

# EHR Interoperability

## The 13606 Reference Model ... and its limitations

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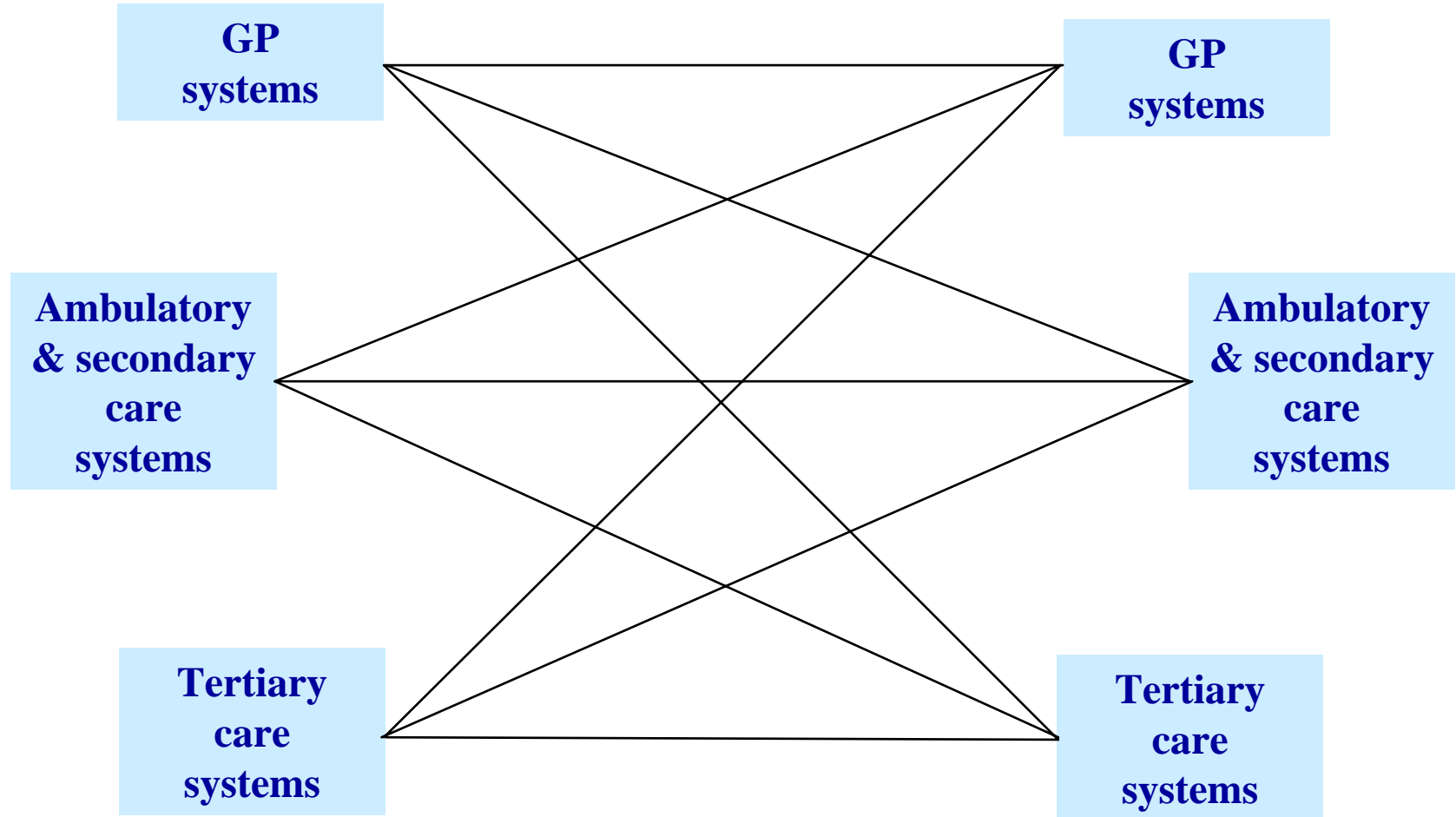
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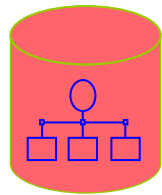
# Why standardise EHR communication?

