary
- Entities such as people and organizations usually have both formal identifiers and names

Putting it all together...



HL7 Clinical Document Architecture

Principles and Basic Structure

Why did HL7 develop CDA?

- Exchanging clinical information is hard
 - Reusable, long-lived, community-scale solutions are very hard
- Clinical documents (letters, reports, forms) have developed over centuries as a way that works
- Electronic clinical documents take established genres and ways of working directly into electronic implementation
- Separation of concerns between:
 - Introducing electronic communication and shared records
 - Deeper business change such as full clinical coding and managing variation in clinical practice
- CDA is designed to support step by step progression from just sharing text documents to a combination of text and structured, coded communication

Clinical Document

- CDA is a data exchange standard for **Clinical Documents**
 - Formal documentation of clinical observations and actions
- Defining characteristics as stated in CDA Release 2:
 - **Persistence** – A clinical document continues to exist in an unaltered state, for a time period defined by local and regulatory requirements.
 - **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 is intended to be legally authenticated.
 - **Context** - A clinical document establishes the default context for its contents.
 - **Wholeness** - 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 human readable.

HL7 Clinical Document Architecture

- CDA is a **data exchange standard** for Clinical Documents
 - Specifies the structure and semantics of a clinical document (such as a discharge summary or consultation note) for the purpose of data exchange.
- A CDA document is a **complete information object**
 - Can be sent as the payload of a message however can also **exist independently**, outside a transferring message
 - Can include text, images, sounds, and other multimedia content
- CDA documents are encoded XML, taking advantage of how XML accommodates **both narrative text and structured data**
 - CDA documents often convey data that is fully understandable **only** by humans
 - CDA documents derive their machine readable meaning from the HL7v3 Reference Information Model (RIM) coupled with terminology
 - such as SNOMED CT and LOINC

CDA Releases 1 and 2

- CDA Release 1
 - Reliable data exchange for human readable (narrative) clinical notes.
- CDA Release 2
 - Adds the ability to exchange clinical information that can be safely interpreted and acted on by a computer (eg to generate alerts)
 - Includes structured, coded data representation of clinical statements (such as observations, medication administrations, and adverse events) alongside human readable narrative
- CDA Release 2 (still) offers a “low bar” for minimal adoption
 1. Conveying a non-XML document or image with a CDA header
 2. Creating a document consisting of a CDA header with sections containing only narrative content
- The intent is to facilitate fast and widespread adoption, together with gradual progress towards **semantic interoperability**

Semantic Interoperability:

Information systems working together automatically in a way that shares the **intended meaning** of shared data

Early implementations

- Unlocking the clinical content stored in “silos” of free-text clinical notes
 - Mayo Clinic – Clinical Notes programme
- Enable exchange of information (in human readable form) from existing information systems with widely varying characteristics
 - “Low bar” solution with proven clinical value
 - Enables basic organizational issues about sharing information to be resolved in advance of deeper clinical information integration
 - Scalable to national information infrastructures
 - CDA documents are a relatively tractable common target format for information from old and new systems in many care settings
 - Cost-effective and rapid proliferation of accessibility to (human readable) clinical information

Moving on to CDA Release 2

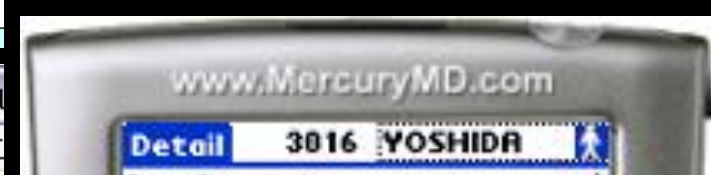
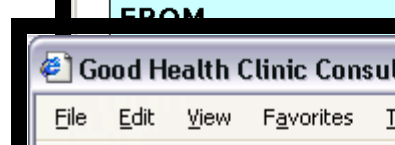
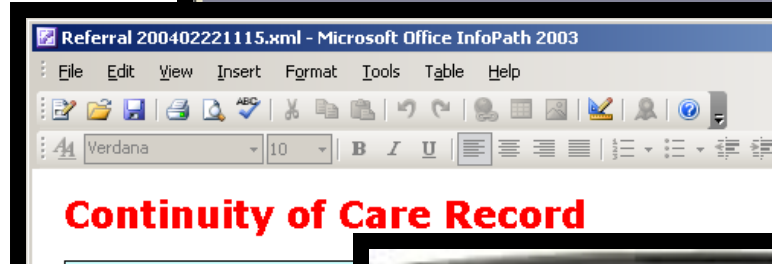
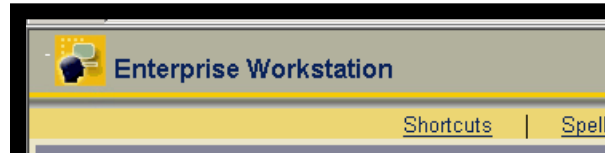
- Machine processing of CDA for decision support already being implemented
 - Early implementations using CDA R1 with local extensions, or prenormative drafts of CDA R2
 - Only within one organizational “span of control”
 - Larger issues for pan-community implementation
- The NHS adopted CDA R2 for clinical documents in the Spine (PSIS) and now more widely for “connecting all” using the Interoperability Toolkit (ITK)
 - Using templates and implementation guidance to constrain the CDA specification within a particular implementation
 - Providing validating rule sets that check conformance to these constraints
 - Providing simple subsets for data mapping with transforms to full CDA (coming soon!)
 - For information about the ITK contact toolkit.enquiries@nhs.net

Examples from the developers of CDA

- Thanks to Liora Alschuler and Bob Dolin for the examples in the following slides
- One Clinical Document Architecture, many ways to make it available to healthcare professionals
- Fully international
- Balance between simplicity of presentation and saying what needs saying

CDA Documents in many guises

- This is a CDA
- and this
- and this
- and this
- and this
- and this
- and this



C:\KEG\implementations\Japan\message\message.xml

File Edit View Favorites Tools Help

Back Forward Stop Refresh Home Search Favorites

Address C:\KEG\implementations\Japan\message\message.xml

```
<?xml version="1.0" encoding="UTF-8" ?>
- <ClinicalDocumentEvent classCode="DOCCLIN" m
  <id root="0.2.440.200194.1.1" extension="SD
    assigningAuthorityName="Hamamatsu Univer
  <code code="FU" codeSystem="2.16.840.1.11
    codeSystemName="ReferralReasonCategory"
  <title>診療情報提供書(患者紹介)</title>
  <effectiveTime value="19991117" xsi:type="TS
    instance" />
  <confidentialityCode code="N" codeSystem="2.
    codeSystemVersion="V161" displayName="nc
  <setId root="0.2.440.200194.2.2" extension=
    assigningAuthorityName="Hamamatsu Univer
  <versionNumber value="1" />
- <!--
  *****
  * 患者情報
  *****
  -->
- <recordTarget typeCode="RCT" contextControlC
  - <patientRole classCode="PAT">
    <id root="0.2.440.200194.2.1" extension=
      assigningAuthorityName="Hamamatsu Un
    <addr>港区芝5-29-23</addr>
  - <addr>
    <country partType="CNT">日本</country>
    <state partType="STA">東京都</state>
    <city partType="CTY">港区芝5-29-23</
    <postalCode partType="ZIP">108-8420<
    </addr>
```

MERIT-9

診療情報提供書 (患者紹介)

