ΕΚΠΑΙΔΕΥΤΙΚΟ ΣΕΜΙΝΑΡΙΟ: ΤΟ ΔΙΕΘΝΕΣ ΠΡΟΤΥΠΟ ΚΛΙΝΙΚΩΝ ΕΓΓΡΑΦΩΝ ISO/HL7 27932:2009 CLINICAL DOCUMENT ARCHITECTURE (CDA)

eHealth FORUM 2015

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Αθήνα, 3 Νοεμβρίου 2015

Agenda

- Ο Διεθνής Οργανισμός HL7
- HL7 Hellas
- Τα πρότυπα του HL7
  - HL7 v2.x
  - HL7 FHIR
  - HL7 EHR-S
- HL7 v3 RIM
- **HL7 CDA**
  - **CDA in Details**
  - **CDA Templates, Implementation Guides, Cases**
  - **CDA implementation**
  - **Art-Décor**
- **Demo CDAs**
- Ερωτήσεις – Περαιτέρω ανάλυση

HL7 International

HEALTH LEVEL SEVEN® INTERNATIONAL

Ο Οργανισμός HL7

- ANSI-approved Standards Developing Organisation (SDO)
- Μη κερδοσκοπικός οργανισμός
- >2200 μέλη
- >500 εταιρίες μέλη
- Αναπτύσσει και παρέχει πρότυπα κυρίως για ανταλλαγή ιατρικών δεδομένων
- Περιλαμβάνει το 90% από τις μεγαλύτερες εταιρίας συστημάτων Ιατρικής Πληροφορικής
- Παραρτήματα σε περισσότερες από 39 χώρες.
- Ευρώπη – HL7 Europe Office www.hl7.eu
- www.hl7.org

HEALTH LEVEL 7

HL7 around the world

Το HL7 Hellas

- Ιδρύθηκε το 2003 (επίσημο HL7 παράρτημα στην Ελλάδα -International Affiliate)
- Μέλη του (φυσικά & νομικά πρόσωπα)
  - Εταιρίες με συστήματα πληροφορικής στο χώρο της υγείας
  - Πανεπιστήμια
  - Ερευνητικά Ιδρύματα
  - Φυσικά πρόσωπα
- www.hl7.org.gr

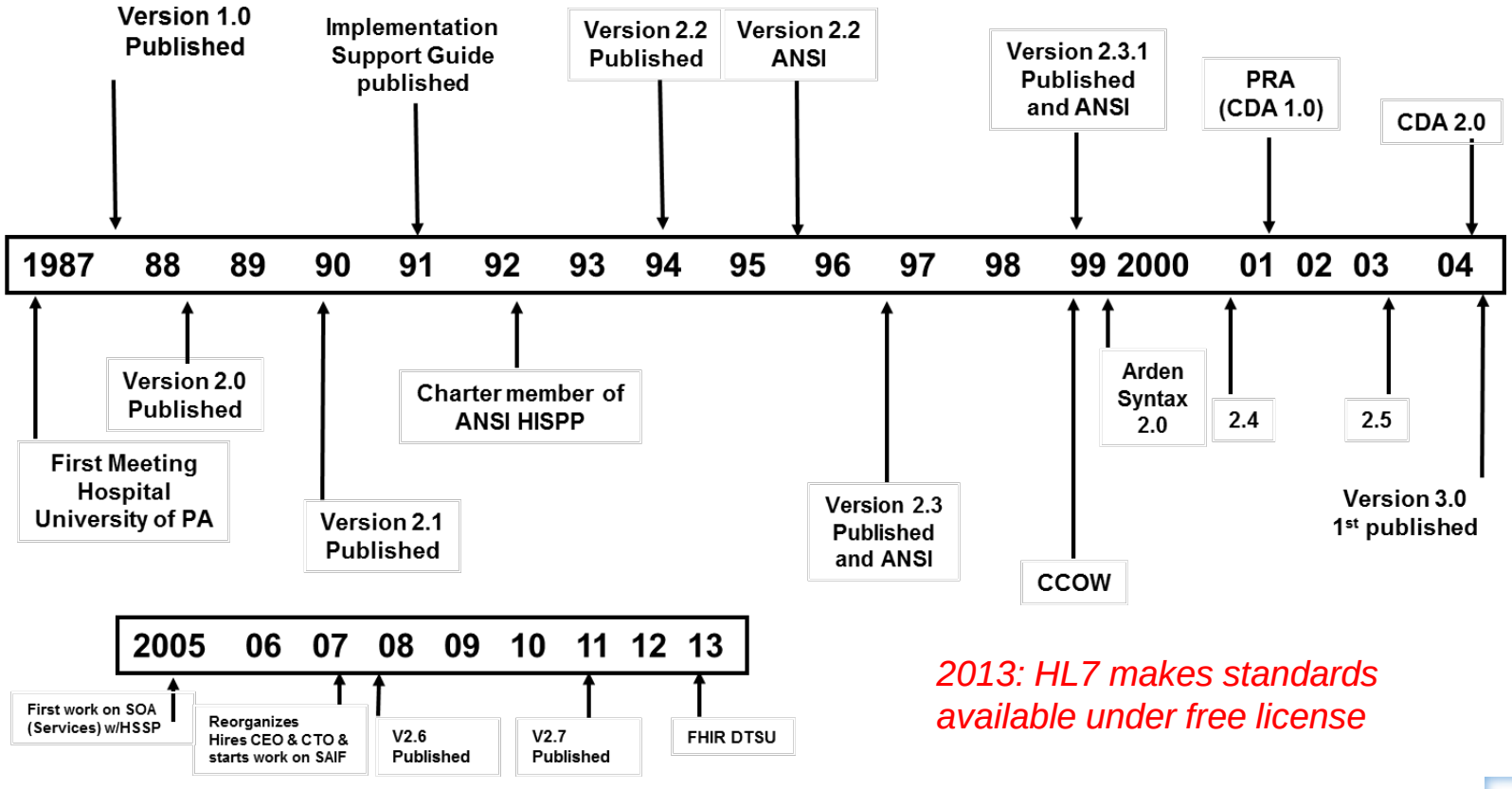
HL7 is more than you think

- ISO certified series of standards - Examples
  - ISO/HL7 10781:2009 = HL7 Electronic Health Record-System Functional Model, Release 1.1
  - ISO/HL7 27932:2009 = HL7 Clinical Document Architecture, Release 2
  - ISO/HL7 21731:2014 = HL7 version 3 -- Reference information model -- Release 4
  - ISO/HL7 27951:2009 = HL7 Common terminology services, release 1
  - ISO/HL7 27931:2009 = HL7 Version 2.5 -- An application protocol for electronic data exchange in healthcare environments
  - ISO/HL7 27953-2:2011 = HL7 Individual case safety reports (ICSRs) in pharmacovigilance -- Part 2: Human pharmaceutical reporting requirements for ICSR

HL7 mission

- Ensure interoperability between information systems in order to achieve:
  - Best treatment and health prevention
  - Integration of procedures in healthcare
  - Improvement and quality assurance of medical data
  - Knowledge exchange between all involved stakeholders
- 4 interoperability methods
  - Messaging interface (HL7 v2.x)
  - Interfaces through web services (SOA web-services) (HL7 v3)
  - XML Structured file exchange (HL7 CDA R2)
  - Data exchange focusing on mobile apps (Web Methods – REST – JSON) (HL7 FHIR)

HL7 Standards timeline



2013: HL7 makes standards available under free license

HL7 Standards Types

- Healthcare-related data/information/routing Standards
  - Messaging Standards (V2.x, V3, **FHIR**)
  - Document Standards (**CDA**)
- Healthcare-related Functional Standards (**EHR-S FM**)
- Other Standards (CCOW, Vocabulary, Security, Healthcare Devices, etc.)

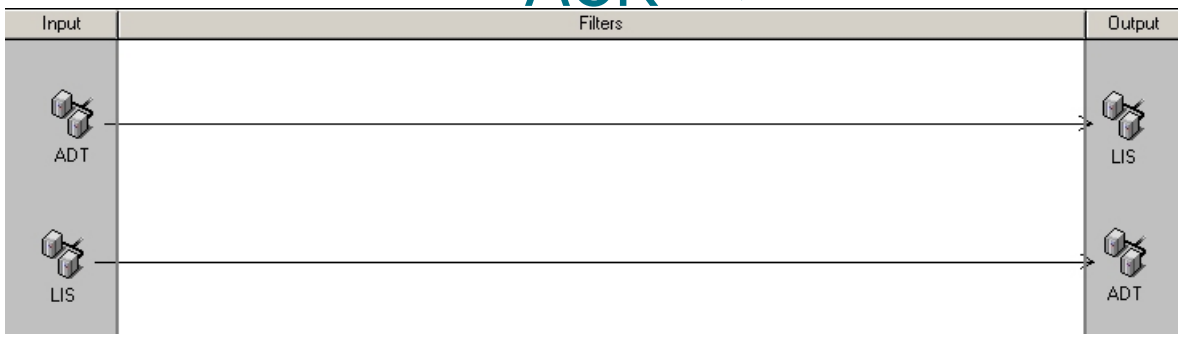
HL7 v2.x

ADT <-> LIS

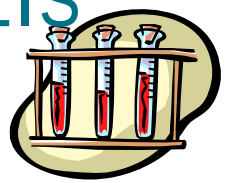
ORM - >

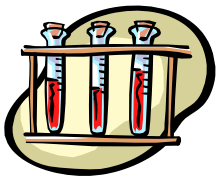
ACK - >

ADT



LIS



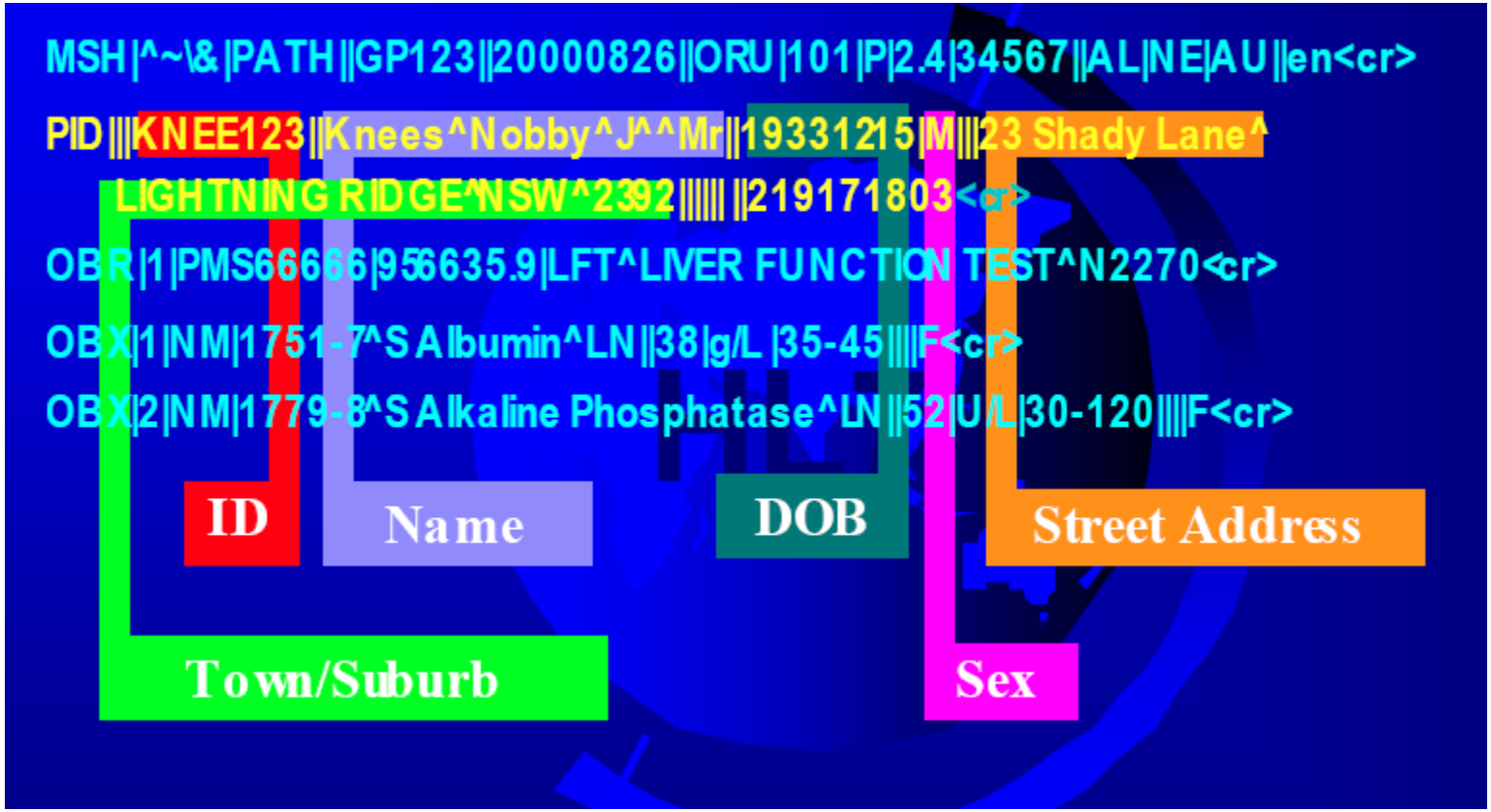


ORR - >

ORU - >

ADT

LIS message sample v2.x



HL7 FHIR

F H I R




Fast Healthcare Interoperability Resources

HL7 FHIR – Βασικά Δομικά Στοιχεία

Resources

Μικρές Δομικές Μονάδες (πόροι) χρήσιμες στην ανταλλαγή δεδομένων

References

Διασύνδεση με αναφορές μεταξύ των δομικών στοιχείων (πόροι)

Profiles

Πώς μπορεί να χρησιμοποιηθεί «εξειδίκευση»

HL7 FHIR

- Το πιο νέο πρότυπο με την μεγαλύτερη δυναμική
- Αποτέλεσμα της προσπάθειας να υπερκεραστούν τα υπάρχοντα προβλήματα:
  - HL7 V2 – Γενικότητα/ Προαιρετικότητα
  - HL7 V3 – Πολυπλοκότητα
- Έμφαση σε αυτούς που υλοποιούν
- Χρήση μοντέρνων τεχνολογιών
- Πληροφορίες αναγνώσιμες από ανθρώπους
- FHIR εμπεριέχει μια καινούργια αρχιτεκτονική προσέγγιση (RESTful) σε σύγκριση με το HL7v2 και το CDA η οποία επιτρέπει σε ανεξάρτητους πόρους να δημιουργηθούν, ανακληθούν και ενημερωθούν
- Το μόνο πλήρως «ανοικτό» και ελεύθερο πρότυπο