- Patient care requires access to longitudinal health information
  - to manage complex health care safely
  - to share care between teams and enterprises
- Patients wish to play an active role in their health management
- Much of the necessary fine grained clinical information cannot yet be exchanged between heterogeneous systems
- Conventional data-sets and messages do not deal with the requirement to exchange parts or whole EHRs between systems

# A combinatorial explosion: of interfaces or of messages



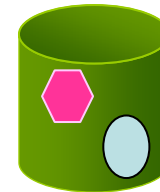
Clinical trials,  
functional genomics  
and inherited genotype



EHR systems  
and servers



Decision support,  
knowledge management  
and analysis components



Personnel registers,  
security services



Mobile devices



Clinical devices,  
instruments



Clinical  
applications

# Scope of EN 13606

- To produce a rigorous and durable information architecture for communicating the EHR
- in order to support the interoperability of systems and components that need to interact with EHR services
  - as discrete systems or as middleware components
  - to access, transfer, add or modify health record entries
  - via messages or distributed objects (services)
  - preserving clinical meaning
  - protecting confidentiality

# Parts of EN 13606

## Part 1: Reference Model

- comprehensive, generic model for communicating part or all of an EHR

## Part 2: Archetype Specification

- adopting the openEHR archetype approach
- constraint-based approach for defining clinical “business objects” that are built from the Reference Model

## Part 3: Reference Archetypes and Term Lists

- initial set of archetypes for use across Europe
- micro-vocabularies for the Part 1 model

## Part 4: Security

- measures to support access control, consent and auditability of EHR communications