1999年11月17日

医療機関 浜松南部病院

担当医 内科
 松永 幸治 殿

医療機関名 浜松医大付属病院
 所在地 〒123-1234 浜松市5丁目8番
 〒789-6789 浜松市6丁目3番
 TEL 053-435-1111

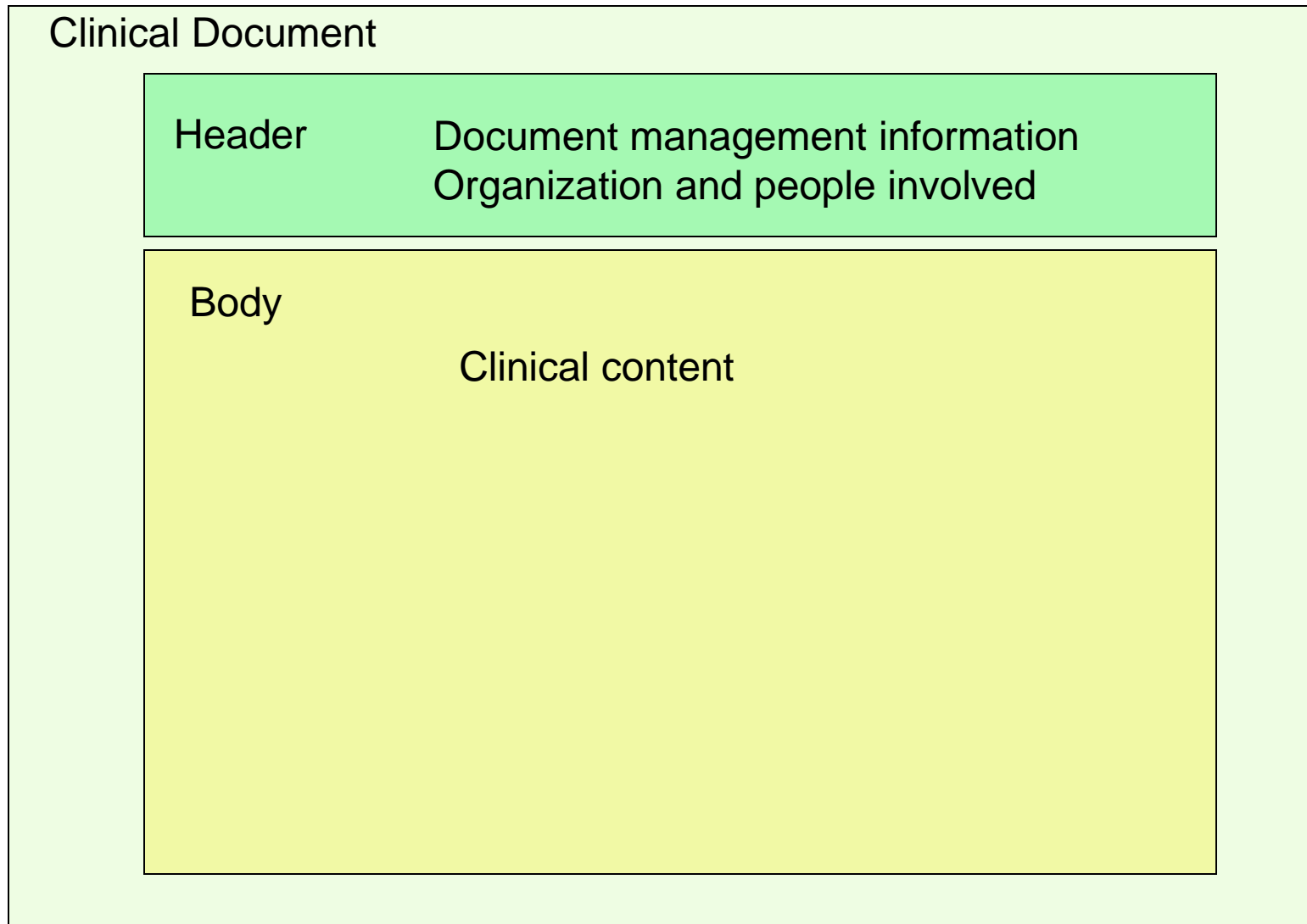
電話番号 053-435-0000
 医師氏名 ○○ 正義

| | | | |
|------|-------|------|-----------|
| 患者氏名 | 患者 女1 | 生年月日 | 1939年3月3日 |
|------|-------|------|-----------|

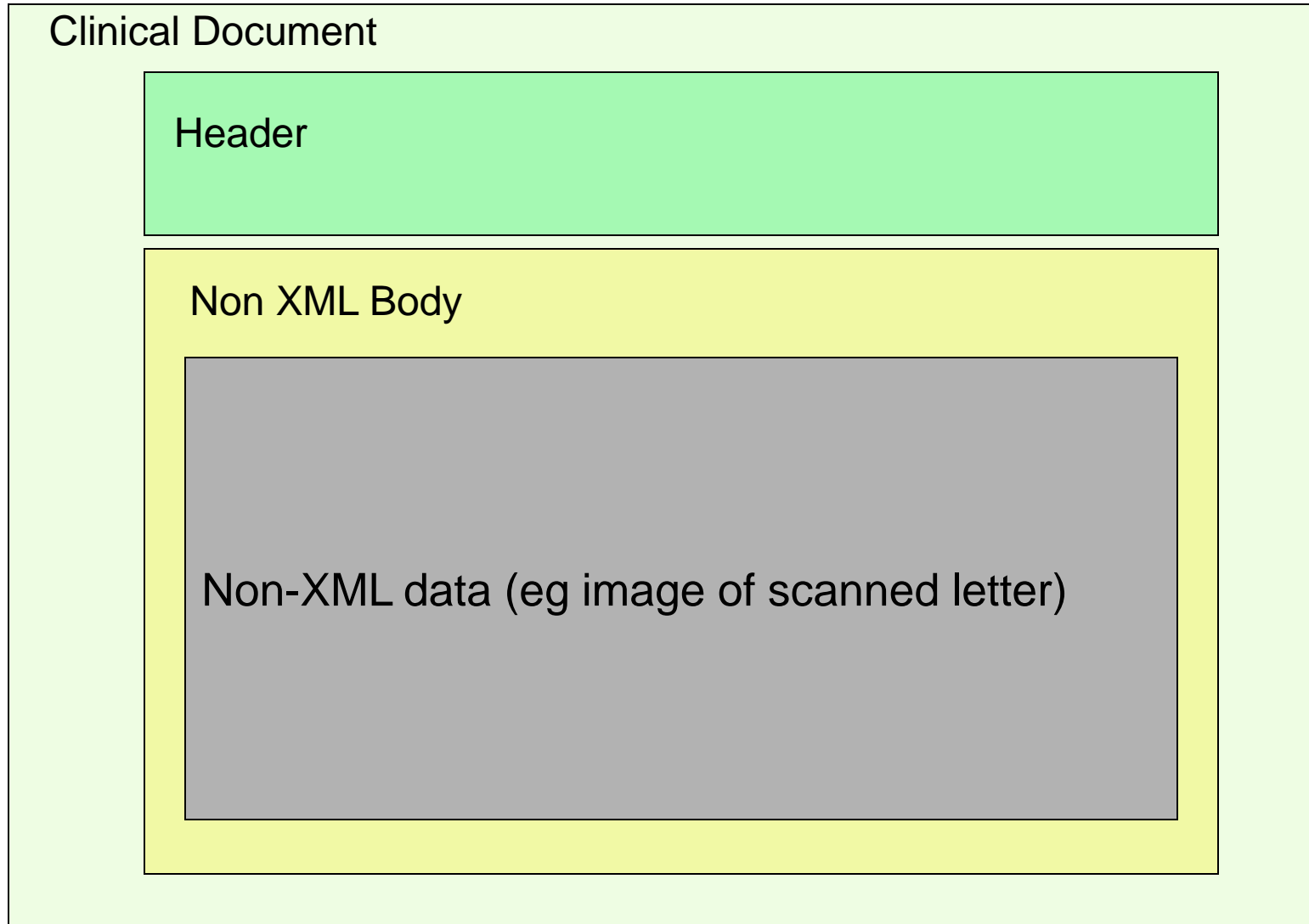
| | |
|----------------|---|
| 傷病名 (主訴、病名) | 肺癌 (小細胞癌) Stage IV |
| 紹介目的 | 御依頼いただきました放射線治療ならびに化学療法の終了 |
| 既往歴 | 特になし |
| 家族歴 | 特になし |
| 症状経過 | 平成11年5月16日当科入院、胸腹部CT、頭部MRI、骨シンチ施行しました。入院翌日より放射線治療開始しております。 |
| 治療経過 | 右側肺門を含めたmain tumorに対し63Gy/35fx、両側鎖上部に45Gy/25fxの照射を行いました。特に副反応みられず、7月3日よりCBDCA 450mg+VP-16 100mg×3の化学療法を3クール行いました。軽度顆粒球減少出現しましたが、現在は落ち着いております。Main tumorは現在径12mmほどに縮小、鎖上リンパ節も触診上ほぼ消失しております。マーカーは添付資料のように相変わらず境界域のみですが、左上葉の含気も十分にあり、咳嗽も下記内服薬程度でコントロールできています。ご本人の希望もあり、今後の経過観察につきよろしく御高診の程、御 |