HL7 FHIR – Παράδειγμα resource

```
<Patient xmlns="http://hl7.org/fhir">
  <text>
    <status value="generated"/>
    <div xmlns="http://www.w3.org/1999/xhtml">
      <p>Henry Levin the 7th</p>
    </div>
  </text>
  <identifier>
    <use value="usual"/>
    <label value="MRN"/>
    <system value="urn:oid:2.16.840.1.113883.19.5"/>
    <value value="12345"/>
  </identifier>
  <name>
    <family value="Levin"/>
    <given value="Henry"/>
  </name>
  <gender>
    <coding>
      <system value="http://hl7.org/fhir/v3/AdministrativeGender"/>
      <code value="M"/>
    </coding>
  </gender>
  <birthDate value="1932-09-24"/>

  <managingOrganization>
    <reference value="Organization/2.16.840.1.113883.19.5"/>
    <display value="Good Health Clinic"/>
  </managingOrganization>
  <active value="true"/>
</Patient>
```

EHR-S Functional Model Standard

- Ένα πολύ σημαντικό βήμα για να οριστεί και πιστοποιηθεί ένα **σύστημα ΗΦΥ (EHR)**
- Το EHR-S FM αναπαριστά ένα υπερσύνολο από λειτουργίες για ένα **σύστημα ΗΦΥ (EHR)**
- Περιγράφει σημαντικά χαρακτηριστικά και λειτουργίες που θα πρέπει να περιέχονται σε ένα σύστημα **ΗΦΥ**
- Παραθέτει μια λίστα από λειτουργίες στις οποίες το κάθε κριτήριο χαρακτηρίζεται σαν «SHALL», «SHOULD» ή «MAY»
- Δημιουργεί μια κοινή πλατφόρμα για τους παρόχους, τους προμηθευτές, και άλλους εμπλεκόμενους για να περιγράψει την απαραίτητη λειτουργικότητα του **ΗΦΥ**

EHR-S Functional Model Standard

- Έχει δημιουργηθεί από την αρχή με **διεθνή χαρακτηριστικά**
- Χαρακτηρίζεται από **ευελιξία**, για να διαφοροποιούνται οι υλοποιήσεις
- Είναι **εναρμονισμένο** με «παρόμοιες» προσπάθειες στο χώρο της υγείας όπως:
  - Committee é Européen de Normalisation (CEN 13606)
  - Institute Of Medicine
  - openEHR
  - ISO/TC 215 International Standards Organization Technical Specification 18308
  - ASTM E31
- Περιέχει ~ 160 Λειτουργίες και ~1000 κριτήρια συμμόρφωσης
- Διαθέσιμο στο διαδίκτυο http://www.hl7.org/ehr/

Άξονες Βασικών Λειτουργιών EHR-S FM

Direct Care	DC.1	Care Management
	DC.2	Clinical Decision Support
	DC.3	Operations Management and Communication
Supportive	S.1	Clinical Support
	S.2	Measurement, Analysis, Research and Reports
	S.3	Administrative and Financial
Information Infrastructure	IN.1	Security
	IN.2	Health Record Information and Management
	IN.3	Registry and Directory Services
	IN.4	Standard Terminologies & Terminology Services
	IN.5	Standards-based Interoperability
	IN.6	Business Rules Management
	IN.7	Workflow Management

Άμεση Φροντίδα

Υποστηρικτικές Λειτουργίες

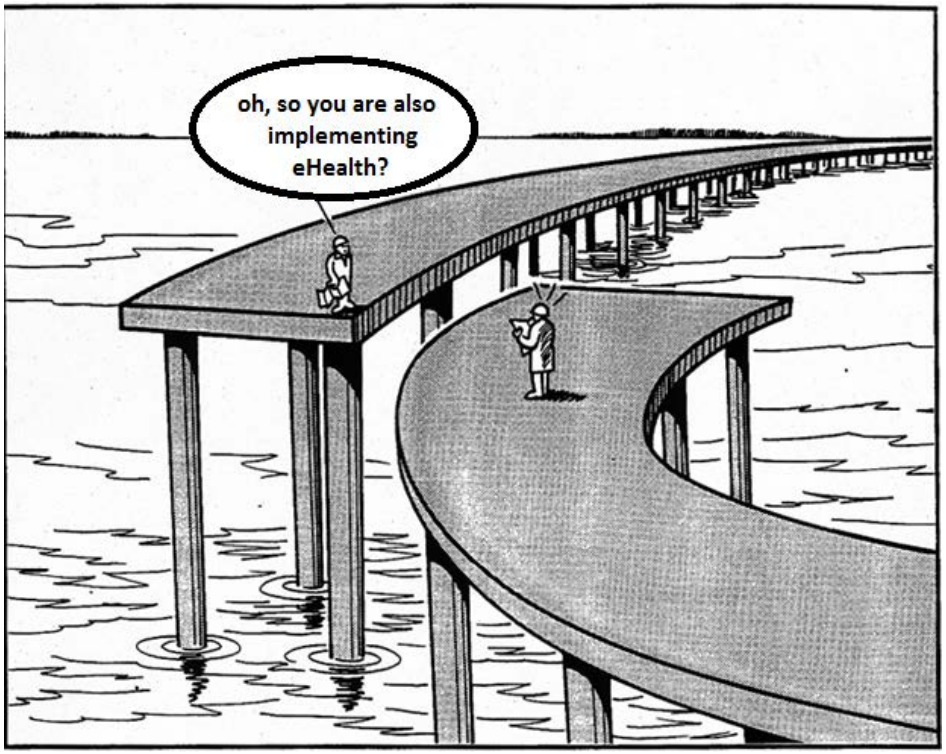
Πληροφοριακές Υποδομές

Source: HL7 EHR-S FM Overview Chapter

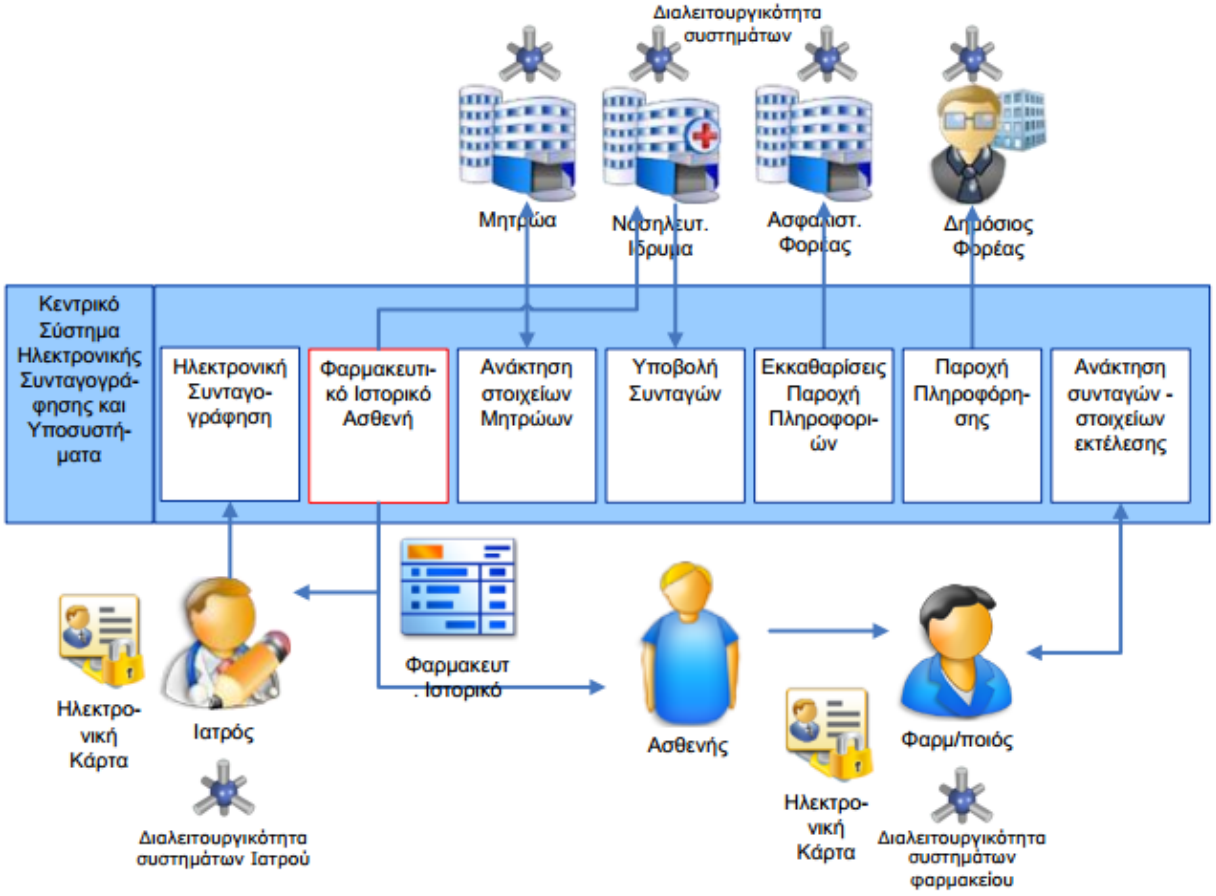
EHR-S FM Παράδειγμα-κριτήρια συμμόρφωσης

ID#	Type	Name	Statement/Description	See Also	
DC.1.1.1	F	Identify and Maintain a Patient Record	**Statement**: Identify and maintain a single patient record for each patient. **Description**: A single record is needed for legal purposes, as well as to organize it unambiguously for the provider. Health information is captured and linked to the patient record. Static data elements as well as data elements that will change over time are maintained. The patient is uniquely identified, after which the record is tied to that patient. Combining information on the same patient, or separating information where it was inadvertently captured for the wrong patient, helps maintain health information for a single patient. In the process of creating a patient record, it is at times advantageous to replicate identical information across multiple records, so that such data does not have to be re-entered. For example, when a parent registers children as new patients, the address, guarantor, and insurance data may be propagated in the children's records without having to re-enter them.	S.1.4.1 S.2.2.1 S.3.1.2 S.3.1.5 IN.2.1 IN.2.3	1. The system **SHALL** create a single logical record for each patient. 2. The system **SHALL** provide the ability to create a record for a patient when the identity of the patient is unknown. 3. The system **SHALL** provide the ability to store more than one identifier for each patient record. 4. The system **SHALL** associate key identifier information (e.g., system ID, medical record number) with each patient record. 5. The system **SHALL** provide the ability to uniquely identify a patient and tie the record to a single patient. 6. The system **SHALL** provide the ability, through a controlled method, to merge or link dispersed information for an individual patient upon recognizing the identity of the patient. 7. IF health information has been mistakenly associated with a patient, THEN the system **SHALL** provide the ability to mark the information as erroneous in the record of the patient in which it was mistakenly associated and represent that information as erroneous in all outputs containing that information. 8. IF health information has been mistakenly associated with a patient, THEN the system **SHALL** provide the ability to associate it with the correct patient. 9. The system **SHALL** provide the ability to retrieve parts of a patient record using a primary identifier, secondary identifiers, or other information which are not identifiers, but could be used to help identify the patient.