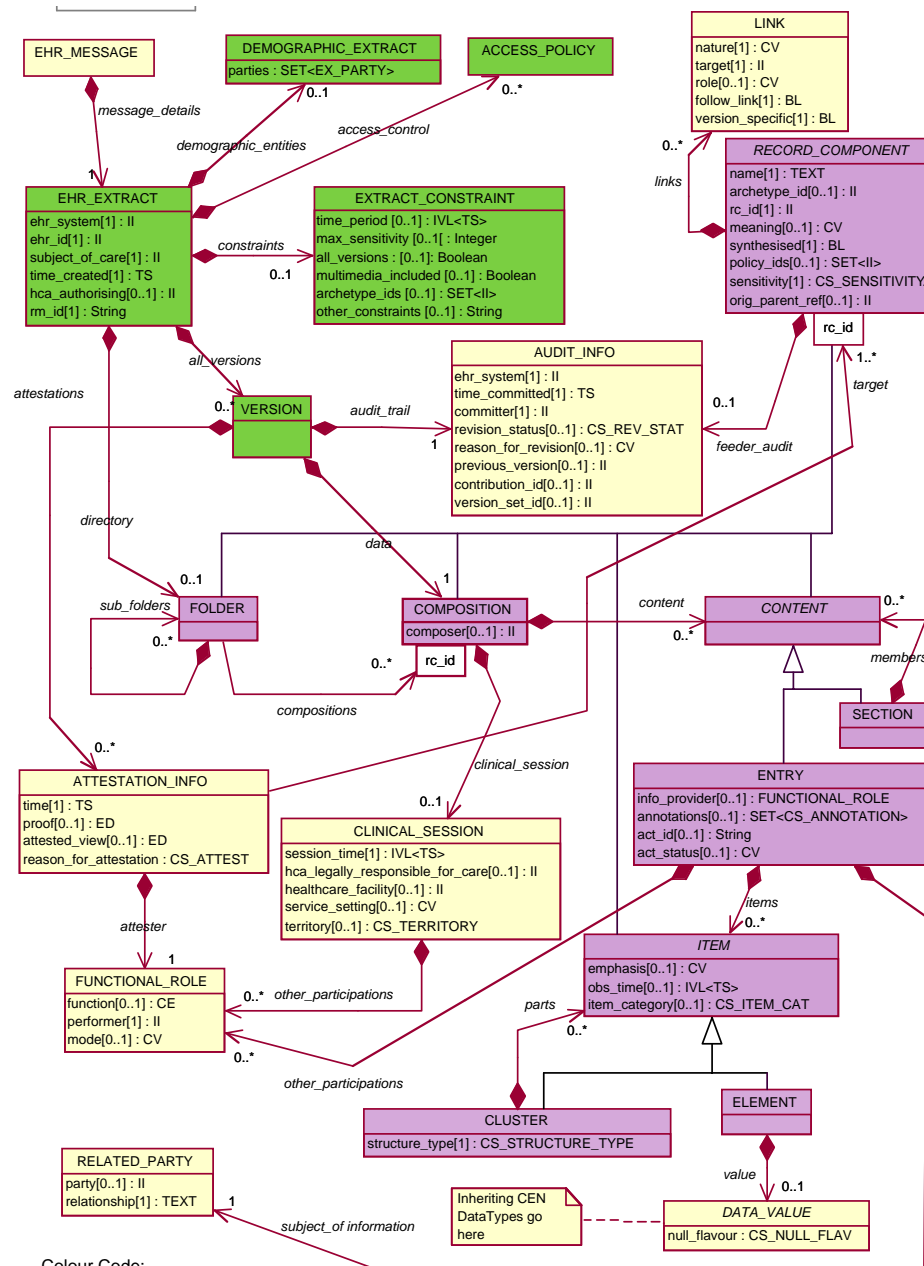
## Part 5: Exchange Models

- message and service interfaces to enable EHR and archetype communication

# On what basis has the Reference Model been developed?

- Research results: 13 years
  - implementation experience including
    - many EU projects
    - *openEHR* Foundation
- Requirements: ISO, European R&D, HL7
- Previous EHR standards: CEN 1995, 1999
- Vendor experience
- The RFC process of previous drafts

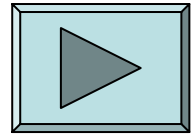
# 13606-1 Reference Model



Colour Code:

- EHR\_Extract and immediate associates
- Record Component and its inheritors
- Others

Inheriting CEN DataTypes go here



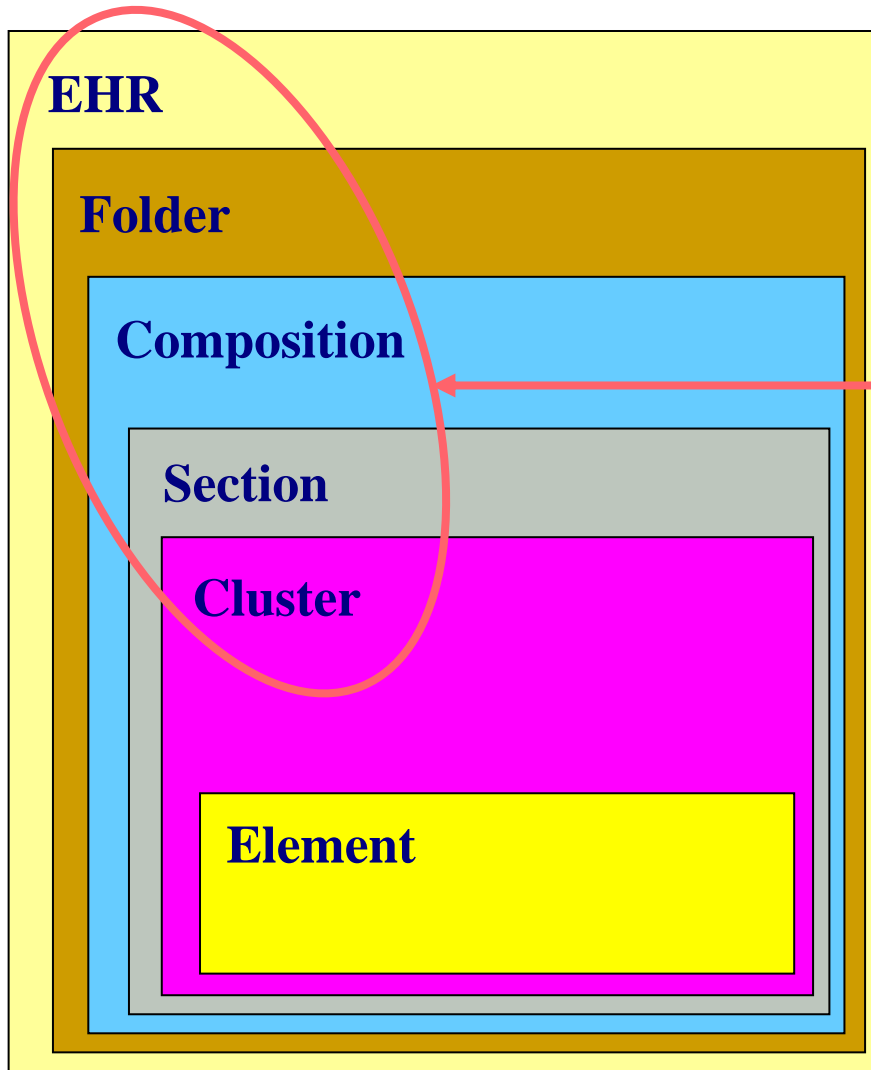
# Harmonisation with other related standardisation efforts