Inside a CDA document

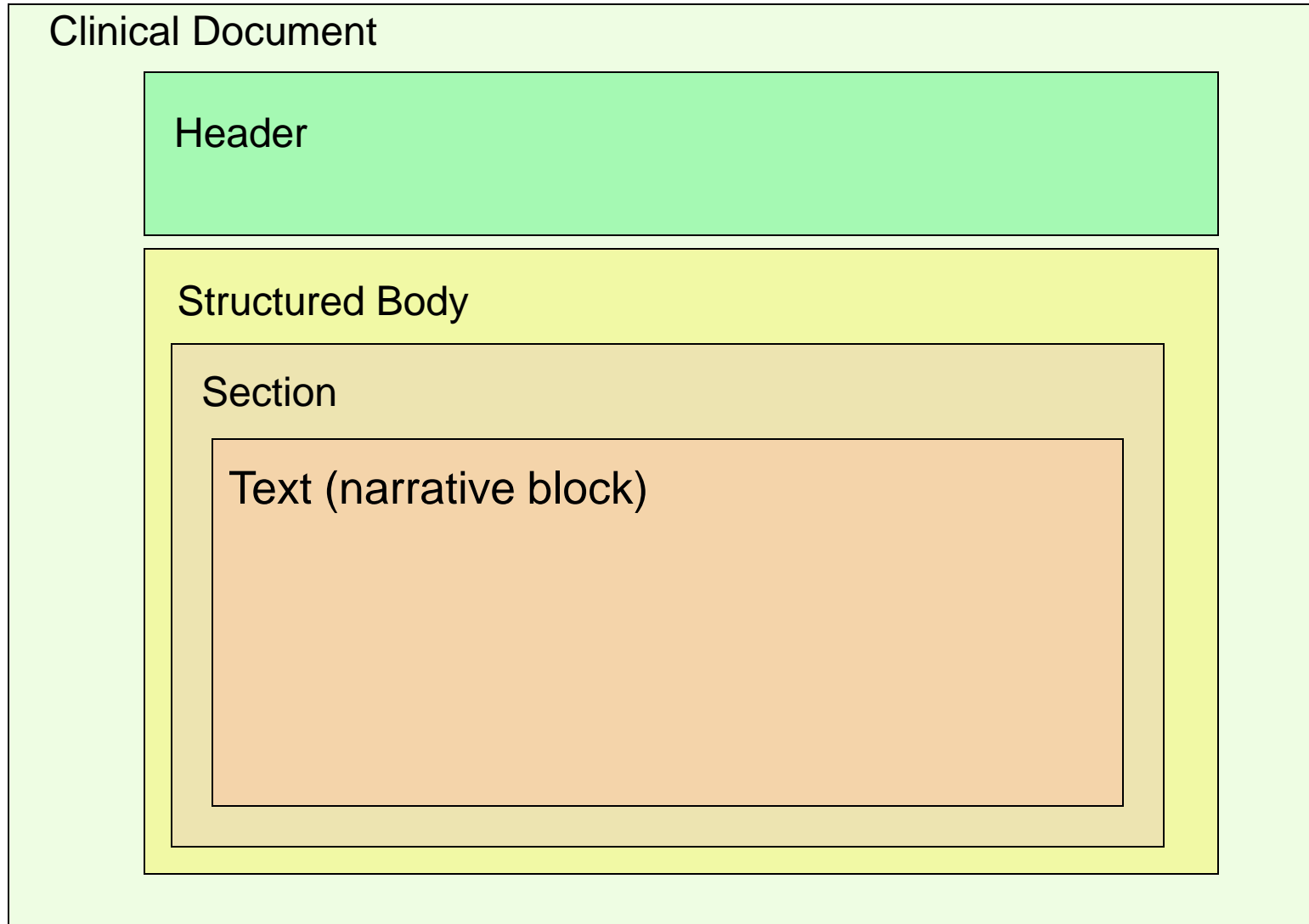
Basic structure: header and body



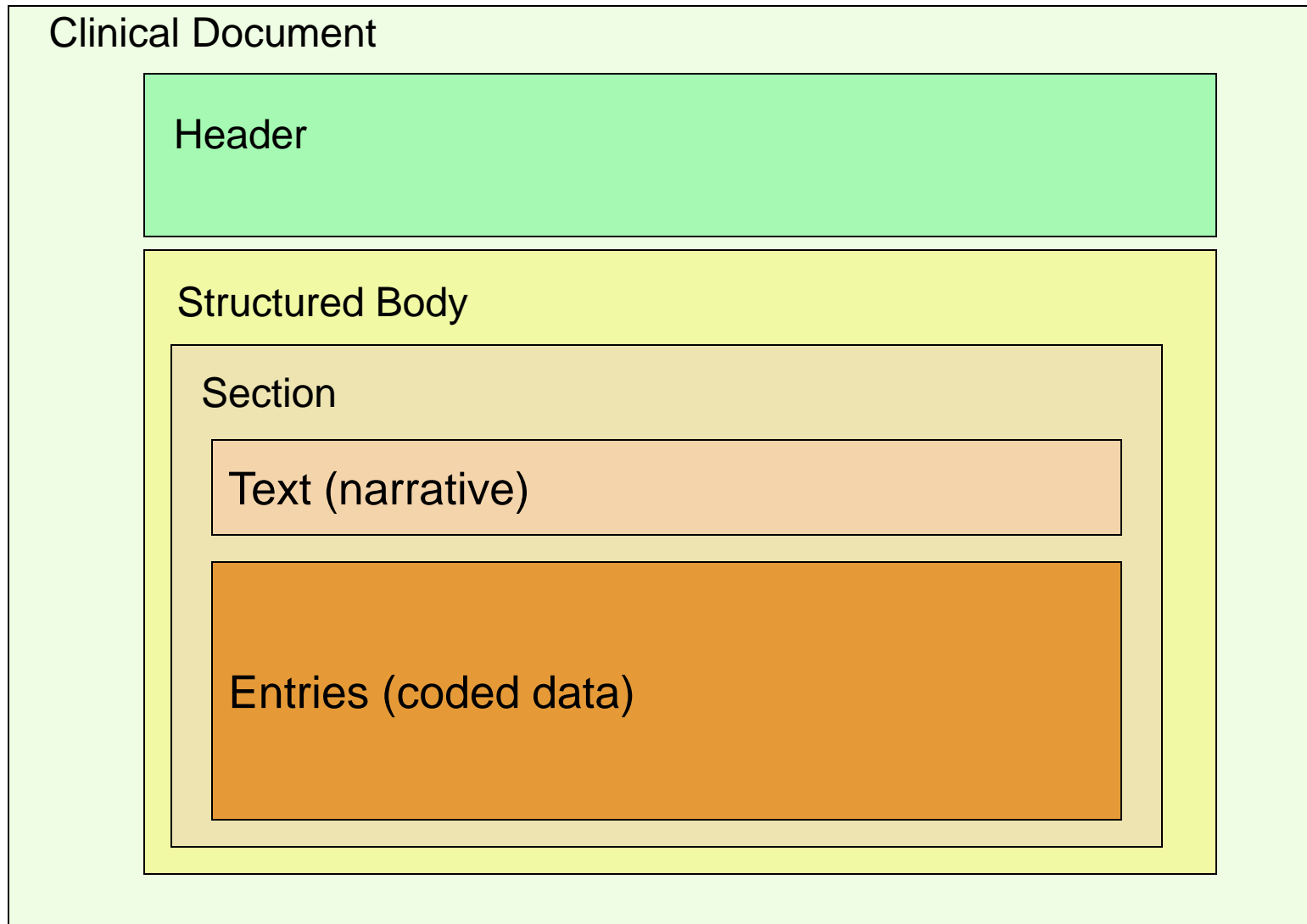
Body carrying “blob” of data



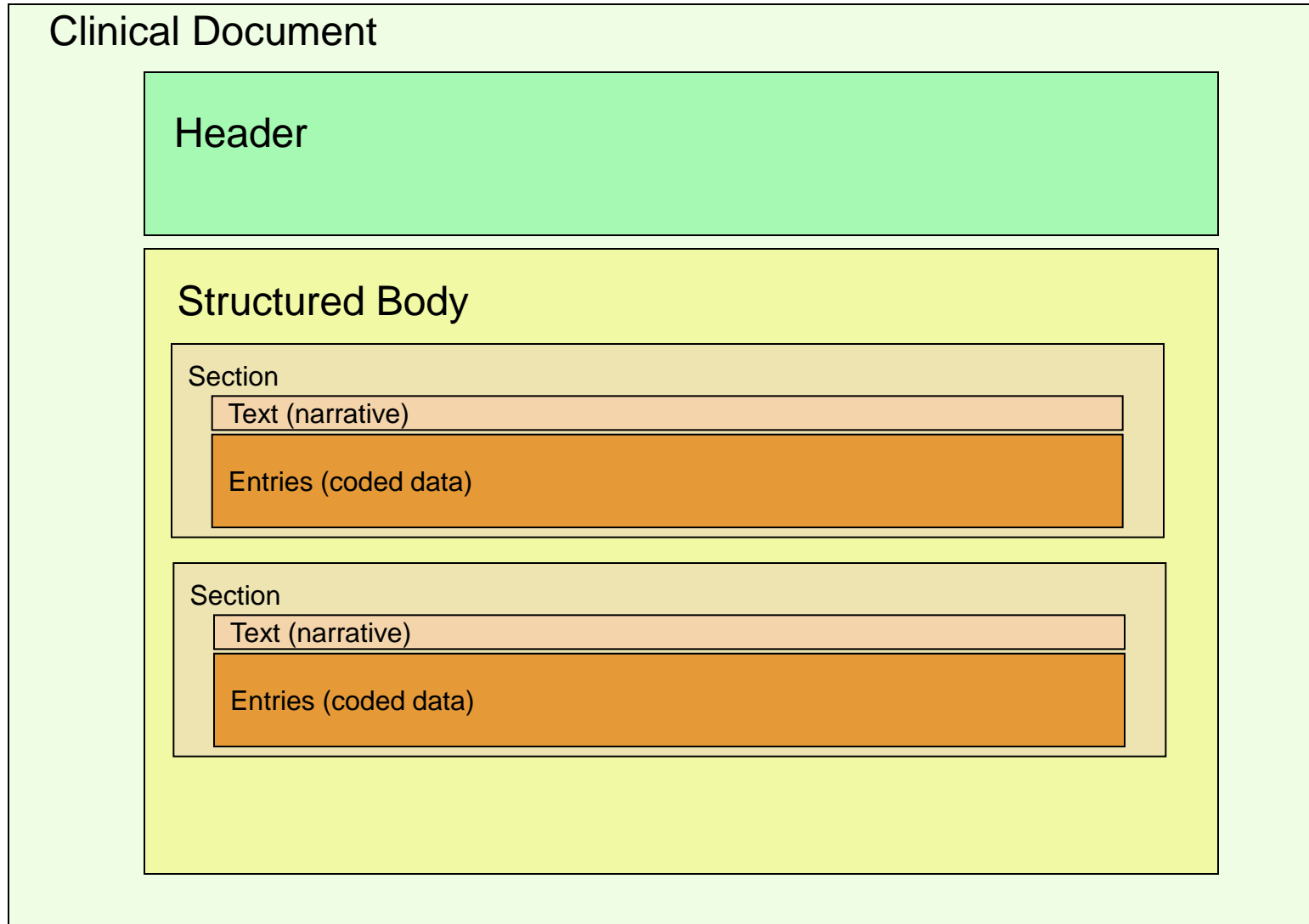
Narrative text only



Add coded entries



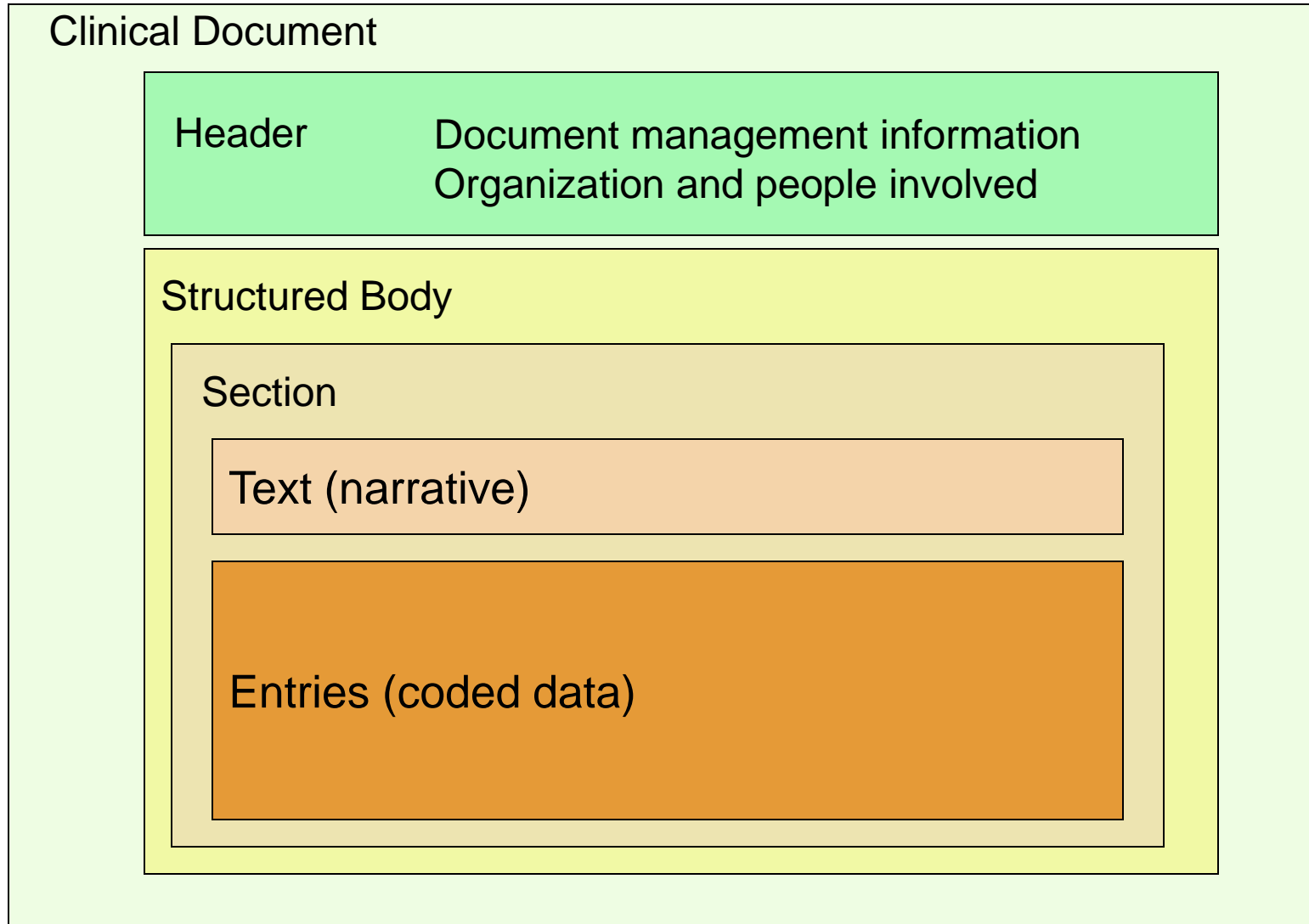
Building blocks for more structure



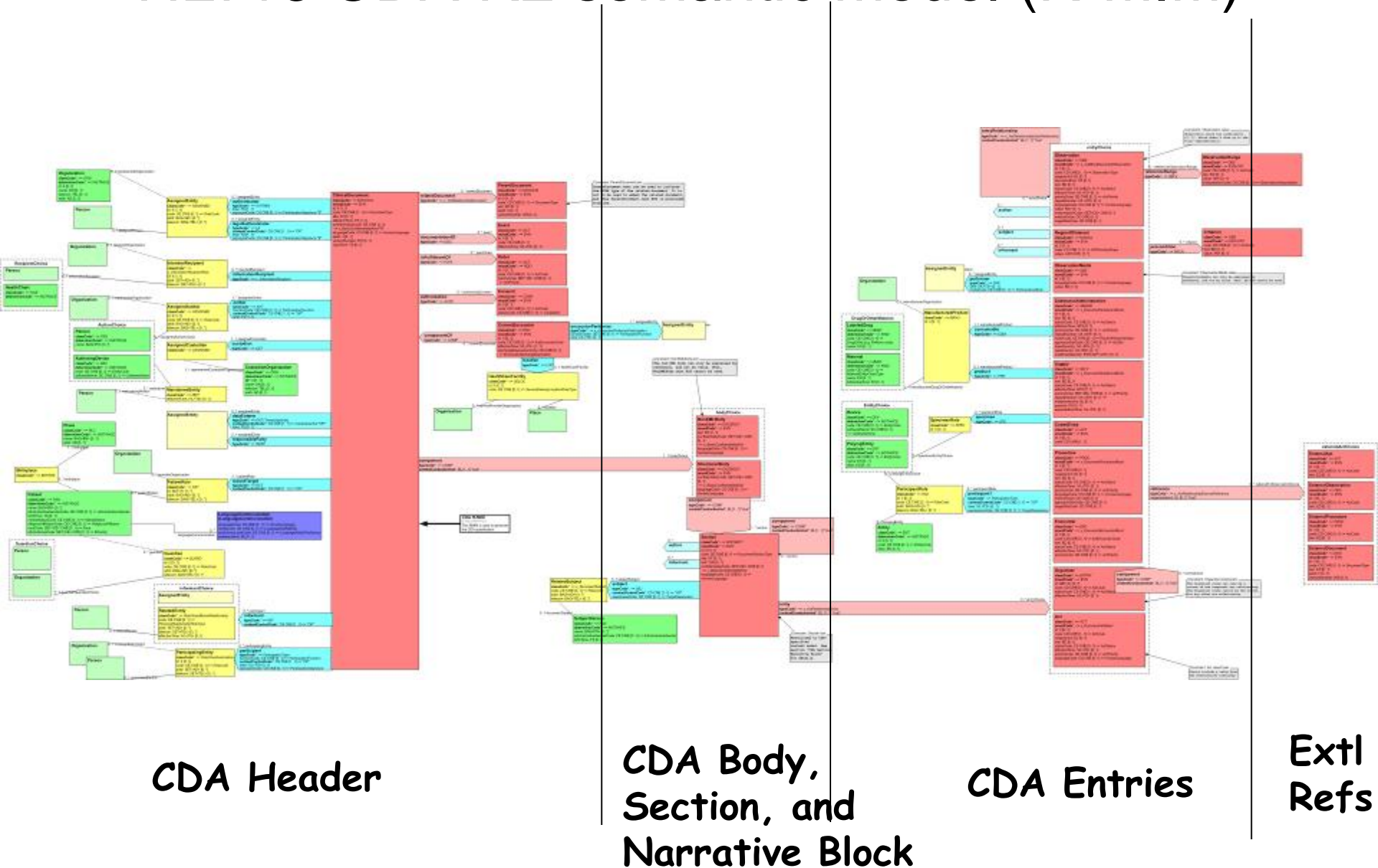
HL7 Clinical Document Architecture

Taking a closer look

CDA document with coded entries



HL7v3 CDA R2 semantic model (R-MIM)



CDA Header

- The CDA header contains four kinds of information:
 - **Document information:** identity, custodian, and relationships (to other documents) of the document itself
 - **Encounter data:** setting and context for the whole document
 - **Service actors:** healthcare practitioners etc involved in the clinical activity described
 - **Service targets:** other significant people including the patient or service user

CDA Header: Document, Encounter

- Document information
 - Identity of the document itself
 - Confidentiality status
 - Relationships to other documents and orders (requests)
- Encounter data
 - Setting in which the documented clinical activities occurred
 - Healthcare provider organization, can specify which site etc