Interoperability



Παράδειγμα: Διαλειτουργικότητα – Ηλεκτρονική Συνταγογράφηση

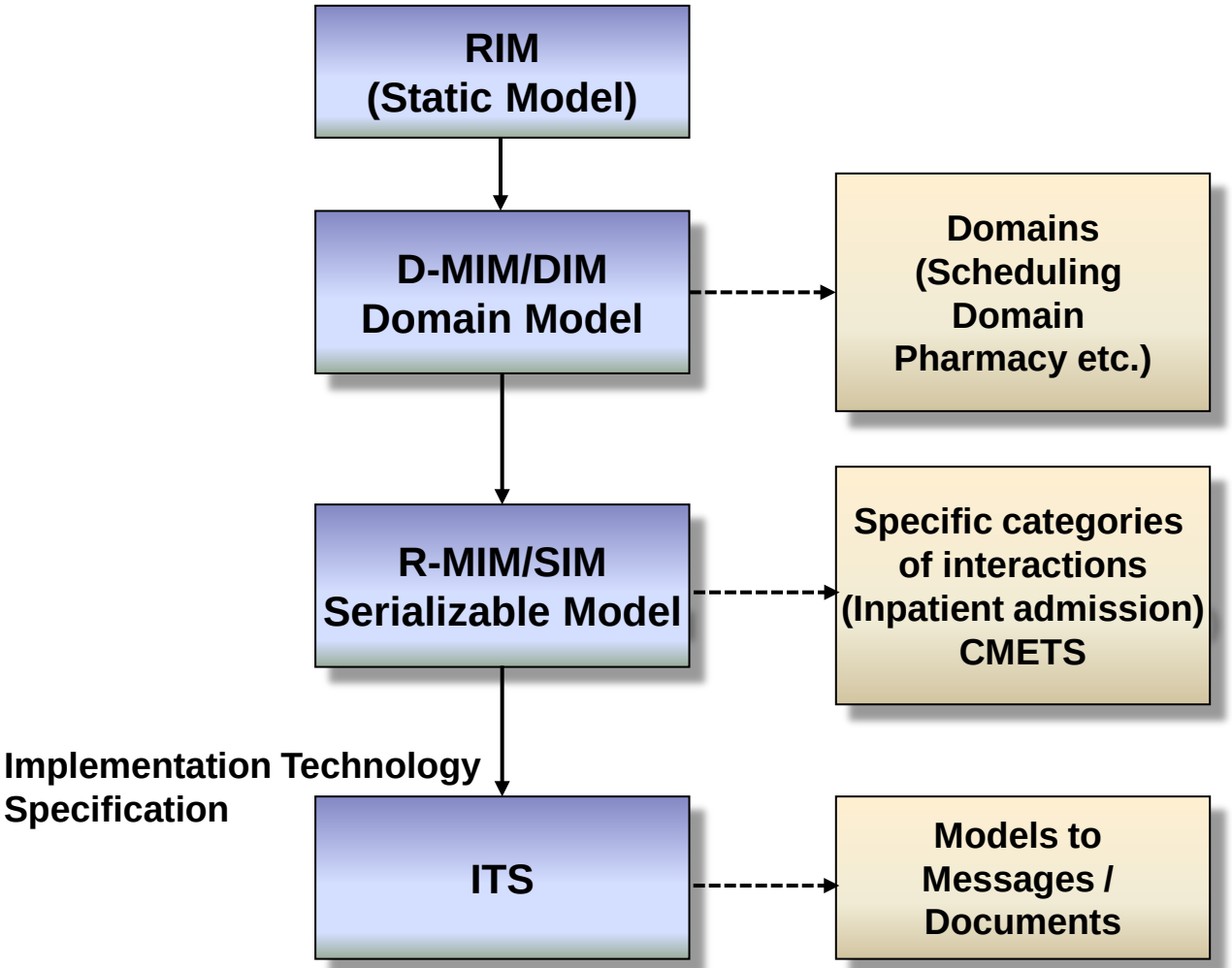


HL7 v3 RIM

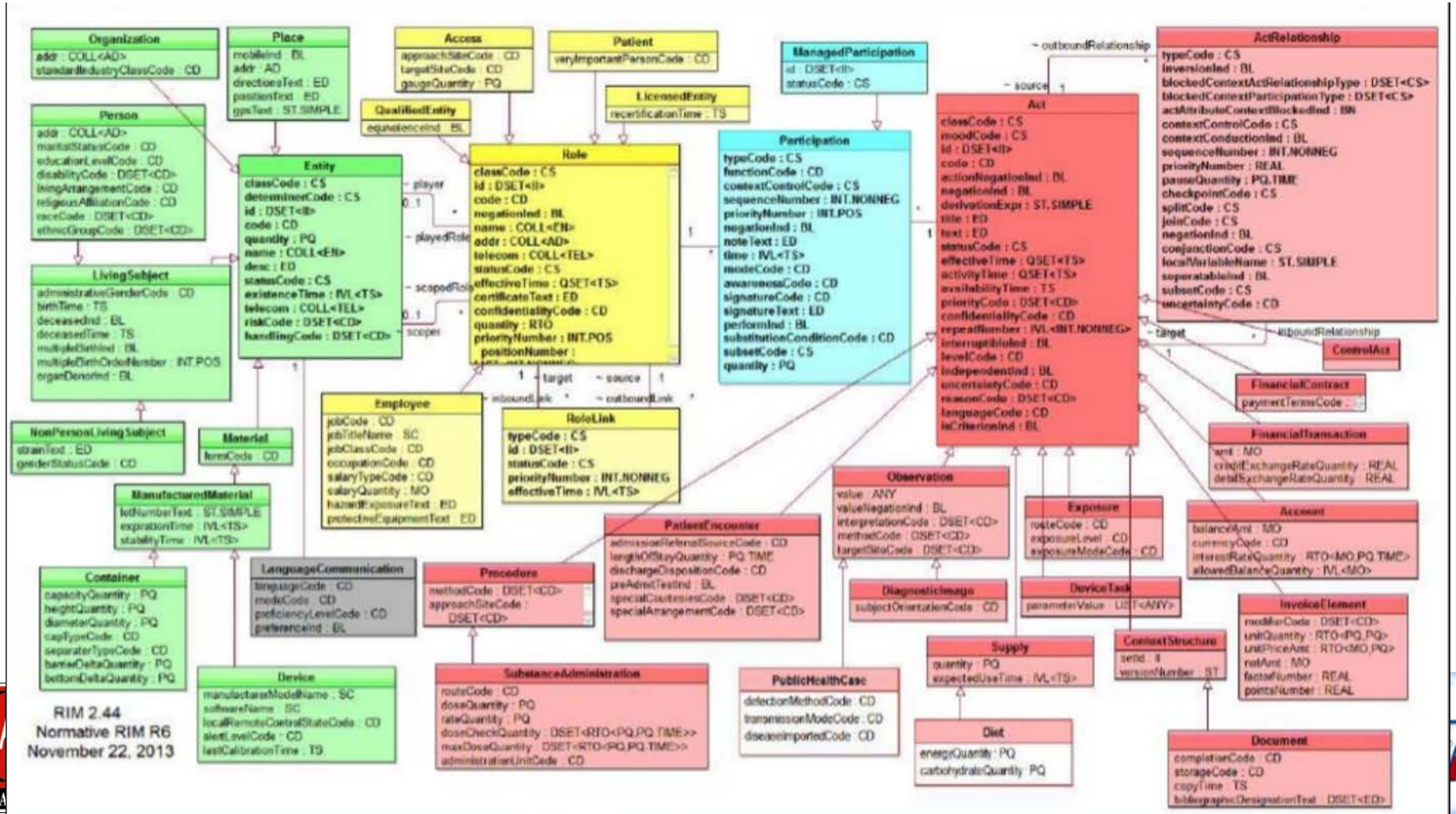
HL7 v3 RIM

- The HL7 Reference Information Model (RIM) is **a static model** of health and health care information
- Combined consensus **view of information** from the **perspective of the HL7**
- Content of all **HL7 version 3.0 protocol specification** standards is **drawn**
- The RIM is **modeled using** the modeling syntax defined by **UML**
- **UML is a graphical language** for visualizing, specifying, constructing, and documenting the artifacts of a software-intensive system

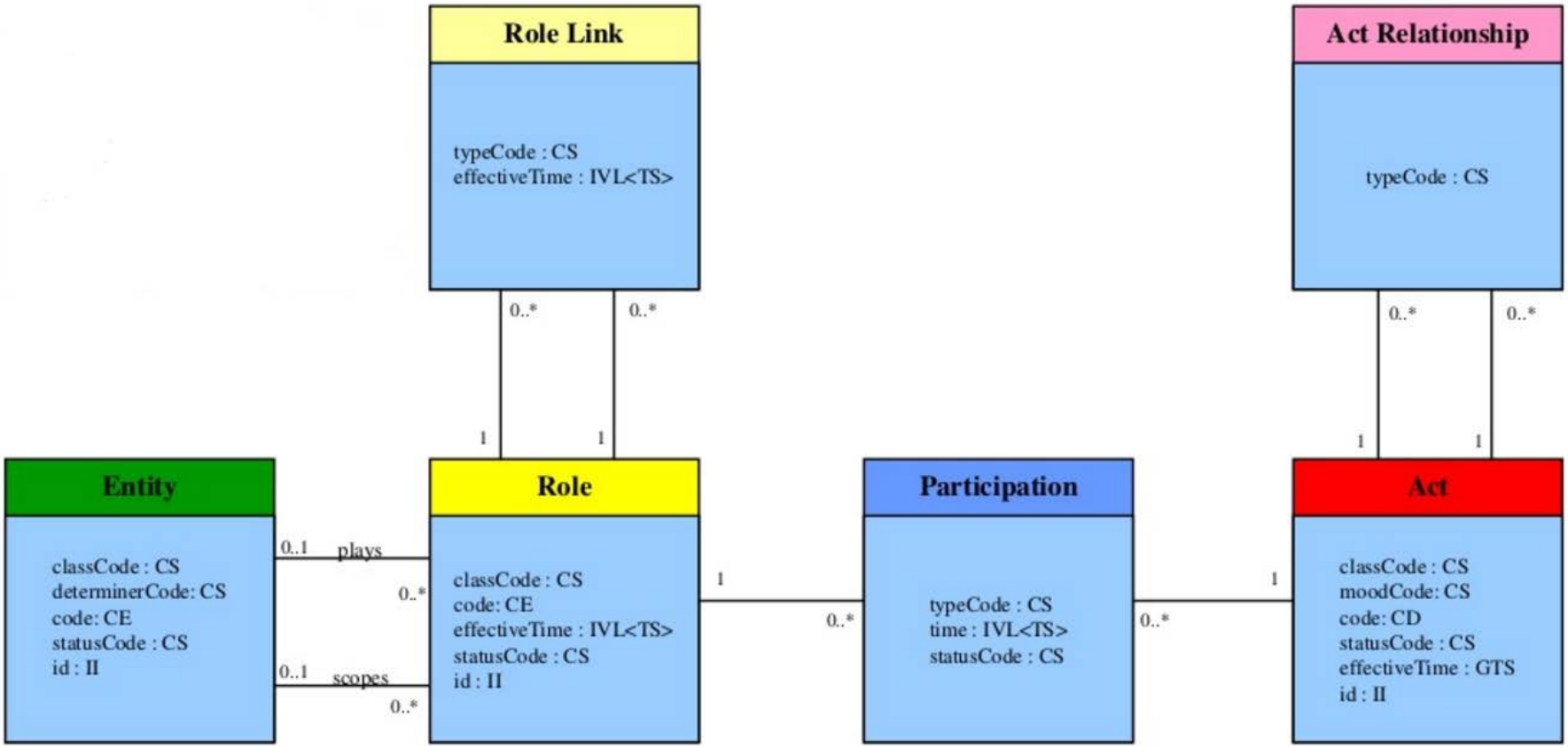
HL7 RIM – Domain Model (HL7 –DF)



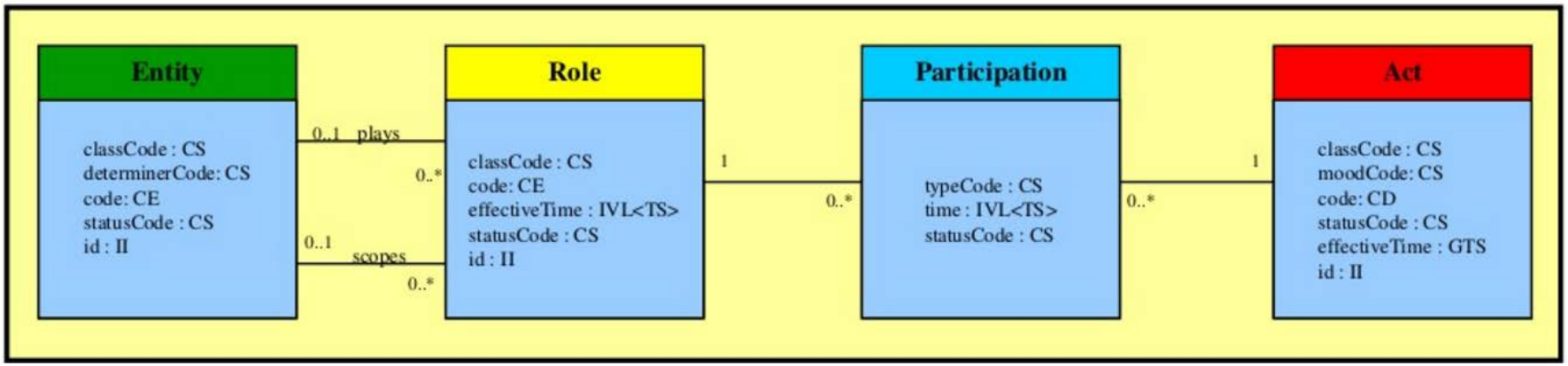
HL7 v3 RIM – Abstract Data Model



HL7 v3 RIM – Core Classes



HL7 v3 RIM – Back Bone Classes



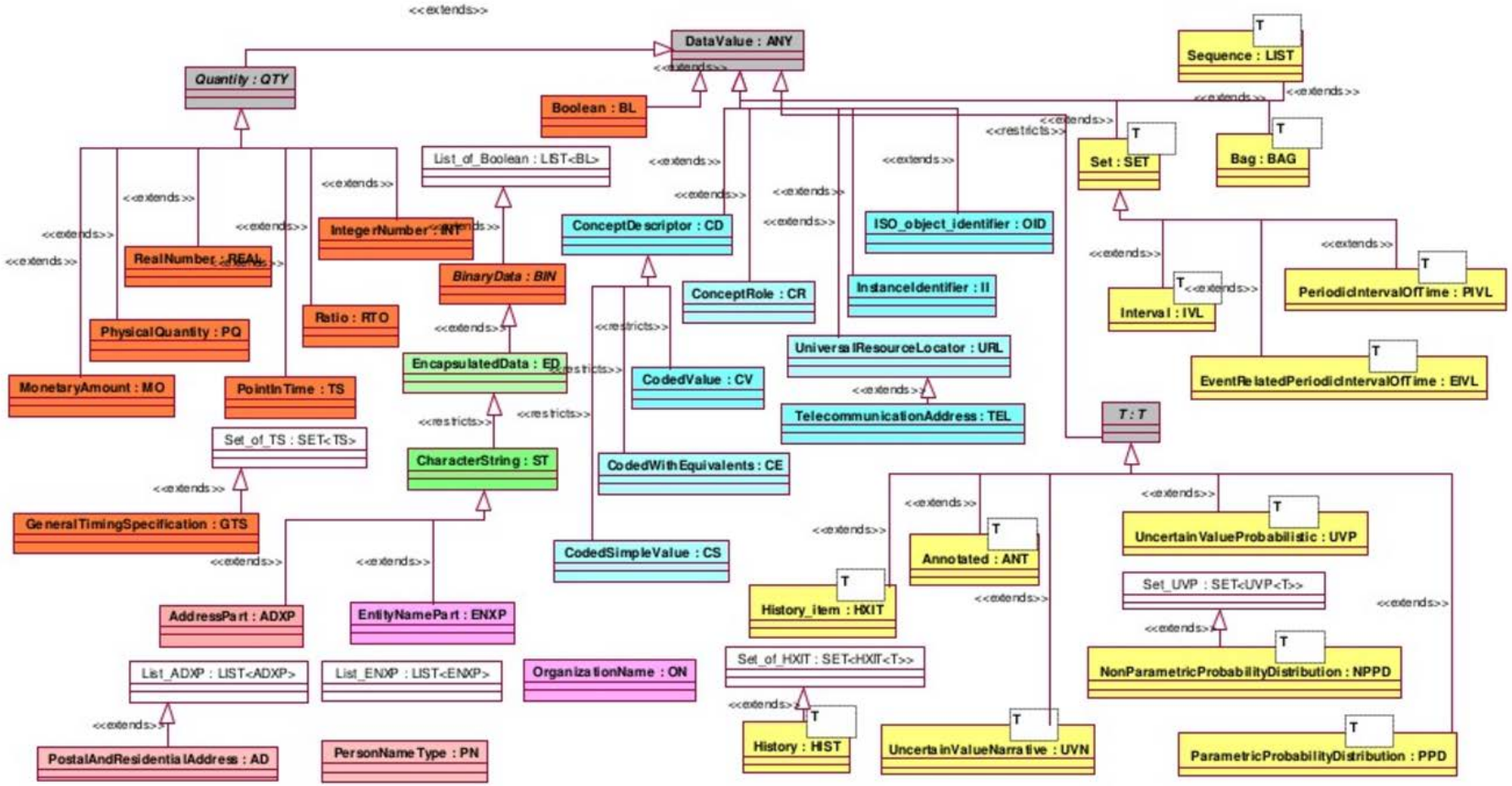
Living Subject
Place
Organization
Material

Patient
Access
Employee
Licensed Entity

Managed
Participation

Observation
Encounter
Procedure
Substance
Adm.
Financial
Transaction
Invoice
Control Act
…….