- CEN
  - Healthcare Information Systems Architecture (HISA)
  - Systems of concepts for continuity of care (CONTSYS)
  - General Purpose Information Components (GPICs)
  - CEN data types
- ISO
  - ISO TS 18308 requirements adopted as the official requirements basis for the standard
  - 13606 has been related to concepts defined in ISO DTR 20514
  - Access control approach maps to Privilege Management and Access Control draft standard

# Harmonisation with other related standardisation efforts

- HL7
  - Clinical Document Architecture: detailed cross-mapping
  - Templates: working together on a joint CEN/HL7 archetype specification
  - Clinical Statement model: contributing to its design
  - A formal 13606-1 HL7 D-MIM has been produced
  - 13606 is being mapped into Patient Care Provision message
- IHE
  - XDS specification: mapping to registry metadata

# 13606 correspondence with HL7 & CDA



All of the 13606 container classes now have a corresponding Act classCode

# 13606 correspondence with HL7 & CDA

## **EHR**

### **Folder**

### **Composition**

### **Section**

### **Cluster**

### **Element**

(Act: classCode = EHR)

(Act: classCode = Folder)

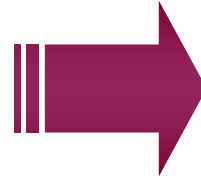
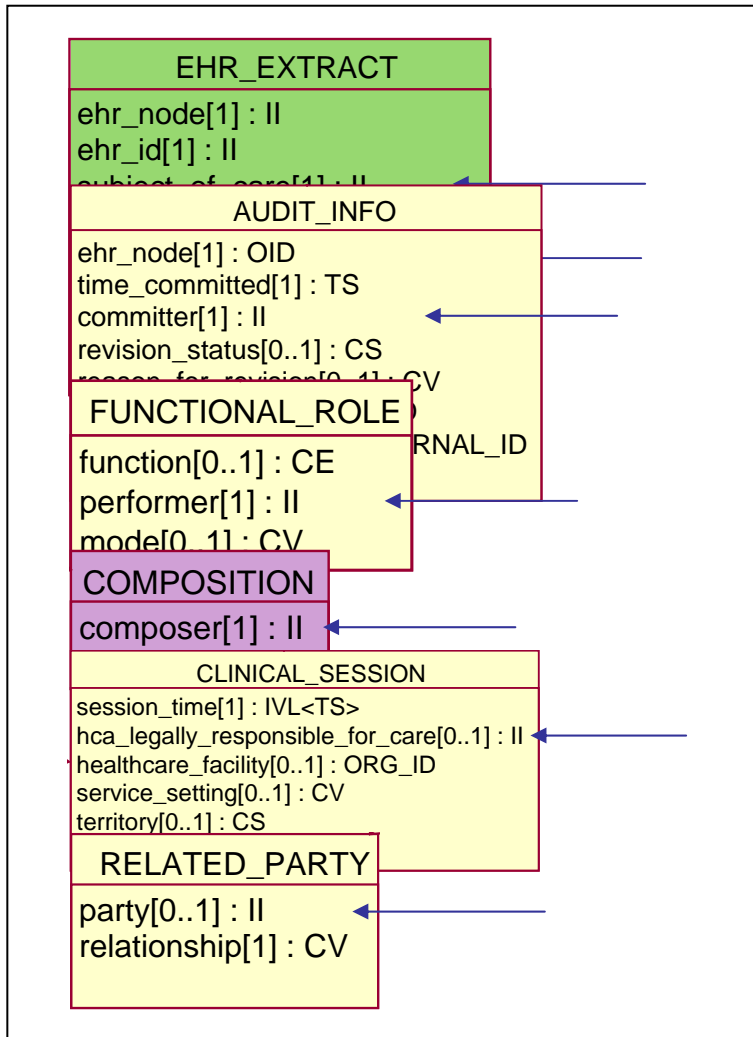
### **Clinical Document**