CDA Header: Service Actors, Targets

- Service actors include those who:
 - Participate in the clinical activities being documented
 - Draft or transcribe the document
 - Authenticate the document
 - Receive a copy of the document
 - More exactly, those who are intended to receive a copy
- Service targets are the patient or service user and other significant participants (such as family members, patient advocates etc)

CDA Header

Authentication

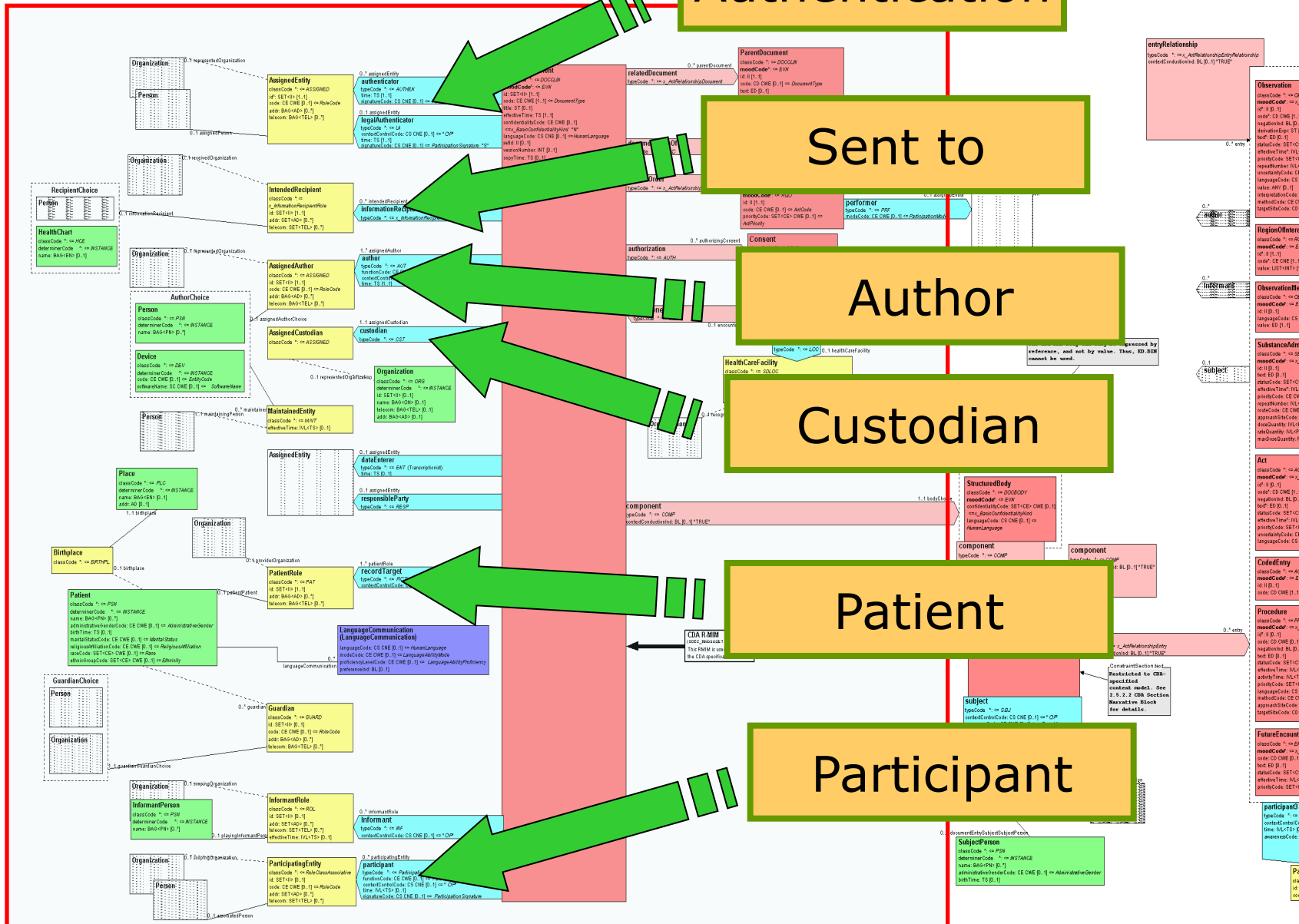
Sent to

Author

Custodian

Patient

Participant



entityRelationship
classCode = "C8"
mooseCDEP = "E" => DocumentType
docID = "E" => DocumentID
docType = "E" => DocumentType
docID = "E" => DocumentID

Observation
classCode = "C8"
mooseCDEP = "E" => DocumentType
docID = "E" => DocumentID
docType = "E" => DocumentType
docID = "E" => DocumentID

RegionOfInterest
classCode = "C8"
mooseCDEP = "E" => DocumentType
docID = "E" => DocumentID
docType = "E" => DocumentID
docID = "E" => DocumentID

ObservationEvent
classCode = "C8"
mooseCDEP = "E" => DocumentType
docID = "E" => DocumentID
docType = "E" => DocumentID
docID = "E" => DocumentID

SubstanceAdministration
classCode = "C8"
mooseCDEP = "E" => DocumentType
docID = "E" => DocumentID
docType = "E" => DocumentID
docID = "E" => DocumentID

Act
classCode = "C8"
mooseCDEP = "E" => DocumentType
docID = "E" => DocumentID
docType = "E" => DocumentID
docID = "E" => DocumentID

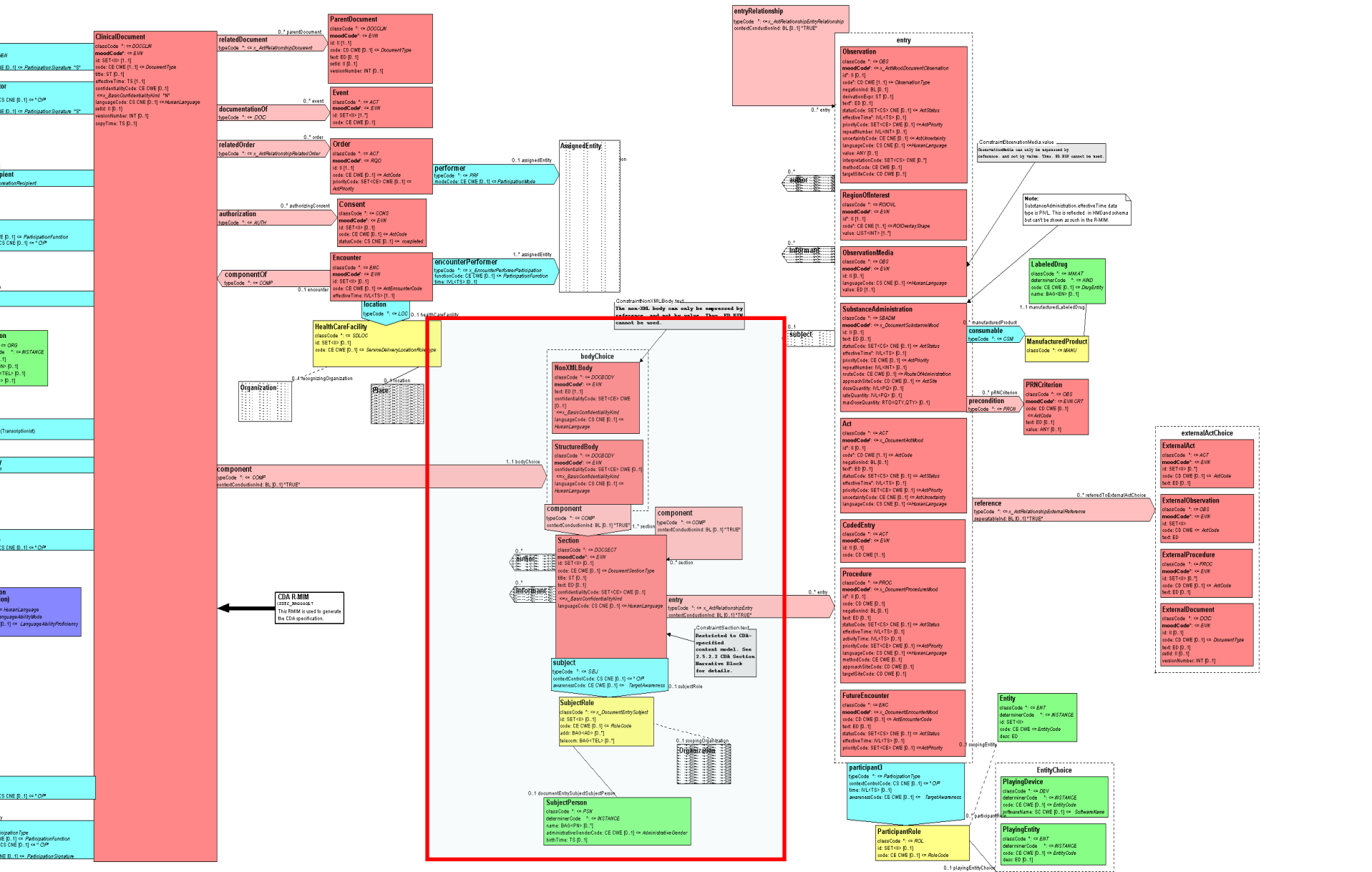
CaseEntity
classCode = "C8"
mooseCDEP = "E" => DocumentType
docID = "E" => DocumentID
docType = "E" => DocumentID
docID = "E" => DocumentID