HL7 v3 RIM – Data Type Diagram



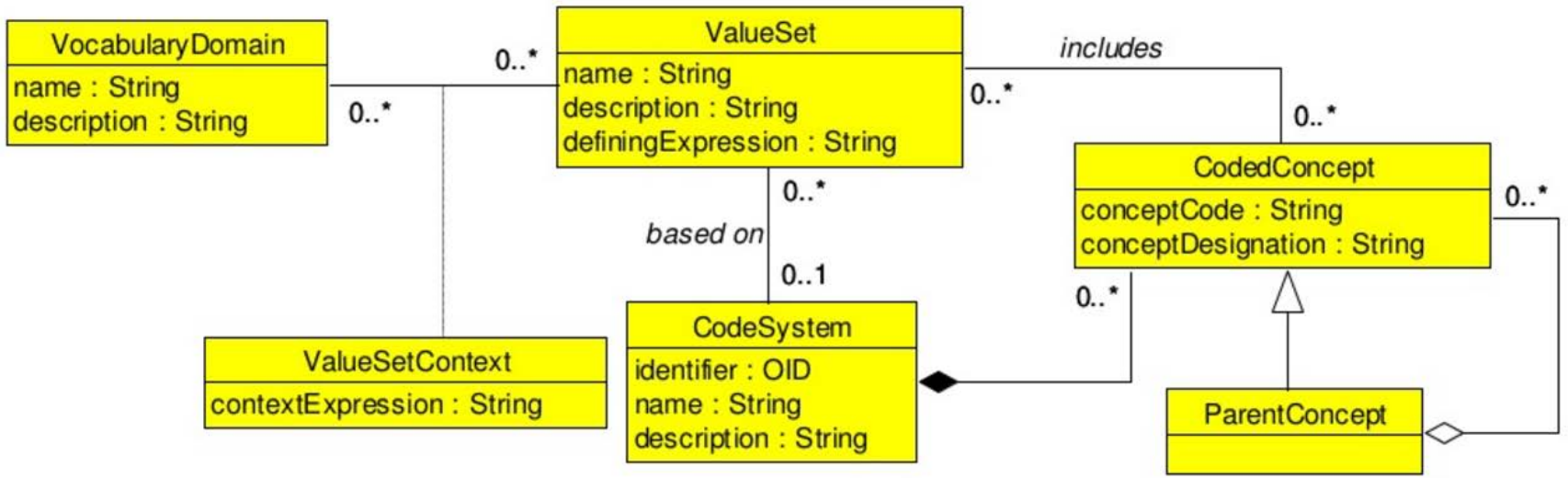
null Flavor ... a special datatype case

- NullFlavor does **not** mean “null” **behaves like it** in many ways
- Every data type (including properties) implicitly carry information **about how or why they are incomplete or an improper value**
- Every data type may carry other information **even when null**
- Implementers must always consider null value!

nullFlavor Types

code	Name
NI	no information
OTH	Other
NINF	negative infinity
PINF	positive infinity
UNK	Unknown
ASKU	asked but unknown
NAV	temporarily unavailable
NASK	not asked
TRC	Trace
MSK	masked
NA	not applicable

HL7 v3 RIM – Vocabulary Specifications



Clinical Document Architecture: CDA

Clinical Document Architecture: CDA

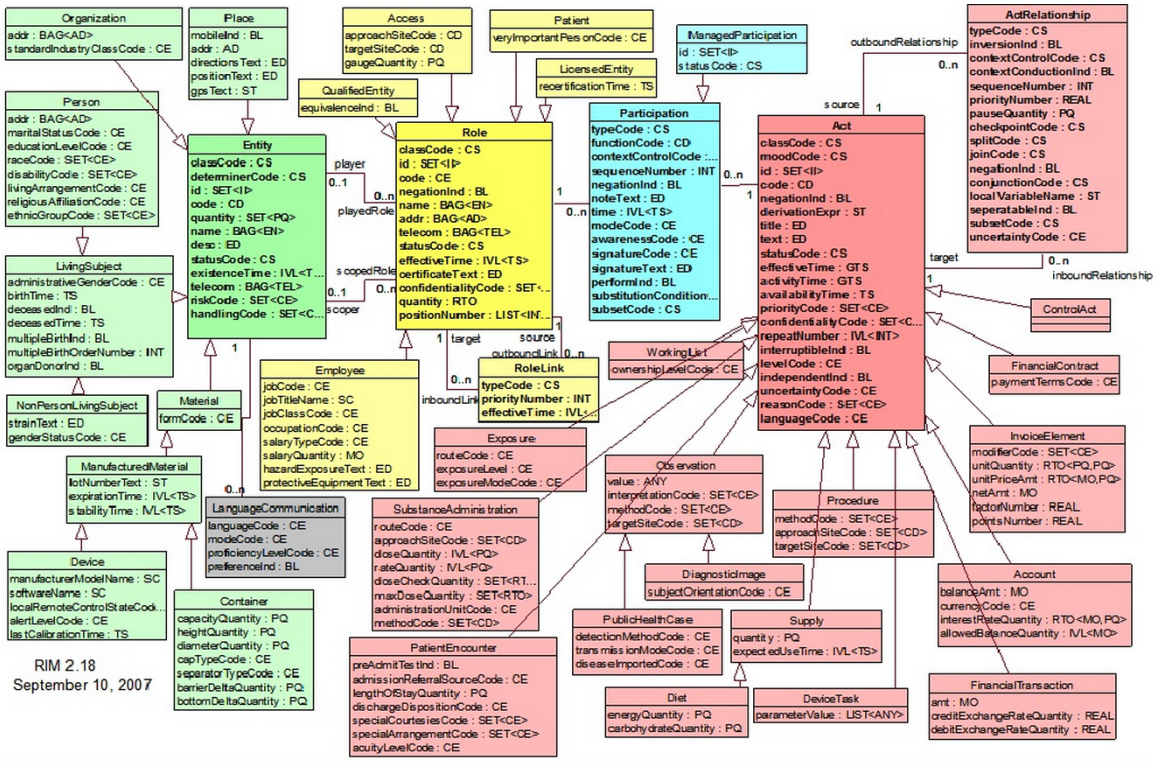
- ANSI/HL7 CDA® Release 2
- Περιγράφει την δομή και τις οντότητες ενός **«Κλινικού Έγγραφου»** (Clinical Document)
- Αποτελεί προδιαγραφές για την ανταλλαγή **εγγράφων** με τη χρήση **τεχνολογιών** όπως
  - XML
  - HL7 Reference Information Model (RIM)
  - Version 3 methodology
  - Ιατρικές Κωδικοποιήσεις (SNOMED, ICD, local,…)

Clinical Document Architecture: CDA

- Παραδείγματα CDA είναι:
  - Σύνοψη **Εξιτηρίου** για ασθενή
  - **Παραπομπή** ασθενή
  - Ιατρικές **σημειώσεις «προόδου»** ασθενή
  - **Έκθεση** για τη δημόσια υγεία
  - **Συνταγογράφηση** ασθενή
  - **Αναγγελία** αιμοκάθαρσης ασθενή
- Μπορεί να διαβαστεί από άνθρωπο

Clinical Document Architecture: CDA

- Το CDA βασίζεται στο HL7 RIM και κάνει χρήση των HL7 V3 Data Types



CDA - Sample

```
<?xml version="1.0" encoding="UTF-8" standalone="no" ?>
- <ClinicalDocument NS2:schemaLocation="urn:hl7-org:v3 CDA.ReleaseTwo.Committee.2004.xsd" templateId="2.16.840.1.113883.3.27.1776" xmlns="urn:hl7-org:v3"
    xmlns:NS2="http://www.w3.org/2001/XMLSchema-instance">
    <id extension="c266" root="2.16.840.1.113883.3.933" />
  + <recordTarget>
  - <component>
    - <StructuredBody>
      - <section>
          <code code="10160-0" codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC" />
          <title>Medications</title>
        + <Observation>
        + <Observation>
        - <SubstanceAdministration>
          - <text>
              <content ID="m1">Theophylline</content>
              20 mg every other day, alternating with 18 mg every other day, for 2 weeks. Stop if temperature is above 103F.
            </text>
          + <consumable>
          </SubstanceAdministration>
        </section>
      - <component>
        - <section>
            <code code="10164-2" codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC" />
            <title>History of Present Illness</title>
          - <text>
              3 month old baby who has been transferred to MCH CICU for VSD repair. He was born FT, but had resp. distress requiring mehcanical ventilation for 3 days for
              pulmonary edema. He was diagnosed then to have a large VSD. He was prescribed
              <medication IDREF="m1">Theophylline.</medication>
              He was admitted in the hospital for about a month for his resp. issues. He was sent home but after 3 weeks developed bronchiolitis and had been in the hospital
              since then. During this admission he was also diagnosed to have GE Reflux and Aspiration. He was also found to have Chronic lung disease -- possibly due to
              aspiration. He also had complex partial seizures due to resp. distress which were being treated with Phenobarb. For the last 4 days his feeds were switched to
              NJ and is now transferred to Miami for surgery on 11/15/06 to have the VSD closed.
            </text>
          </section>
        </component>
      </StructuredBody>
    </component>
  </ClinicalDocument>
```

CDA History

- 1997 – HL7 SGML SIG begins work on the Patient Record Architecture
- 1998 – Patient Record Architecture draft
- 1999 – CDA Release 1.0 Approved by HL7 Membership
- **2000** – CDA Release 1.0 adopted as an American National Standard
- 2000 – HL7 XML SIG becomes Structured Documents Technical Committee
- **2005** – Clinical Document Architecture Release 2 Adopted
- 2006 – Care Record Summary Implementation Guide
- 2007 – Continuity of Care Document Implementation Guide
- 2008 – Recognition of HL7 CDA by the Secretary of HHS
- 2008 – Submission of CDA to ISO TC-215
- **2009** – ISO TC-215 Approves CDA as an ISO Standard
- 2010 – CDA reaffirmed by HL7 and ANSI as an American National Standard
- **2011** – Consolidated CDA Implementation Guide

CDA in Details

CDA Characteristics

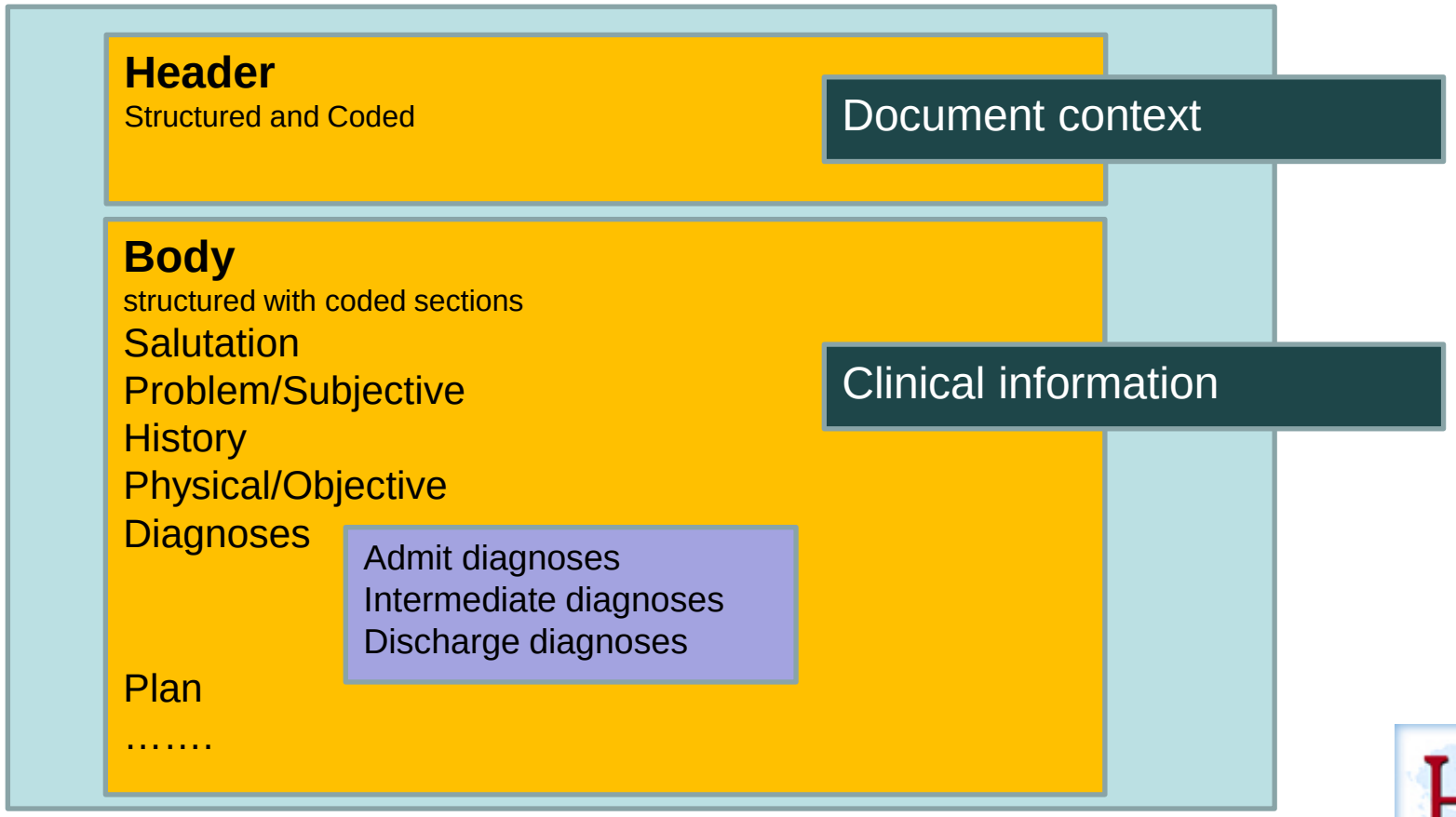
- Basic (CDA R2 #2.1)
  - Persistence
  - Stewardship (administration)
  - Potential for Authentication
  - Wholeness
  - Human readability
  - Context
- Additional
  - Render arbitrary documents
  - Additional information for computation
  - Flexibility to support different document types