### **Section**

**choice of Entries:**  
e.g. Observation, Encounter,  
SubstanceAdministration

**attributes of Entries**

# 13606 correspondence with HL7 & CDA: parties



## Participation

**recordTarget**

**informant**

**dataEnterer**

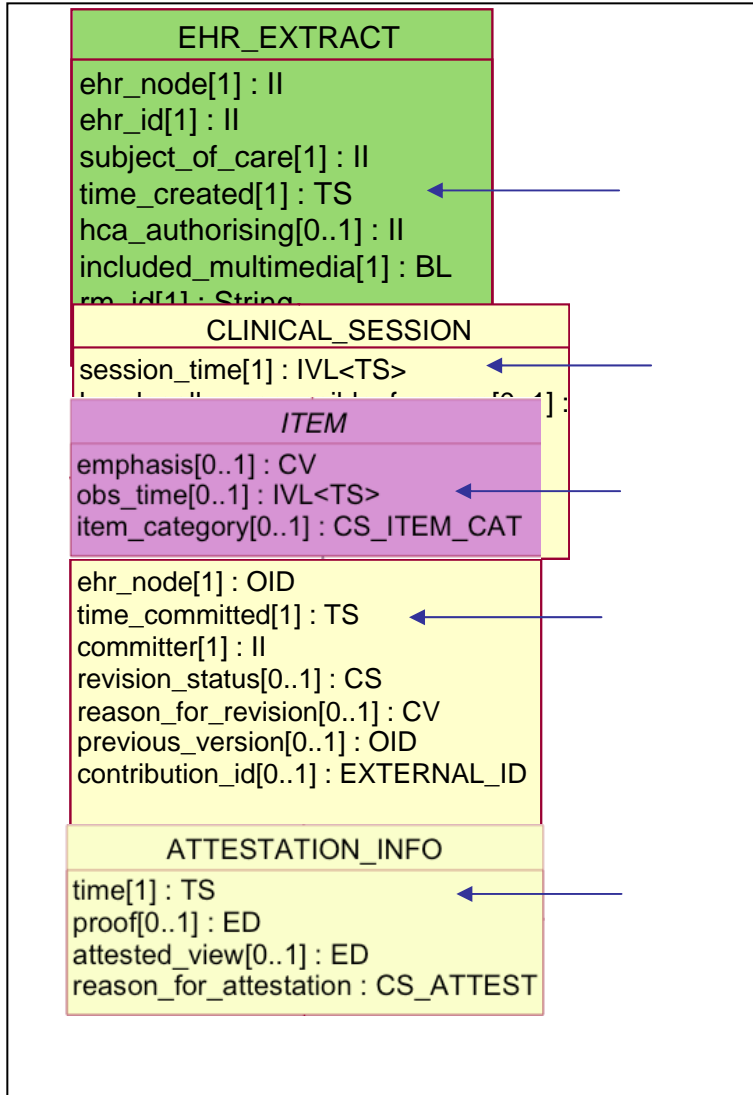
**encounterPerformer**

**author**

**legalAuthenticator**

**participant,  
legalAuthenticator**

# 13606 correspondence with HL7 & CDA: dates and times



(Property of the message header)