Procedure
classCode = "C8"
mooseCDEP = "E" => DocumentType
docID = "E" => DocumentID
docType = "E" => DocumentID
docID = "E" => DocumentID

FutureEncounter
classCode = "C8"
mooseCDEP = "E" => DocumentType
docID = "E" => DocumentID
docType = "E" => DocumentID
docID = "E" => DocumentID

Participant
classCode = "C8"
mooseCDEP = "E" => DocumentType
docID = "E" => DocumentID
docType = "E" => DocumentID
docID = "E" => DocumentID

CDA Body



CDA Body: Influences

- Development of CDA Release 2 was influenced by:
 - CEN ENV 13606
 - openEHR
 - DICOM
- ...together with the CDA guiding principles:
 - Give priority to the needs of direct patient care
 - Minimize technical barriers to implementation
 - Ensure information can live as long as its subjects
 - Make information exchange independent of underlying transfer & storage mechanisms
 - Provide an extensibility mechanism to accommodate information not already represented in the standard

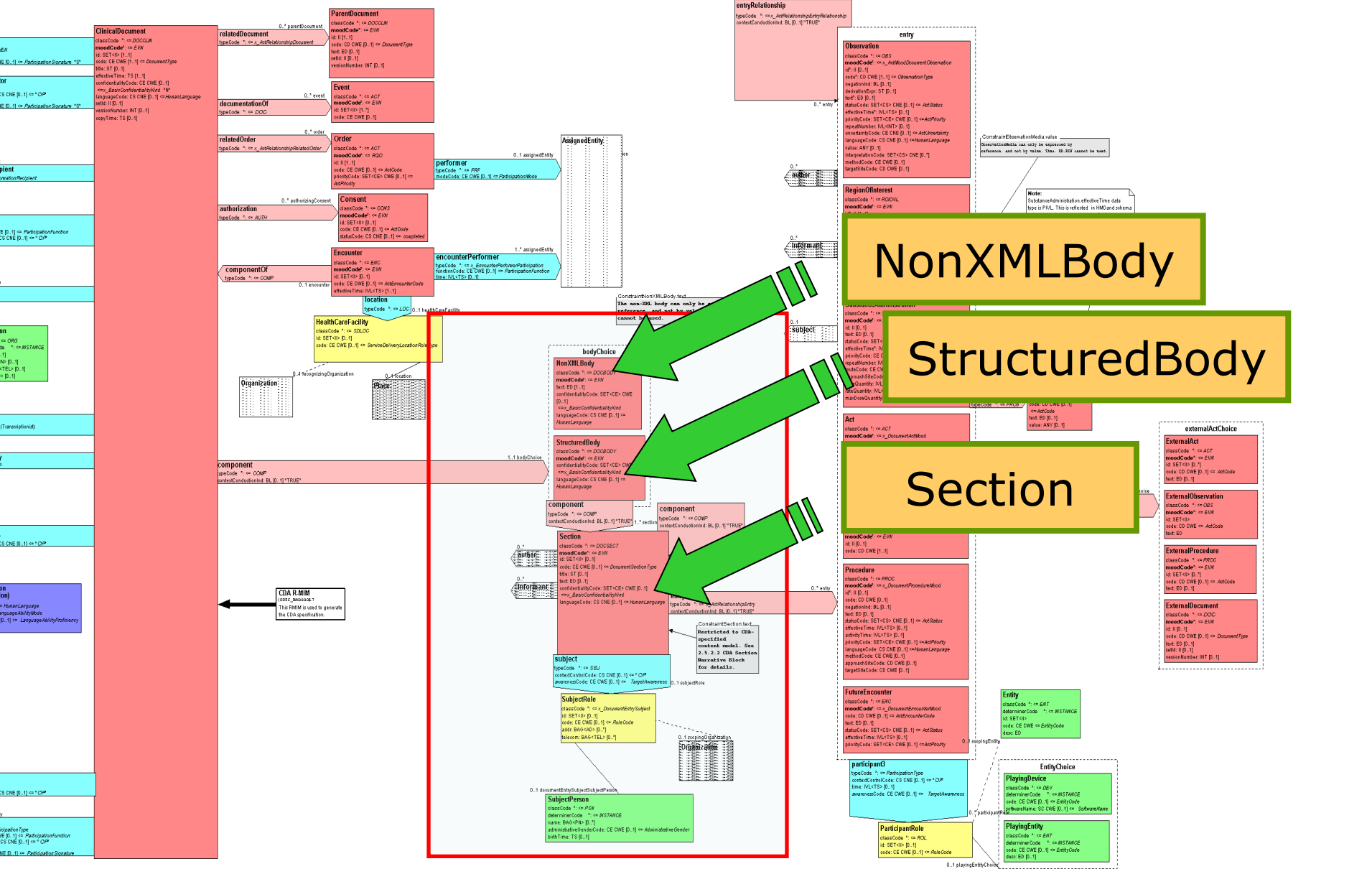
CDA Body: content

- The CDA Body may contain either of two kinds of information:
 - A reference to some external data (eg an image)
 - This is a NonXMLBody
 - Rendering of the referenced data by the recipient is, of course, dependent on having an application that knows how to obtain and deal with it
 - Sections that each contain narrative text with or without accompanying CDA entries
 - This is a StructuredBody
 - A narrative block contains content to be rendered for human readers
 - CDA entries contain structured data intended for computation (such as decision support)
- A Section may have its own specific author and subject
 - Otherwise, the author etc for a section is the same as for the whole document
- There may be a structure of nested (sub)sections
 - This needs to be used with care to limit complexity in implementation

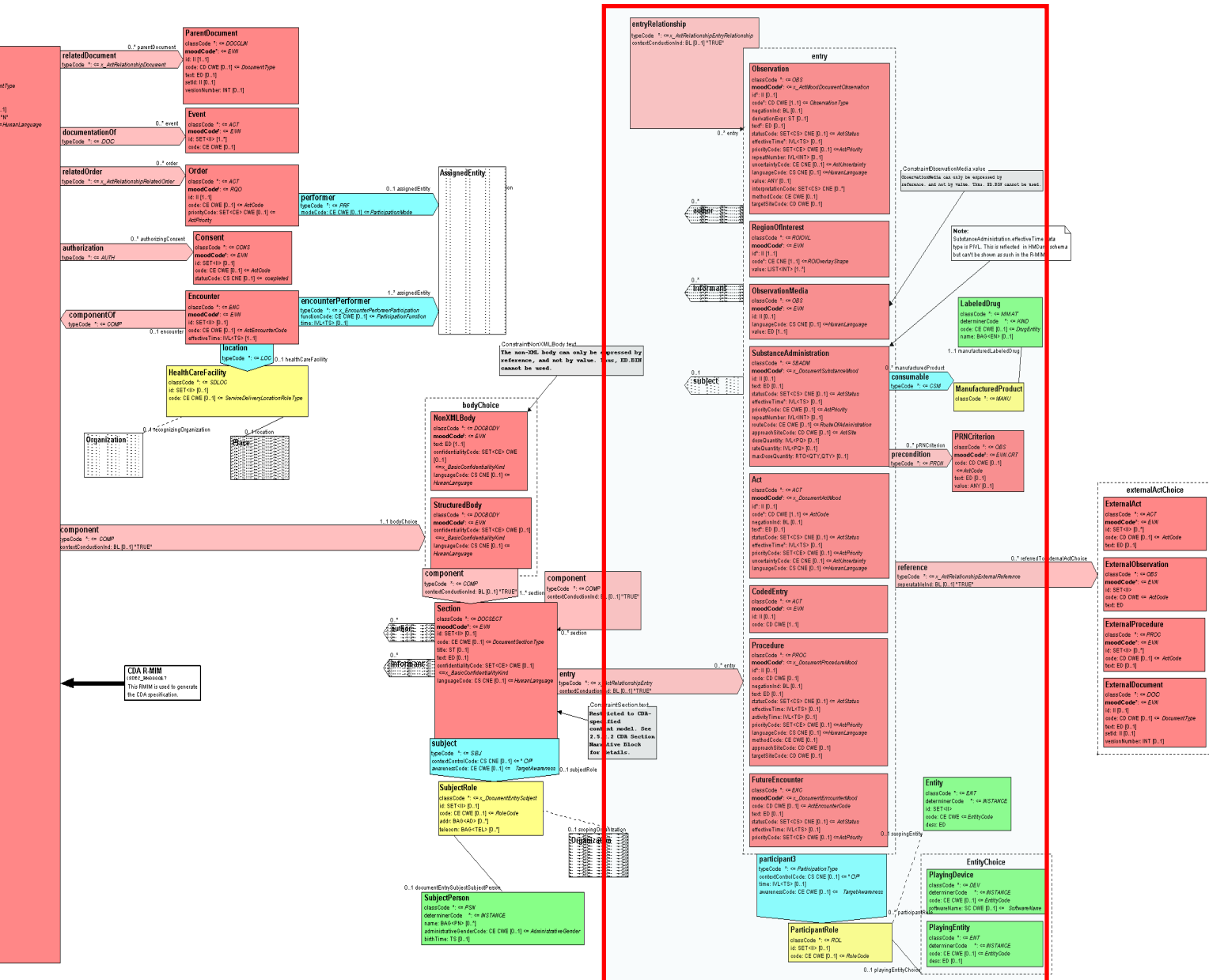
CDA StructuredBody

- The narrative blocks must **always be present**
 - The CDA entries are **optional**.
- All significant information in the coded entries must be included in the narrative text
 - “The originator must ensure that the **attested portion of the document body is conveyed in narrative blocks** such that a recipient, adhering to recipient rendering rules, will correctly render the document”
- CDA entries typically encode content present in the narrative block of the same section – **but there is no obligation to do so**
 - “An originator of a CDA document is not required to fully encode all narrative into CDA entries within the CDA body, nor is a recipient required to parse and interpret the complete set of CDA entries contained within the CDA body”