CDA is based on XML

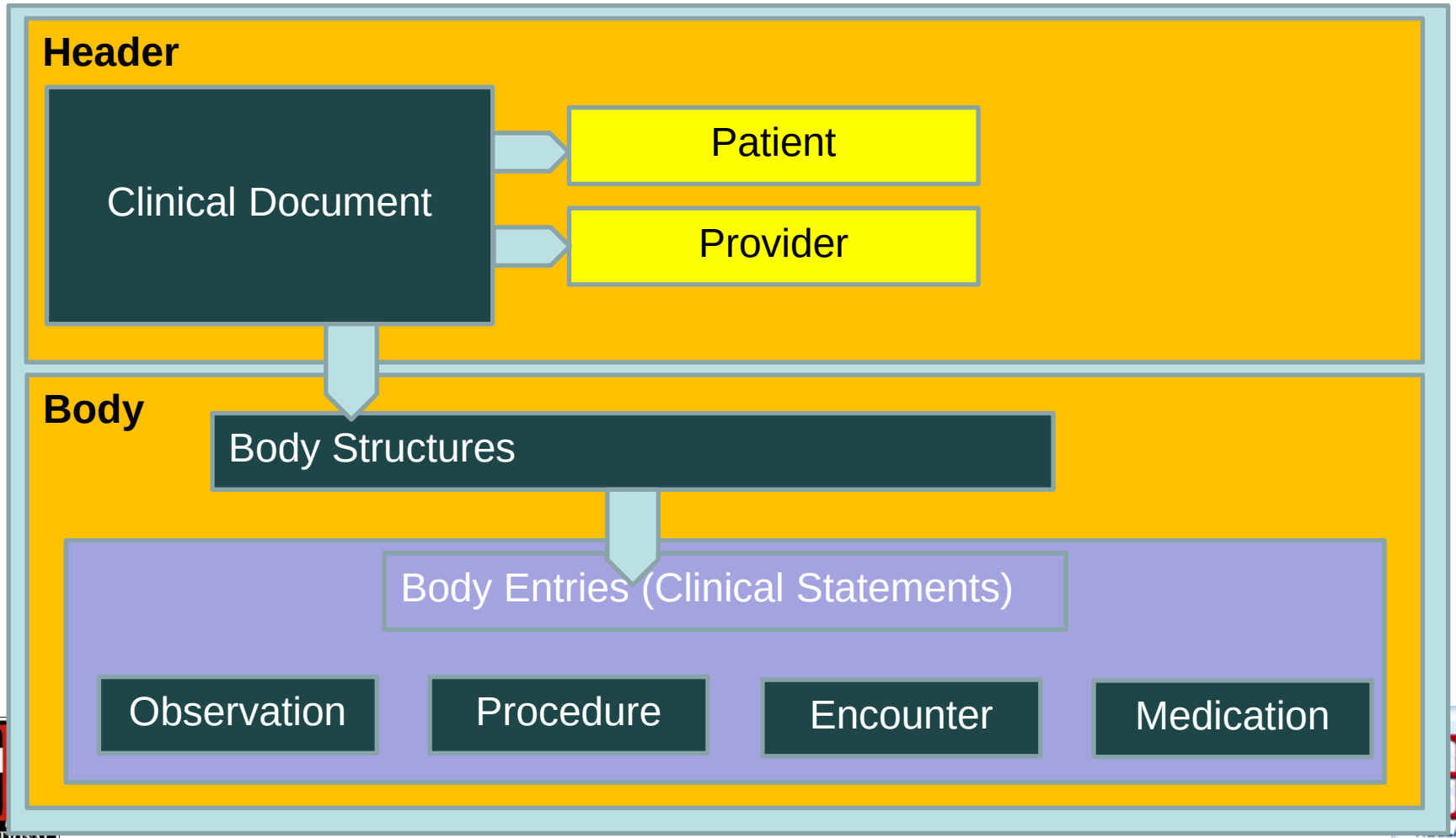
- XML is Extensible Markup Language (www.w3c.org)
- In XML, **structure & format** are conveyed by **markup** which is embedded into the information
- With a **few simple tags**, and controlled vocabulary, XML **can describe anything**

- XML alone isn't enough
  - the **tags** need to be **defined**:
  - <orderNum> : HL7: order placed
  - <orderNum> : CDISC: visit sequence
  - CDA tags are defined by the HL7 Reference Information Model (RIM) and use standard controlled vocabulary

Structure of a CDA document



Structure of a CDA document

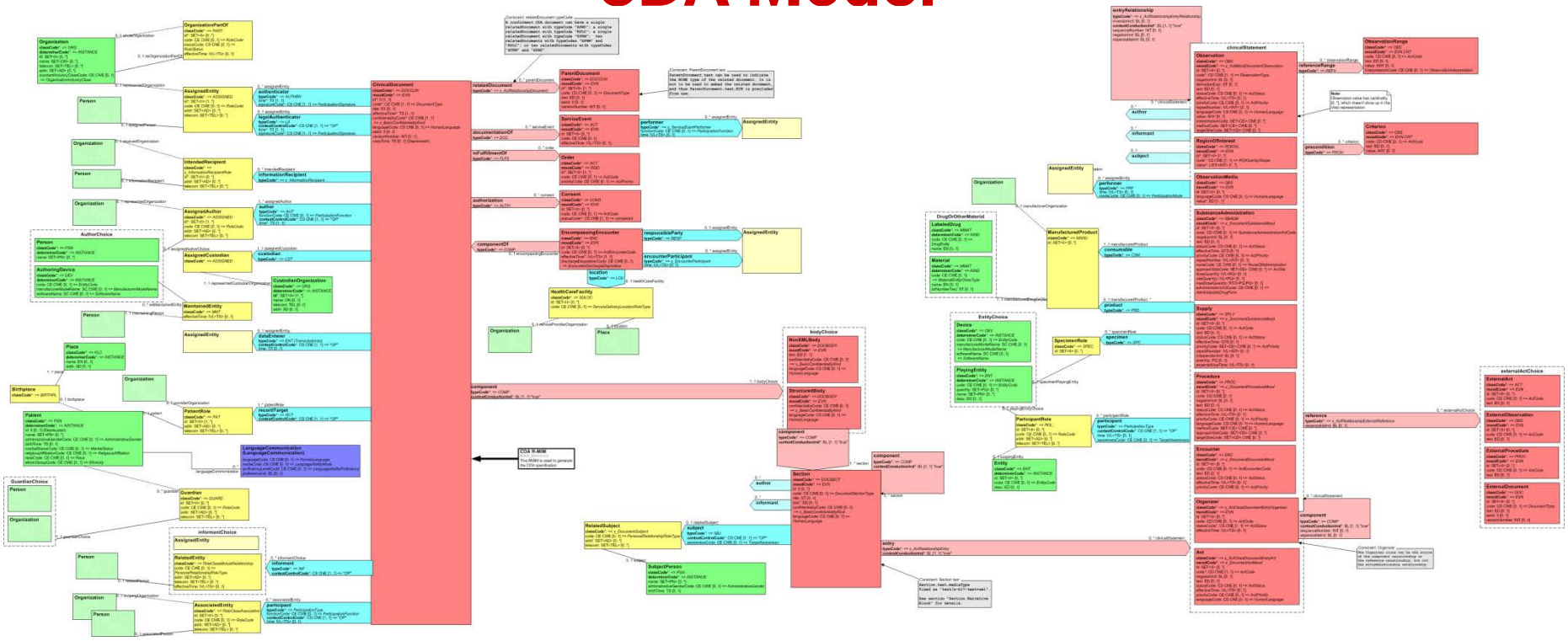


Structure of a CDA document

- Header
  (structured and coded)
- Body
  (structured content with coded sections)
  - Problem/Subjective
  - History
    - Family History
    - Past Medical History
  - Physical/Objective
  - Diagnoses
    - Admit diagnoses
    - Intermediate diagnoses
    - Discharge diagnoses
      - Coded / ICD10
  - Therapy Plan
  - ……

```
<ClinicalDocument>
    ...
  <StructuredBody>
    <Section>
      <text> ... </text>
      <Observation>
        ...
      </Observation>
      <Observation>
        ...
      </Observation>
    </Section>
      ...
      ...
      ...
  </StructuredBody>
</ClinicalDocument>
```

CDA Model



Header

Body Structures

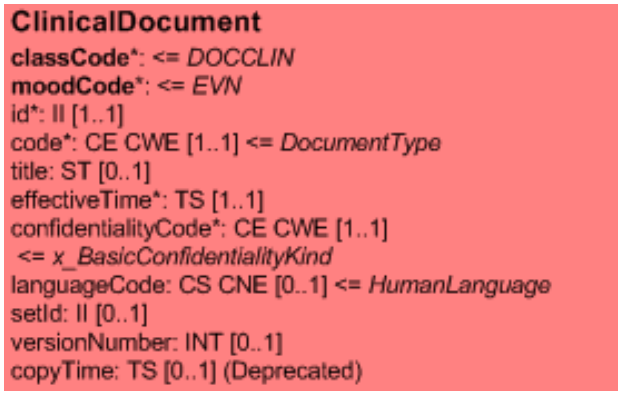
Body Entries

CDA Header

- Document Identification (ID, code, title, date …)
- Confidentiality, language, authorisations
- Authenticator(s), including legal authenticator
- recipient(s) of the content
- Author(s), Data enterer
- Patient
- Informants, Content Producer
- Related Document(s)
- Service Event(s), Participant(s), Encounter

Clinical Document

- id
  - document unique identification
  - root & extension
  - OID
- Code
  - what type of document
  - using LOINC Codes
  - describe content



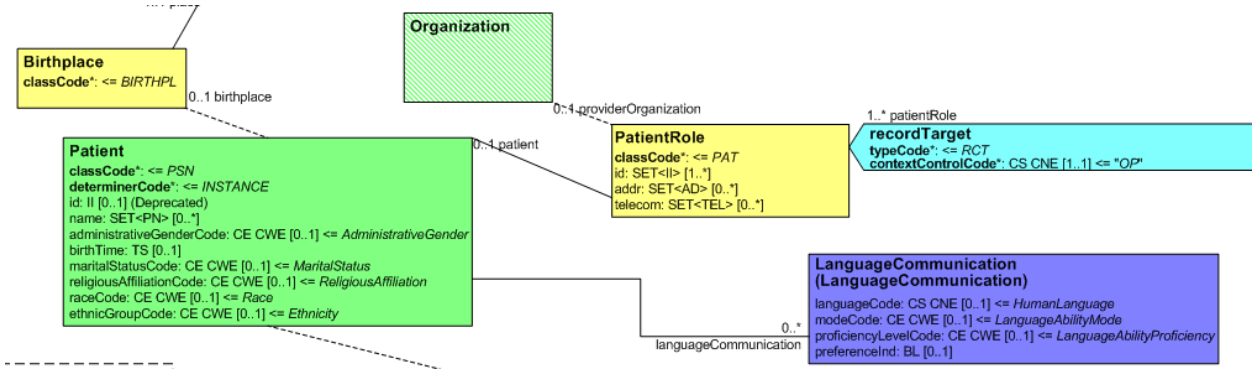

```
 <id root="2.16.840.1.113883.3.1937.99.62.3.25.2" extension="9e1ed519"/>
    <!-- Loinc Code for Document Nephrology Referral note -->
    <code code="57144-8" codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC" displayName="Nephrology
Referral note"/>
```

Clinical Document - Parties

- **recordTarget**: Patient
- **author**: who has written the document
- **custodian**: responsible organization
- **informationRecipient**: intended receivers (as known at the time of creation of the document)
- **legalAuthenticator**: who has signed this document
- **authenticator**: other signing persons
- **dataEnterer**: secretary
- **participant**: other assigned person

Clinical Document – Record Target - Patient

- id
  - unique id




```
<!-- Foreigner Social Security TYP Indicator - Τύπος Πιστοποιητικού Ασφάλισης Πολίτη ΕΕ -εκτός Ελλάδας:(1= ΕΚΑΑ
/2=ΠΠΑ) -->
<id extension="1" root="2.16.840.1.113883.3.1937.99.62.3.25.13"/>
<!-- ΑΜΚΑ ή SSN -->
<id extension="1234567890" root="2.16.840.1.113883.3.1937.99.62.3.25.7"/>
```

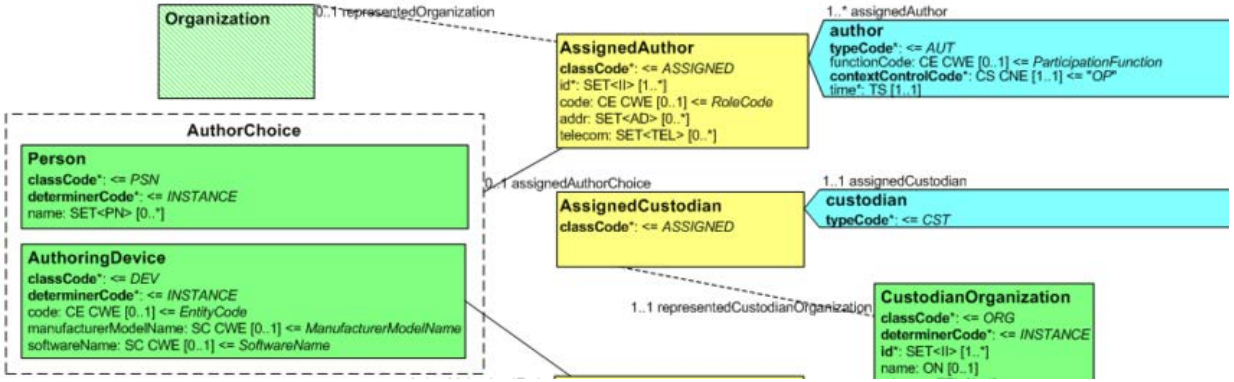
Clinical Document – Record Target - Patient

```
<recordTarget typeCode="RCT" contextControlCode="OP">
       <!-- Patient Role - Default "PAT" -->
       <patientRole classCode="PAT">
           <!-- AMKA ή SSN -->
           <id extension="1234567890" root="2.16.840.1.113883.3.1937.99.62.3.25.7"/>
           <!-- Address Details - Στοιχεία Διεύθυνσης -->
           <addr use="H PST">
               <!-- Οδος -->
               <streetAddressLine>ΛΑΥΡΙΟΥ</streetAddressLine>
               <!-- Αριθμός -->
               <streetAddressLine>11</streetAddressLine>
               <!-- ΤΚ -->
               <postalCode>15662</postalCode>
               <!-- Πόλη -->
               <city>ΑΘΗΝΑ</city>
               <!-- Χώρα -->
               <country>GREECE</country>
           </addr>
           <!-- Αριθμός Τηλεφώνου use="H" - Αριθμός Τηλεφώνου-Κινητό use="MC" - email use="HP" -->
           <!-- Αριθμός Τηλεφώνου: <telecom use="H" value="tel:55354257"/> -->
           <!-- Αριθμός Τηλεφώνου-Κινητό: <telecom use="MC" value="tel:55354257"/> -->
           <!-- email: <telecom use='HP' value='mailto:name@anydomain'/> -->
           <telecom use="H" value="tel:55354257"/>
           <telecom use="MC" value="tel:55354257"/>
           <!-- Patient Name Details - Στοιχεία Ονόματος Ασθενή/Εξεταζόμενου -->
            ……
           </patientRole>
   </recordTarget>
```