## Act

**activityTime**

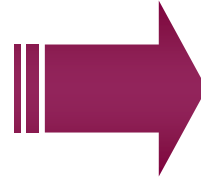
**effectiveTime**

**availabilityTime**

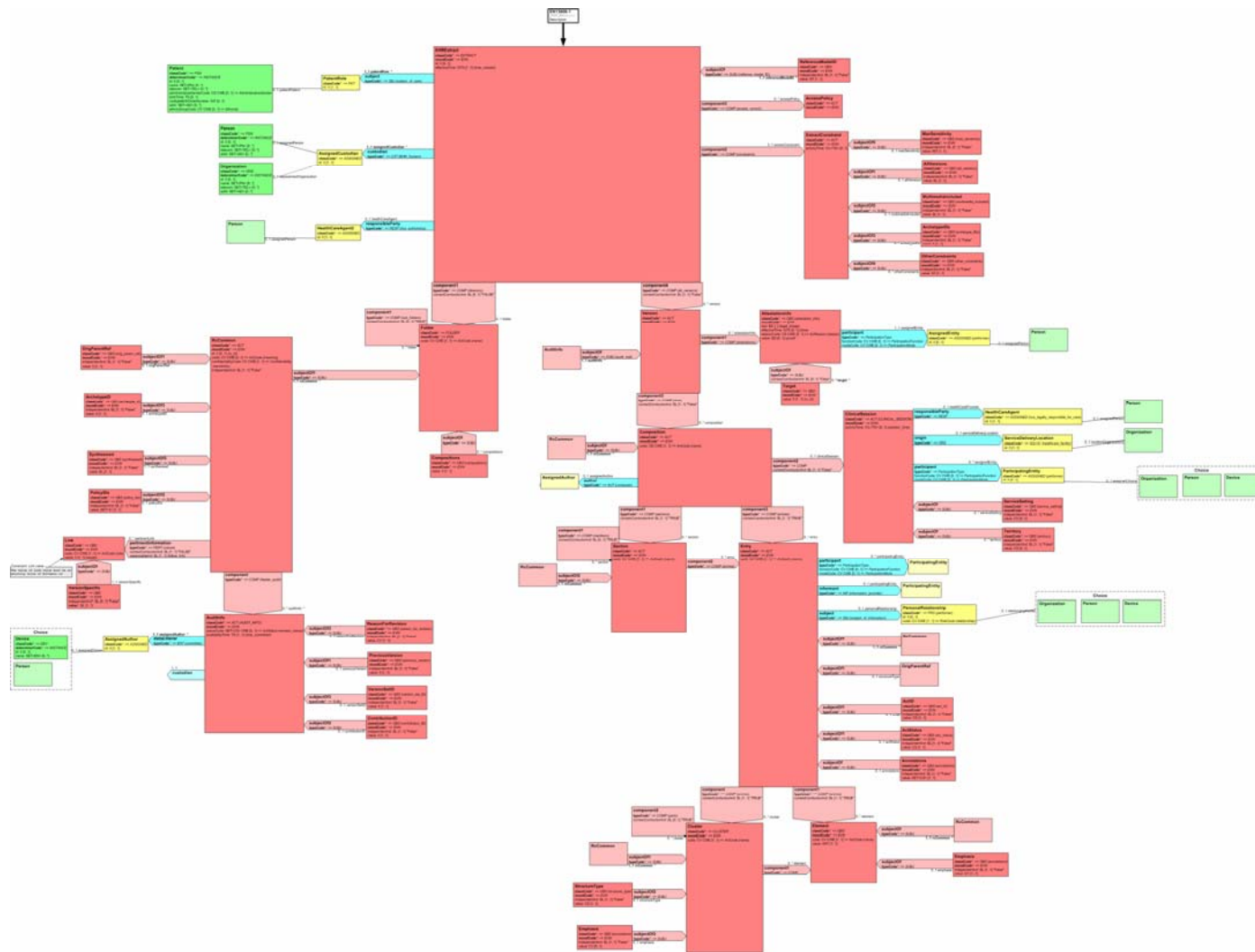
## Participation

**authenticator.time**

**legalAuthenticator.time**



# Representation of 13606 as an HL7 D-MIM



# Some problems with mapping the EHR to the RIM (1)

- The Act is both a class representing an activity and representing its documentation: but requirements differ
- Classes developed primarily for business messages and ADT, and not for clinical documentation
  - e.g. patient encounter
  - i.e. contain inappropriate attributes such as moodCode (mandatory) and reasonCode
- Act classes only for predefined purposes
  - (e.g. to document a procedure or substance administration)
  - i.e. too much clinical content in the model (e.g. observation)
  - no generic equivalents to a Cluster or Element