CDA Body



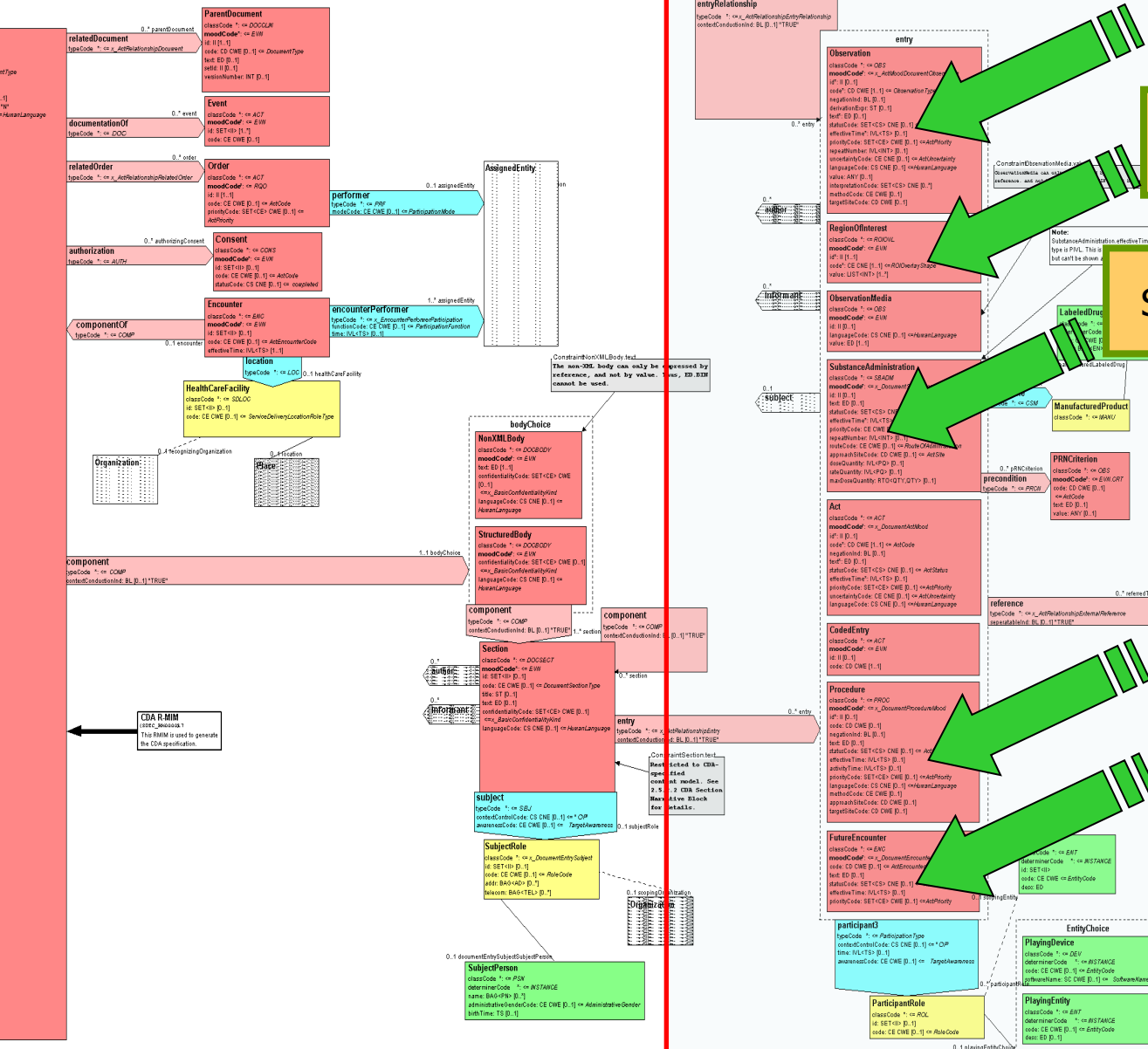
CDA Entries



CDA Entries

- Entries include:
 - Observation
 - RegionOfInterest
 - SubstanceAdministration
 - Procedure
 - FutureEncounter
- Procedure - sample attributes, based on HL7v3 RIM (Reference Information Model) semantics
 - Identifier
 - Clinical code for the procedure
 - Effective time
 - Method (code)
 - Approach (code)
 - Target site (code)