Clinical Document –Patient

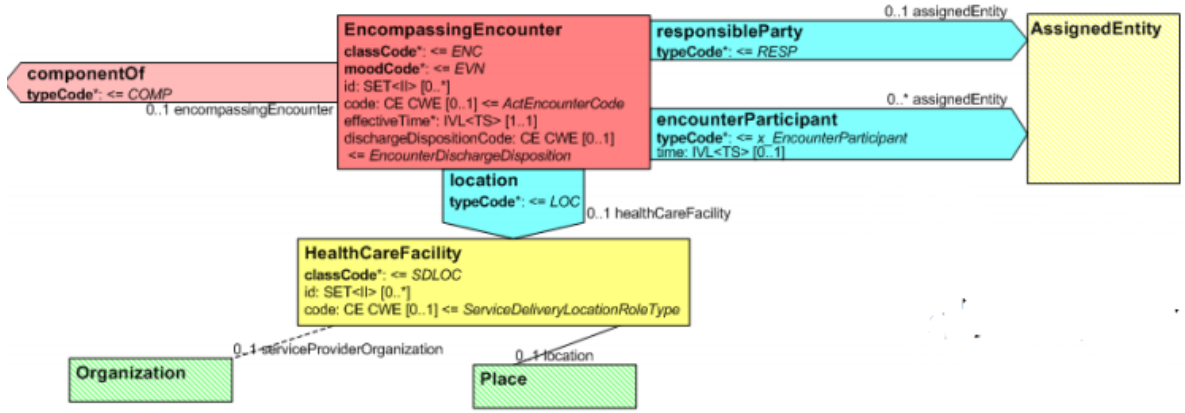
```
<patient classCode="PSN" determinerCode="INSTANCE">
            <name>
                <!-- Όνομα -->
                <given>ΝΙΚΟΣ</given>
                <!-- Όνομα Πατέρα -->
                <given>ΓΕΩΡΓΙΟΣ</given>
                <!-- Επίθετο -->
                <family>ΠΑΠΠΑΣ</family>
            </name>
            <!-- Φύλο - Values: F:Female, M:Male, U:Undifferentiated -->
            <administrativeGenderCode code="M" codeSystem="2.16.840.1.113883.5.1" displayName="Male"/>
            <!-- Ημερομηνία Γέννησης -->
            <birthTime value="19620219"/>
            <!-- Στοιχεία Έμμεσα ασφαλισμένου -->
            <guardian classCode="GUARD">
                    <!-- ΑΜΚΑ ή SSN -->
                <id extension="1234567890" root="2.16.840.1.113883.3.1937.99.62.3.25.7"/>
                <!-- Fully insured coverage sponsor -->
                <code code="FULLINS" codeSystem="2.16.840.1.113883.5.111" codeSystemName="RoleCode"/>
                <guardianPerson>
                    <!-- Όνομα του Αμεσα Ασφαλισμένου-->
                    <name>
                        <!-- Όνομα -->
                        <given>ΓΕΩΡΓΙΟΣ</given>
                        <!-- Επίθετο -->
                        <family>ΠΑΠΠΑΣ</family>
                    </name>
                </guardianPerson>
            </guardian>
        </patient>
```

Clinical Document – Author



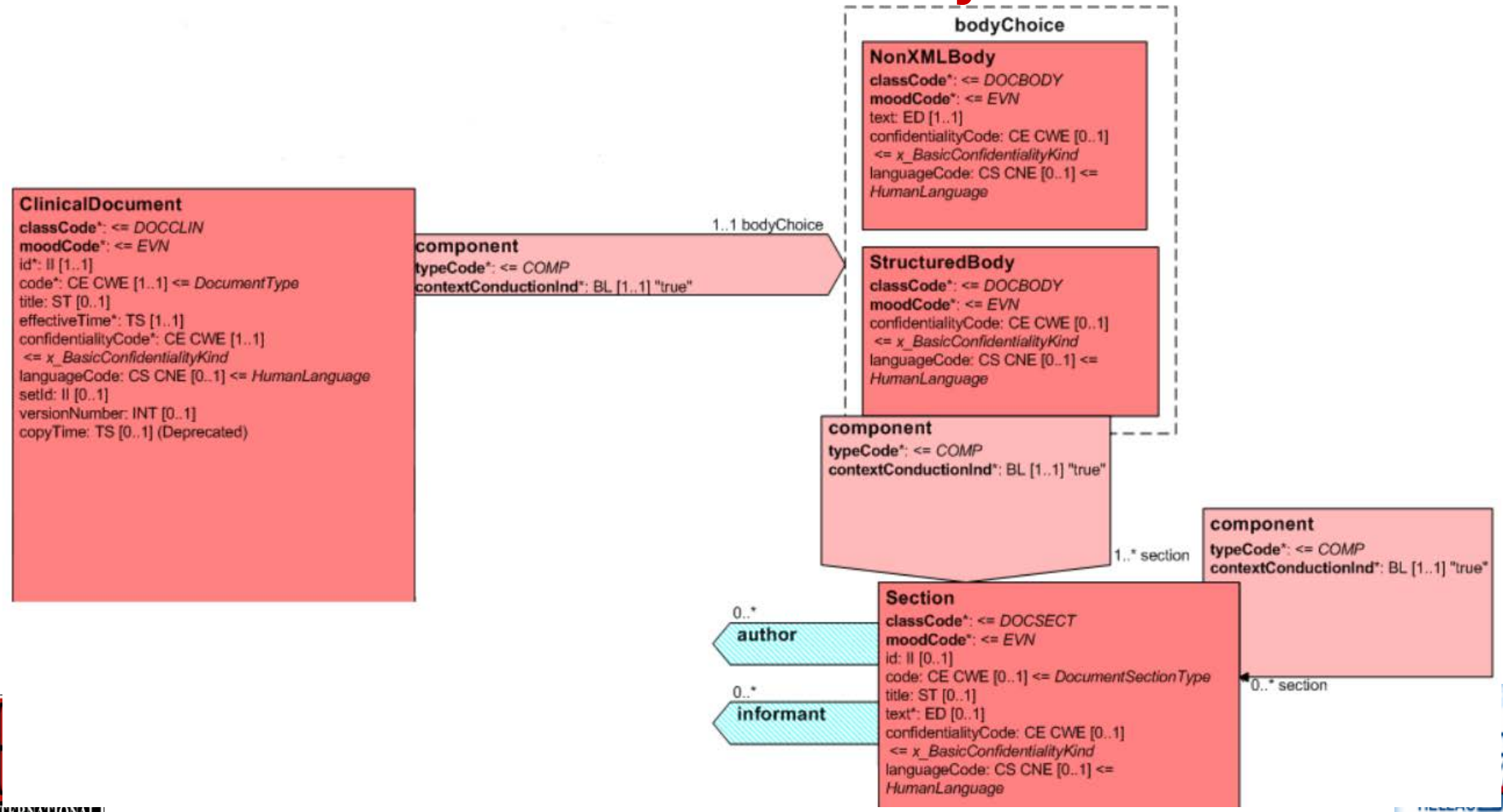

```
<!-- Doctor responsible for the Document - Author of this document -->
    <author typeCode="AUT">
        <functionCode code="221" codeSystem="2.16.840.1.113883.2.25.60.1.10.2" displayName="Doctor"
codeSystemName="epSOSHealthcareProfessionalRoles"/>
        <time nullFlavor="NA"/>
        <assignedAuthor classCode="ASSIGNED">
            <!-- ΑΜΚΑ ή SSN -->
            <id extension="1234567890" root="2.16.840.1.113883.3.1937.99.62.3.25.7"/>
            <assignedPerson classCode="PSN" determinerCode="INSTANCE">
                <name>
                    <given>ΚΩΣΤΑΣ</given>
                    <family>ΦΩΤΙΟΥ</family>
                </name>
            </assignedPerson>
        </assignedAuthor>
    </author>
```

Clinical Document – encompassingEncounter




```
<componentOf>
    <encompassingEncounter>
        <!-- Id Επίσκεψης -->
        <templateId root="1.80" extension="3479" />
        <location>
            <healthCareFacility>
                <!-- Id Μονάδας Συνταγογράφησης, User_Unit_Id -->
                <templateId root="1.80.1" extension="101002"/>
                <location>
                    <!-- Όνομα Μονάδας Συνταγογράφησης -->
                    <name>MEGA</name>
                </location>
            </healthCareFacility>
        </location>
    </encompassingEncounter>
</componentOf>
```

Clinical Document – Body - Model



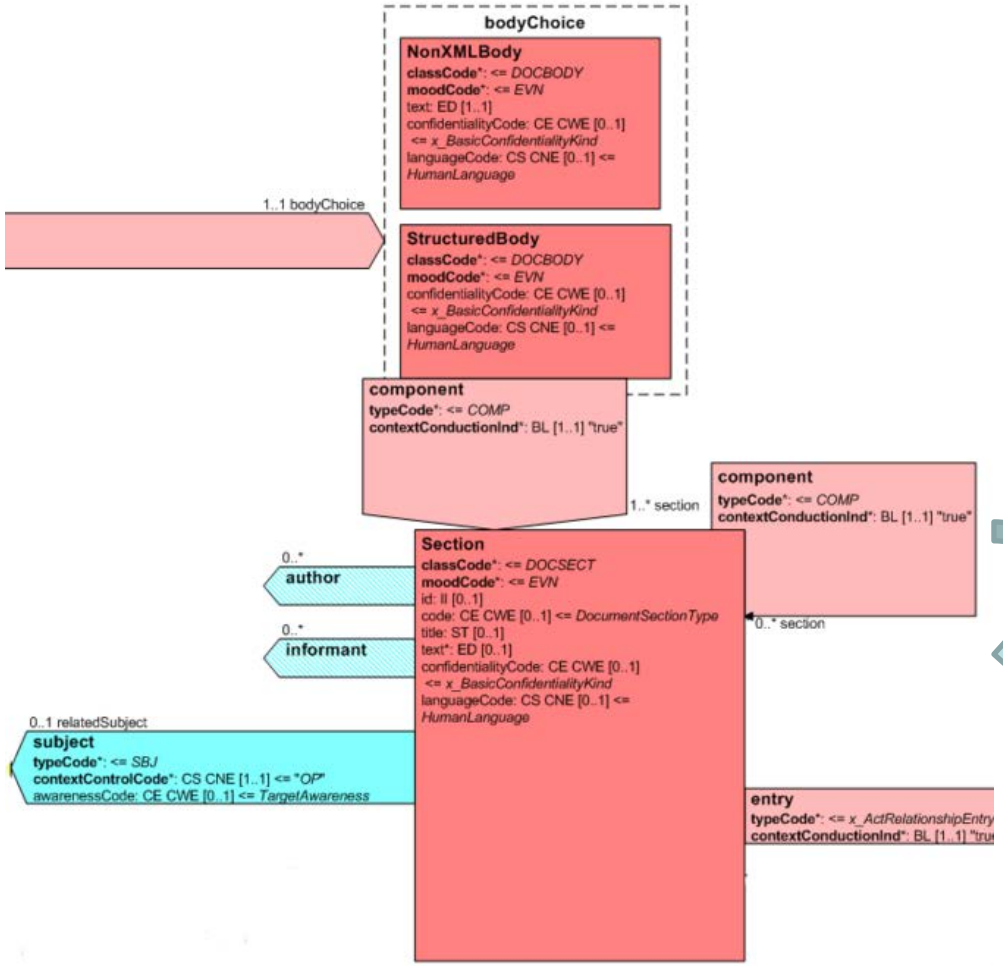
Clinical Document – NonXMLBody

```
<component typeCode="COMP">
    <nonXMLBody>
        <text mediaType="application/pdf" representation="B64"> REPLACE_ME WITH B64 ENCODED PDF </text>
    </nonXMLBody>
</component>
```

```
<component typeCode="COMP">
    <nonXMLBody>
        <text mediaType="image/jpg">
            <reference value="labnonxml.jpg"/>
        </text>
    </nonXMLBody>
</component>
```

```
<component typeCode="COMP">
    <nonXMLBody>
            <text mediaType="text/plain"> Hello, this is a test record. </text>
        </text>
    </nonXMLBody>
</component>
```

Clinical Document – Component Model



Iterative definition

Section Levels

- CDA Release 2
  - CDA Level 1
    - Non constrained CDA specification
  - CDA Level 2
    - CDA specification with section level templates
  - CDA Level 3
    - CDA specification with entry level and optionally section-level templates

Section Levels 1,2,3

```
<Section>
  <code code="10153-2" codeSystem="LOINC">
    Past Medical History
  </code>
  <text><list>
    <item><content>Asthma</content></item>
    <item><content>Hypertension</content></item>
    <item><content ID="a3">Osteoarthritis, right knee</content></item>
  </list></text>
  <component1>
    <contextConductionInd value="TRUE"/>
    <Observation classCode="COND">
      <code code="G-1001" codeSystem="SNOMED" displayName="Prior dx"/>
      <value code="D1-201A8" codeSystem="SNOMED"
        displayName="Osteoarthritis">
        <originalText><reference value="#a3"/></originalText>
      </value>
      <targetSiteCode code="T-15720" codeSystem="SNOMED"
        displayName="Knee joint">
        <qualifier>
          <name code="G-C220" codeSystem="SNOMED"
            displayName="with laterality"/>
          <value code="G-A100" codeSystem="SNOMED" displayName="right"/>
        </qualifier>
        <originalText><reference value="#a4"/></originalText>
      </targetSiteCode>
    </Observation>
  </component1>
</Section>
```

Level 2

human readable

Level 1

machine processible

Level 3

Clinical Document – Sections – Level 1

Human interoperability

```
<component>
    <section>
        <title>History of Present Illness</title>
        <text>
            Henry Levin, the 7th is a 67 year old male referred for further asthma management. He was
            hospitalized twice last year, and already twice this year. He has not been able to be weaned off
            steroids for the past several months.
        </text>
    </section>
</component>
```

Clinical Document – Sections – Level 2

Section Code

Using LOINC

Coding strength: CWE (Coded with Exceptions)

```
<component>
    <section>
        <code code="10164-2" codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC"/>
        <title>History of Present Illness</title>
        <text>
            Henry Levin, the 7th is a 67 year old male referred for further asthma management.
            He was hospitalized twice last year, and already twice this year. He has not been able to be weaned
            off steroids for the past several months.
        </text>
    </section>
</component>
```

Clinical Document – Sections – Level 3

Machine processible

```
<component>
    <section>
        <code code="10153-2" codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC"/>
        <title>Past Medical History</title>
        <text>
            <list>
                <item>
                    <content ID="a1">Asthma</content>
                </item>
            </list>
        </text>
        <entry typeCode = “COMP”>
            <Observation classCode="COND">
                <code code="39154008" codeSystem="2.16.840.1.113883.6.96" codeSystemName="SNOMED CT" displayName="clinical
diagnosis"/>
                <effectiveTime value="1950"/>
                <value xsi:type="CD" code="195967001" codeSystem="2.16.840.1.113883.6.96" codeSystemName="SNOMED CT"
displayName="Asthma">
                    <originalText>
                        <reference value="#a1"/>
                    </originalText>
                </value>
            </Observation>
        </entry>
    </section>
</component>
```

Referencing Entries

entryRelationship types

- COMP (component)
  - narrative is the original authenticated content

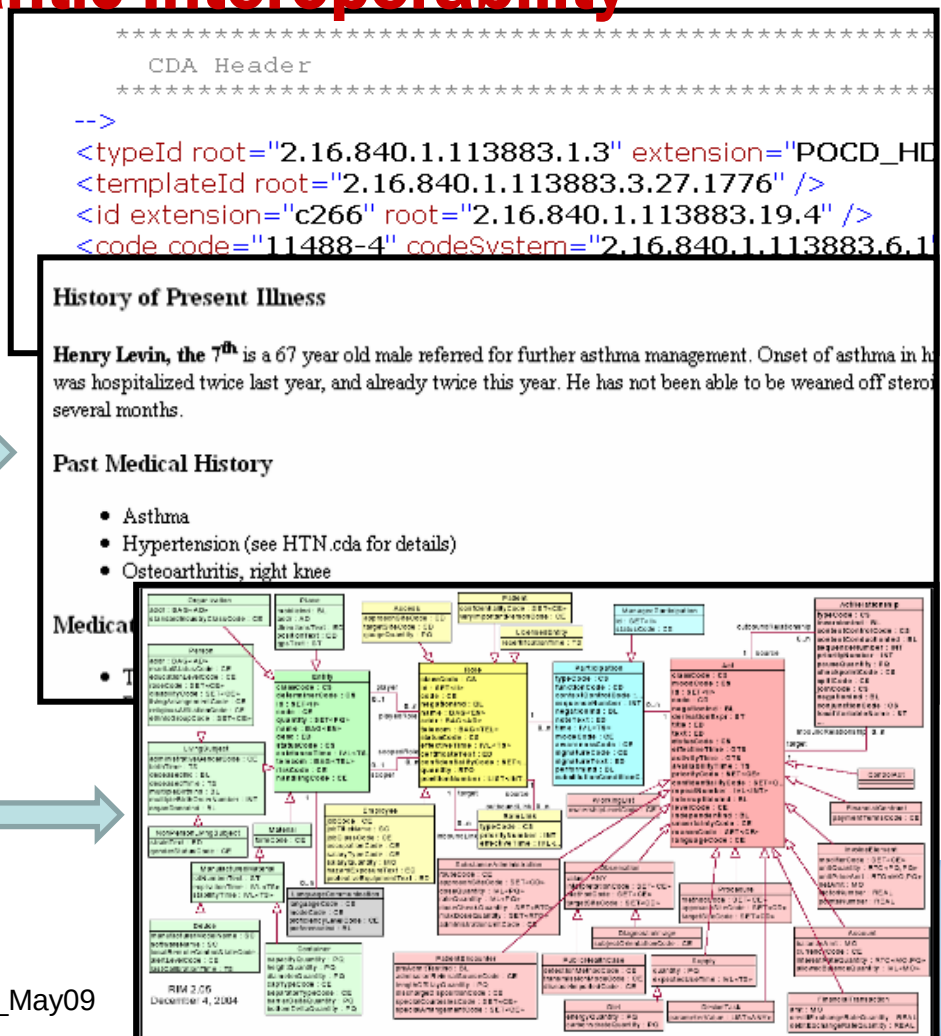
- DRIV (derived from)
  - narrative is fully derived from CDA Entries

CDA: Incremental Semantic Interoperability

Standard HL7 metadata

Simple XML for point of care human readability

RIM semantics for reusable computability ("semantic interoperability")



Source: Alschuler_CCD_May09

CDA vs Messages

Documents vs Messaging

- **Documents**: human-readability, persistence, self containment (wholeness and context)
  - Clinical Document Architecture (CDA) is a **HL7 standard for the representation and machine processing of clinical documents** in a way that makes the documents **both human readable and machine processable**.
- **Messages**: machine processability; oriented towards the **management of the status of business-objects**; uses a **dynamic model (trigger events) based on the status change** of one or more business-objects; capable of **providing real-time information**; messages may have **receiver responsibilities** (i.e. cause response messages to be sent).
  - The v3 Messaging standard is a HL7 standard that covers the above messaging aspect.

Relationship to HL7 messages

- CDA **complements** HL7 messaging specs
- A CDA document is a defined and complete information object that can **exist outside of a messaging context**
- A CDA document can be a MIME-encoded payload **within an HL7 message** (HL7 v2.x)
- CDA documents do **not need an HL7 message** to **provide context**
- v3 messaging support CDA transport

more ... Documents vs Messaging

- HL7 itself **hasn't** created any **recommendation** - how to use it
- Messages are generally used to **support** an ongoing **process** in a **real-time**
- Documents are about persisting "**snapshots**" as understood at a particular time
- Documents are "**passive**"
- CDA is **easier** than v3 messaging

CDA Transport

- xslt transform and then fax, email, etc…
- HL7 messaging (v2.x, v3)
- Custom Web Services (SOAP, XML-RPC, REST)
- IHE XDS

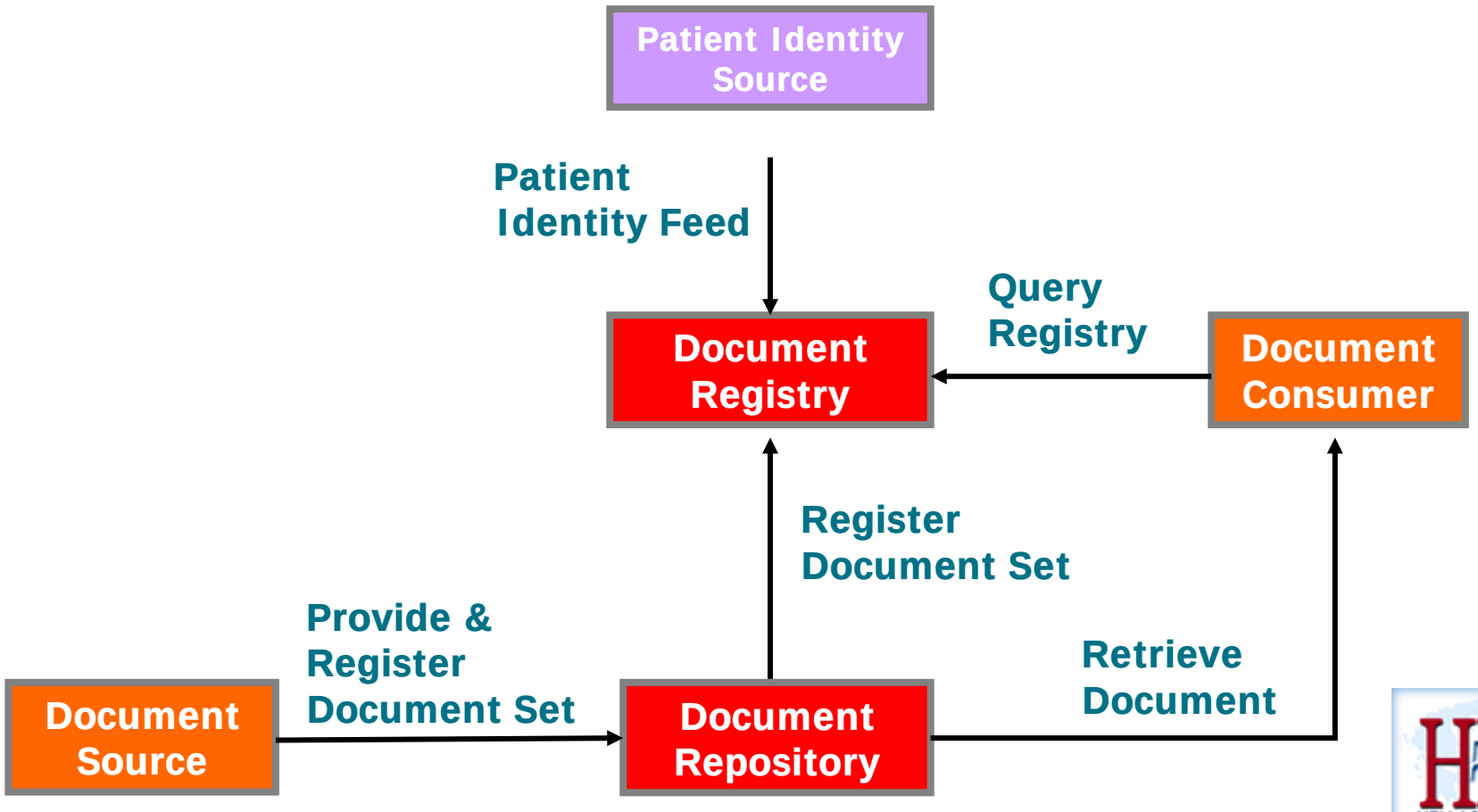
some of IHE Profiles

- XDR – Cross Enterprise Document Reliable Messaging
- **XDS.b – Cross Enterprise Document Sharing**
- PIX – Patient Identifier Cross Referencing
- PDQ – Patient Demographic Query
- ATNA – Audit Trail and Node Authentication

IHE Profiles

- XDR – Cross Enterprise Document Reliable Messaging
- **XDS.b – Cross Enterprise Document Sharing**
- PIX – Patient Identifier Cross Referencing
- PDQ – Patient Demographic Query
- ATNA – Audit Trail and Node Authentication

XDS Actors and Transactions



Security, Confidentiality, and Data Integrity

- **Application systems** sending and receiving CDA documents are **responsible** for meeting all legal requirements for document authentication, confidentiality, and retention.
- For **communications over public media**, cryptographic techniques for source/recipient authentication and secure transport of encapsulated documents may be required, and should be addressed with commercially available tools **outside the scope of this standard**.
- The CDA does **provide confidentiality status** information to aid application systems in managing access to sensitive data. **Confidentiality status** may apply to the entire document or to specified segments of the document.

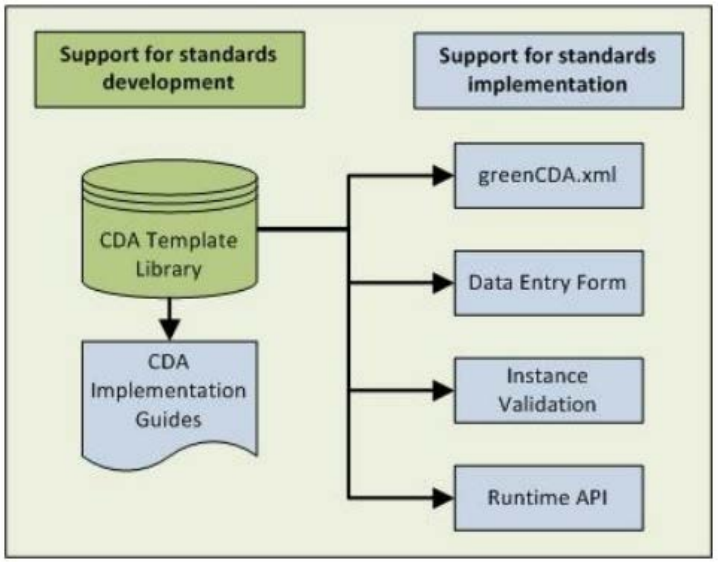
CDA Templates

CDA Templates

- Defines **additional syntax rules** that **constrain** the overall CDA syntax and semantics, for a **specific kind** of CDA document (or **portion** of a CDA document).
- Can be a document template:
  - defines overall rules for an **entire** CDA document
  - more specific **header** template
  - **section** template
  - **entry** template
- Templates form a **hierarchy**
  - Document templates indicate which header templates and section templates should be used, section templates **can reference additional nested section templates** and entry templates, and entry templates can contain other entry templates.
- Templates can be **mixed** and **matched** and **re-used**.
  - For example, the same entry template can be used inside other entry templates or section templates.

CDA Templates

- Model-driven computable objects that **can be stored in a database** that functions as a **CDA template library**.
  - Such template libraries **support both standards development and implementation**
  - Example Art-Décor



Source: Lantana Consulting Group Templated CDA: May 2011

CDA Template Manager

- MDHT
  - Model-Driven Health Tools (MDHT) for CDA
  - mainly in US
  - **generates validation source code**
  - http://www.cdatools.org/
- Art-Décor
  - mainly used in some European countries
  - **schematron based validation**
  - http://www.art-decor.org/

Source: Lantana Consulting Group Templated CDA: May 2011

CDA implementation guides

- Consolidated CDA "**C-CDA**"
  - Doesn't necessarily mean it's a good match for the specific requirements
- IHE **Medical Summary** CDA Implementation guide
  - defined in the IHE PCC profile
- European **epSOS** implementation guide
  - A lot of templates are reusable
- German **Discharge Letter** implementation guide
- A lot of others can be found …

Source: Lantana Consulting Group Templated CDA: May 2011

CDA vs. C-CDA

- C-CDA : **defines a set of CDA documents**

  The HL7 Consolidated CDA is an **implementation guide** which **specifies a library of templates** and describe their use for a set of specific document types

- CDA : **the schema for those documents**

  The HL7 Clinical Document Architecture (CDA) is a document markup standard that **specifies the structure and semantics of "clinical documents" for the purpose of exchange**.