CDA Entries



Observation

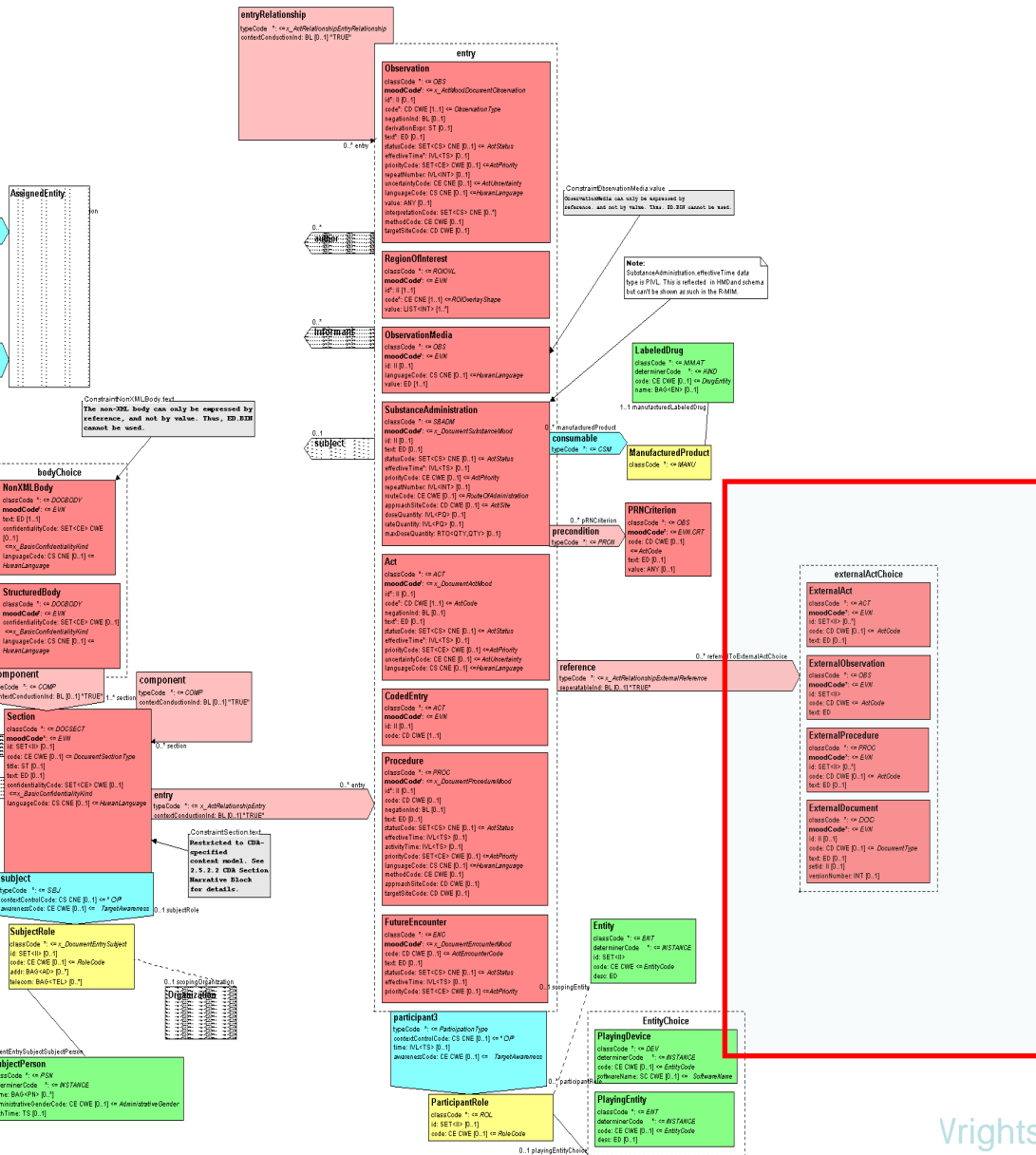
RegionOfInterest

SubstanceAdministration

Procedure

FutureEncounter

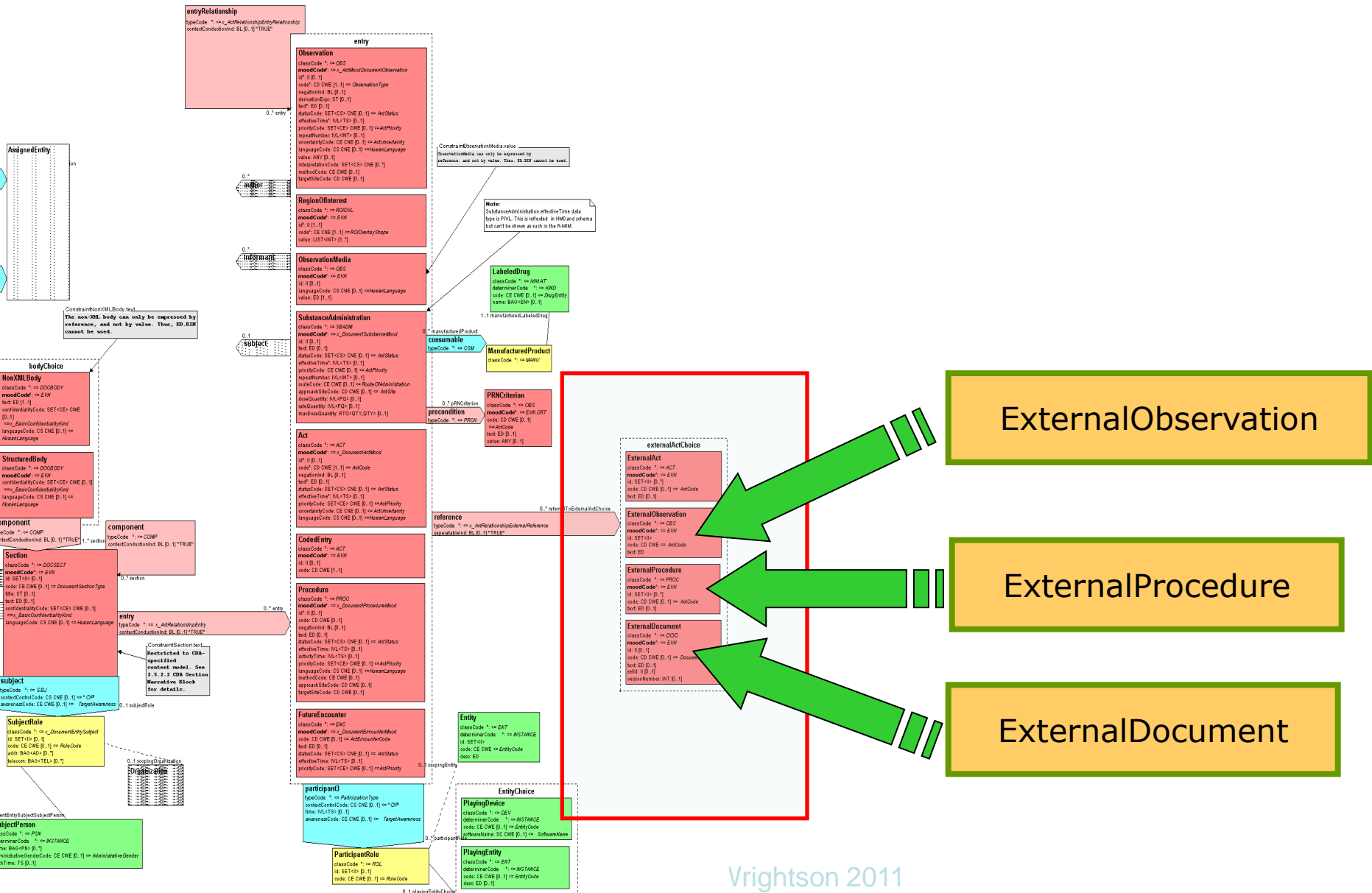
CDA External References



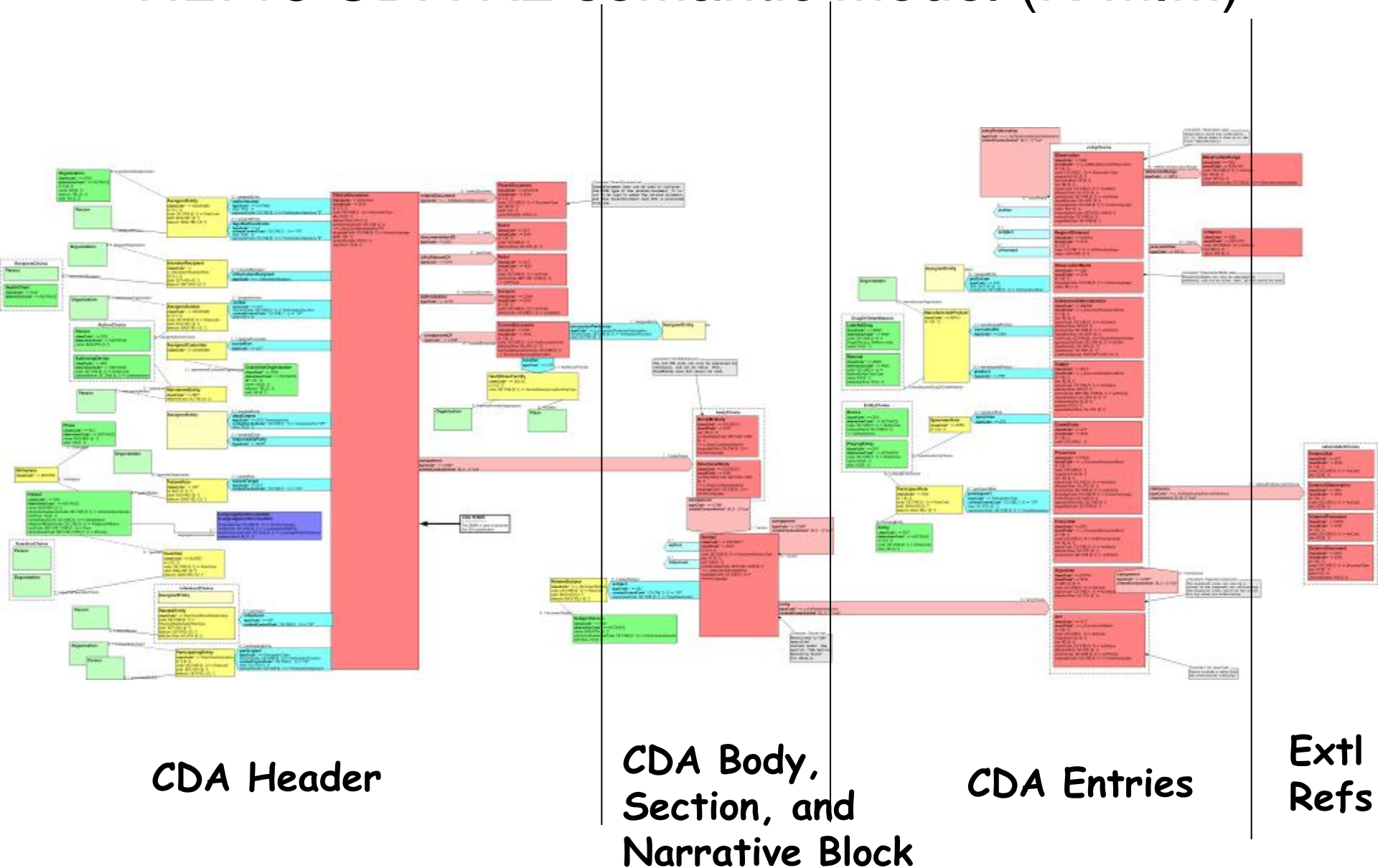
External references

- CDA external references are in the context of a CDA entry
 - That is, these are references at the “entry” level of granularity
- They refer to things that exist outside the CDA document, such as:
 - Some other image or document
 - Some other procedure
 - Some other observation

CDA External References



HL7v3 CDA R2 semantic model (R-MIM)



CDA Header

CDA Body,
Section, and
Narrative Block

CDA Entries

Extl
Refs

References

- The HL7 Clinical Document Architecture
 - ROBERT H. DOLIN, MD, LIORA ALSCHULER, CALVIN BEEBE, PAUL V. BIRON, MLIS, SANDRA LEE BOYER, DANIEL ESSIN, MD, ELLIOT KIMBER, TOM LINCOLN, MD, JOHN E. MATTISON, MD
 - J Am Med Inform Assoc. 2001;8:552–569.
- The HL7 Clinical Document Architecture, Release 2
 - ROBERT H. DOLIN, MD, LIORA ALSCHULER, SANDY BOYER, BSP, CALVIN BEEBE, FRED M. BEHLEN, PHD, PAUL V. BIRON, AMNON SHABO (SHVO), PHD
 - J Am Med Inform Assoc. 2006;13:30–39. DOI 10.1197/jamia.M1888..
- Both these papers are available free in full text on the Web
- The first paper is mostly valuable for principles and motivation of CDA; some of its technical content has been superseded by CDA2

End of slide set 3