Source: Lantana Consulting Group Templated CDA: May 2011

HL7 C-CDA Implementation Guide

- Document Organization
  - Introduction
  - General Header Template
  - Document-Level Templates
  - Section-Level Templates
  - Entry-Level Templates
  - Appendix
    - Template IDs, Code Systems, Value Sets, Extensions, …

Source: Lantana Consulting Group Templated CDA: May 2011

CDA Validation

CDA Validation

- Validates against the published XML Schema
  - XML **Schema** based validation tool
- Validates against the abstract CDA model specification
  - Use a MIF **- Model Interchange Format** (specification of the abstract model) based validation tool, includes **conformance and vocabulary validation**
- Validates against requirements / templates as specified in implementation guides
  - Mostly: a XML **Schematron** based validation tool; could be MIF/OCL based

Source: V3 Software Implementation René Spronk

CDA Validation - Schematron

- A way to test XML documents
  - **Rules-based** validation language
  - **XML schema** language
  - Others are W3C XML Schema, RelaxNG, etc.
  - **ISO** standard
  - Schema is a **collection of patterns**
  - Patterns contain one or more rules with a context
  - Rules **assert** that a test has passed
  - Failures may issue **diagnostics**
  - The **output** of schematron validation is an **XML report** on the validation status of the instance

Source: V3 Software Implementation René Spronk

CDA Validation - Example Schematron

```
<rule context="hl7:typeId">
    <assert role="error“
        test="@extension='POCD_HD000040'">
        ClinicalDocument.typeId (2.16.840.1.113883.2.4.6.10.35.3)
        @extension SHALL have value POCD_HD000040 static </assert>

    <assert role="error" test="@root='2.16.840.1.113883.1.3'">
        ClinicalDocument.typeId (2.16.840.1.113883.2.4.6.10.35.3)
        @root SHALL have value 2.16.840.1.113883.1.3 static </assert>
</rule>
```

Source: V3 Software Implementation René Spronk

CDA Validation - Tools

- Schematron
  - http://www.schematron.com/
  - http://xml.ascc.net/resource/schematron/schematron.html
- National Institute of Standards and Technology (NIST)
  - http://cda-validation.nist.gov/cda-validation/validation.html
- IHE Gazelle
  - http://gazelle.ihe.net/EVSClient/cda/validator.seam
- Art Décor
  - https://art-decor.org/mediawiki/index.php/Main_Page

CDA Development
Art-Décor

Ανάγκες ανάπτυξης CDA - Μεθοδολογία

- Problem Domain – Medical
  - Ανάλυση **σεναρίου χρήσης** (use case)
  - Ανάλυση **διαλειτουργικότητας** (transactions)
  - Προσδιορισμός **δεδομένων** που χρησιμοποιούνται (data sets)

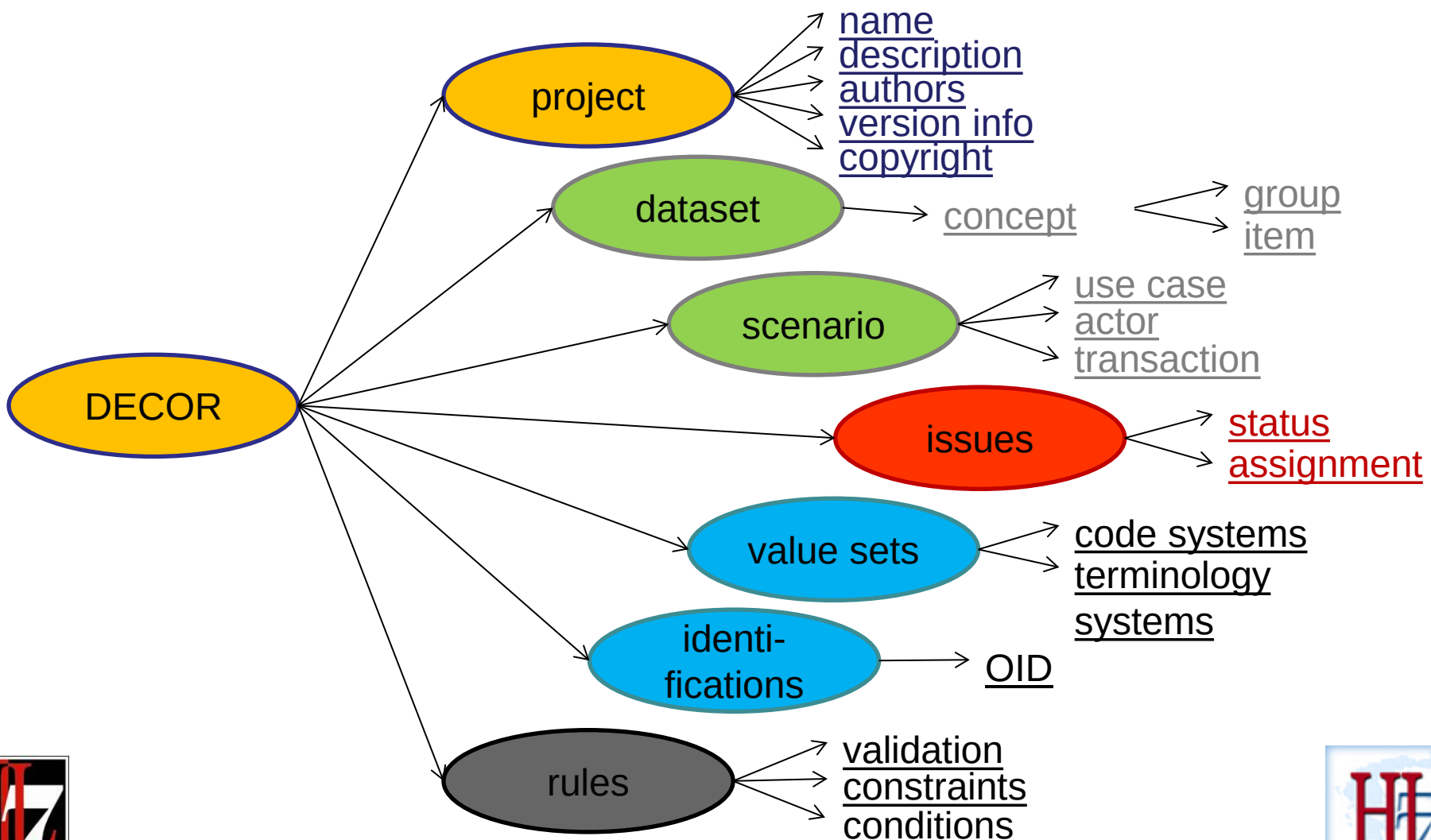
Ανάγκες ανάπτυξης CDA - Μεθοδολογία

- Problem Domain – Terminology
  - Προσδιορισμός **προκαθορισμένων τιμών**
  - Προσδιορισμός **Συστημάτων κωδικοποίησης** (πχ ICD10 κλπ.)
  - Προσδιορισμός **στόχων κωδικοποίησης** (ανάλυση, στατιστική κλπ.)

Ανάγκες ανάπτυξης CDA - Μεθοδολογία

- Problem Domain – ICT
  - HL7v3:
    - Reference Information Model
    - XML serialization
    - XML Schema
    - CDA (part text, part structured data)
- RIM (Reference Information Model) Backbone
- OIDs

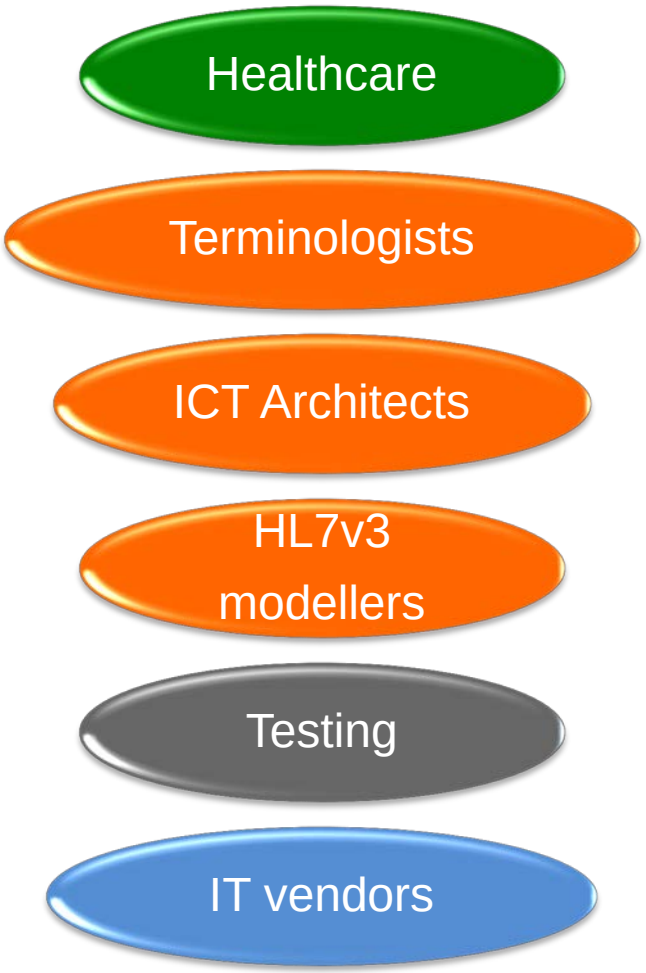
DECOR overview


DECOR
project
name
description
authors
version info
copyright
dataset
concept
group
item
scenario
use case
actor
transaction
issues
status
assignment
value sets
code systems
terminology
systems
identi-
fications
OID
rules
validation
constraints
conditions

DECOR and ART technology

- A DECOR file is an XML file
  - methodology developed by dr. Kai U. Heitmann
  - basis for transformations to other HTML / XML
  - fine basis for schema(tron)
  - has its own schema (DECOR.xsd)
- ART is tooling to make DECOR files
  - tooling developed by Gerrit Boers
  - ART is made with XQuery / XForms
  - open source products eXist / Orbeon
- ART and DECOR are open source (GPL / LGPL)
  - team: Kai, Gerrit, Alexander Henket, Maarten Ligtvoet, Marc

DECOR & ART stakeholders



DECOR Output

- Care Provider view
- Technical Documentation
- XML / CSV resources for implementers
- Schematron / UI-Generation (xml for application)

What Next ... R3

CDA R3

- **First option:** minimal **upgrade** that retains **backwards compatibility** (like R2.1)
- **Second option:** underlying format for the next release of CDA will be based on the technical vehicle of **FHIR** rather than the technical vehicle of the RIM base
  - Same goals with CDA R2 by a different technical route
- Now a lot of design activity has moved to CDA R2 anyway (principally CCDA and EPSOS)
- In future CDA implementation guides will be based on templates

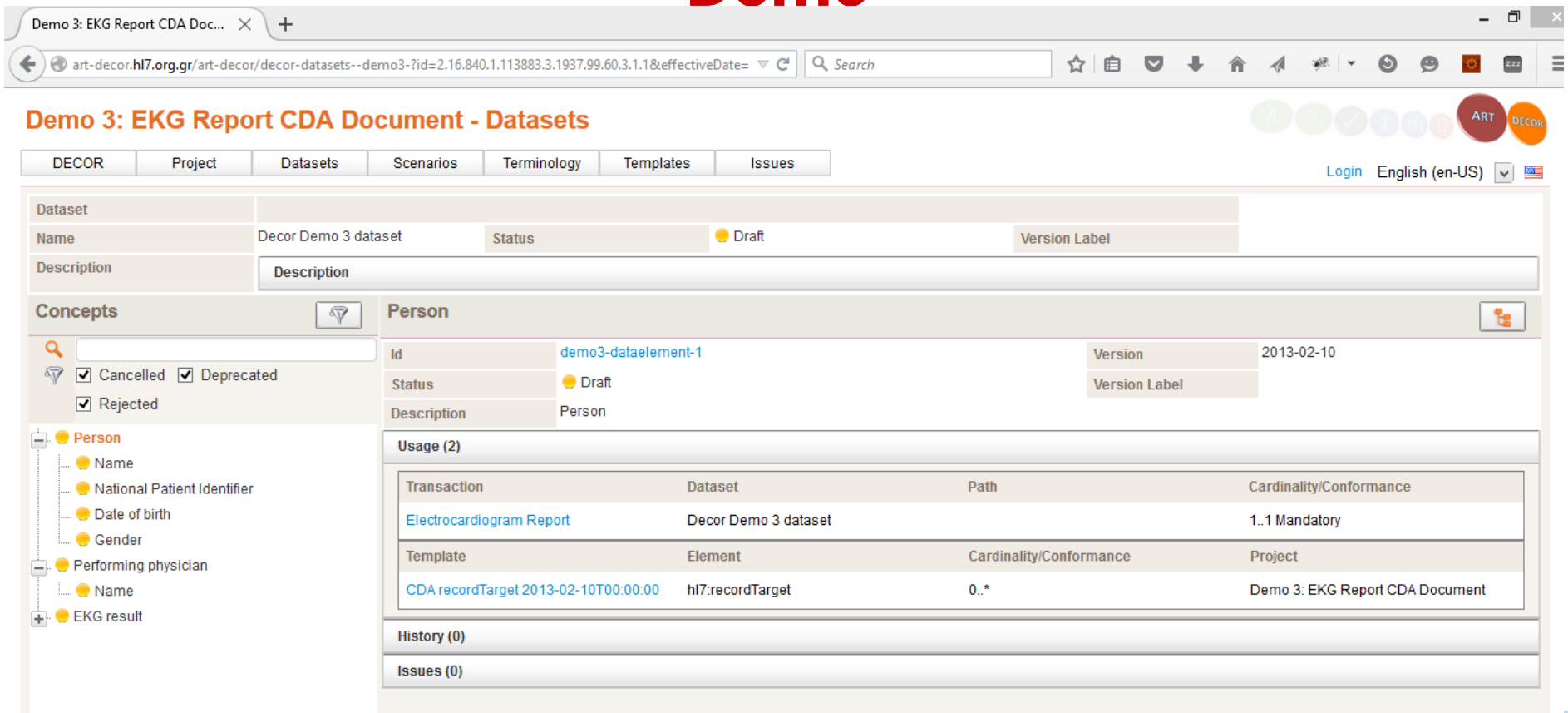
CDA Business

CDA Business Case

- CDA encompasses **all** of clinical documents
- CDA is **ISO** and ANSI
- Worldwide **acceptance** - international
- Provides a mechanism for **incremental** semantic interoperability
- Using “template” mechanism it **easier** to do the right thing
- Lower costs: let’s you implement once, and **reuse** many times for new scenarios

CDA Demo

Demo


Demo 3: EKG Report CDA Doc...
art-decor.hl7.org.gr/art-decor/decor-datasets--demo3-?id=2.16.840.1.113883.3.1937.99.60.3.1.1&effectiveDate=
Search
Demo 3: EKG Report CDA Document - Datasets
ART
DECOR
DECOR
Project
Datasets
Scenarios
Terminology
Templates
Issues
Login
English (en-US)
Dataset
Name
Decor Demo 3 dataset
Status
Draft
Version Label
Description
Description
Concepts
Cancelled
Deprecated
Rejected
Person
Name
National Patient Identifier
Date of birth
Gender
Performing physician
Name
EKG result
Person
Id
demo3-dataelement-1
Version
2013-02-10
Status
Draft
Version Label
Description
Person
Usage (2)
Transaction
Dataset
Path
Cardinality/Conformance
Electrocardiogram Report
Decor Demo 3 dataset
1..1 Mandatory
Template
Element
Cardinality/Conformance
Project
CDA recordTarget 2013-02-10T00:00:00
hl7:recordTarget
0..*
Demo 3: EKG Report CDA Document
History (0)
Issues (0)

Σας ευχαριστώ!

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