# List of Act classes in the RIM

Account

**Act**

ActRelationship

ControlAct

DeviceTask

**DiagnosticImage**

Diet

FinancialContract

FinancialTransaction

InvoiceElement

ManagedParticipation

**Observation**

Participation

*PatientEncounter*

**Procedure**

PublicHealthCase

**SubstanceAdministration**

*Supply*

WorkingList

# Patient Encounter class

PatientEncounter
preAdmitTestInd : BL
admissionReferralSourceCode : CE
lengthOfStayQuantity : PQ
dischargeDispositionCode : CE
specialCourtesiesCode : SET<CE>
specialArrangementCode : SET<CE>
acuityLevelCode : CE

# Observation class

## Observation

**classCode\***: <= OBS  
**moodCode\***: <= *x\_ActMoodOrdPrmsEvn*  
**id**: II [0..1]  
**code\***: CD CWE [1..1] <= *ObservationType*  
**negationInd**: BL [0..1]  
**derivationExpr**: ST [0..1]  
**text**: ED [0..1]  
**statusCode\***: CS CNE [0..1] <= *ActStatus* "completed"  
**effectiveTime**: GTS [0..1]  
**priorityCode**: SET<CE> CWE [0..1] <= *ActPriority*  
**confidentialityCode**: SET<CE> CWE [1..\*] <= *Confidentiality* "N"  
**repeatNumber**: IVL<INT> [0..1] "1"  
**uncertaintyCode**: CE CNE [0..1] <= *ActUncertainty* "N"  
**languageCode**: CS CNE [0..1] <= *HumanLanguage*  
**value**: ANY [0..1]  
**interpretationCode**: SET<CE> CWE [0..\*]  
**methodCode**: CE CWE [0..1]  
**targetSiteCode**: CD CWE [0..1]

# Act reasonCode values

Accommodation Requested Not Available  
Floor Convenience  
Medical Necessity  
Patient request  
coverage suspended  
deceased  
registered in error  
incorrect covered party as patient  
incorrect billing  
incorrect policy  
incorrect provider  
Unexpected Block (of Schedule)  
Patient Deceased

No Financial Backing  
Medical Status Altered  
In an outside meeting  
Patient request  
Physician request  
continuing therapy  
formulary policy  
out of stock  
regulatory requirement  
Error  
Request  
Medical Necessity  
Patient request

# Some problems with mapping the EHR to the RIM (2)

- Attributes cannot be added to RIM classes:
  - reason for revision, reference to previous version and version set
  - original parent identifier (if an entry is a logical copy)
  - access policies relating to a record component
  - the criteria by which an EHR Extract has been produced (e.g. set of archetypes it contains, date range it covers)
- Only coarse grained codes exist, not ideal for clinical shared care
  - the meaning of a Link between two EHR entries
  - the role played by a participant in care delivery
  - the relationship between a patient and a relative

# HL7 actRelationship codes (1)

## **PertinentInfo**

has support  
is cause for  
is manifestation of  
refers to  
has subject

## **ExternalReference**

excerpts  
has support  
refers to  
has subject

## **Conditional**

has contra-indication  
has pre-condition  
is required by  
has reason  
suggests  
has trigger

## **Pertains**

has support  
has bounded support  
authorized by  
is cause for  
covered by  
is derived from  
has explanation  
limited by  
is manifestation of  
assigns name  
has previous instance  
refers to  
has reference values  
has subject

# HL7 actRelationship codes (2)

## **Outcome**

has outcome  
has goal  
has continuing objective  
has final objective  
has risk

## **Rationale**

summarized by

## **Sequel**

is sequel

## **Excerpt**

excerpts  
excerpt verbatim

## **Fulfills**

fulfills  
occurrence  
references order  
schedules request

## **Replacement**

replaces  
succeeds  
is appendage  
documents  
episodeLink  
has generalization  
evaluates (goal)  
instantiates (master)  
matches (trigger)  
has option  
reverses  
updates (condition)  
transformation

# Some problems with mapping the EHR to the RIM (3)

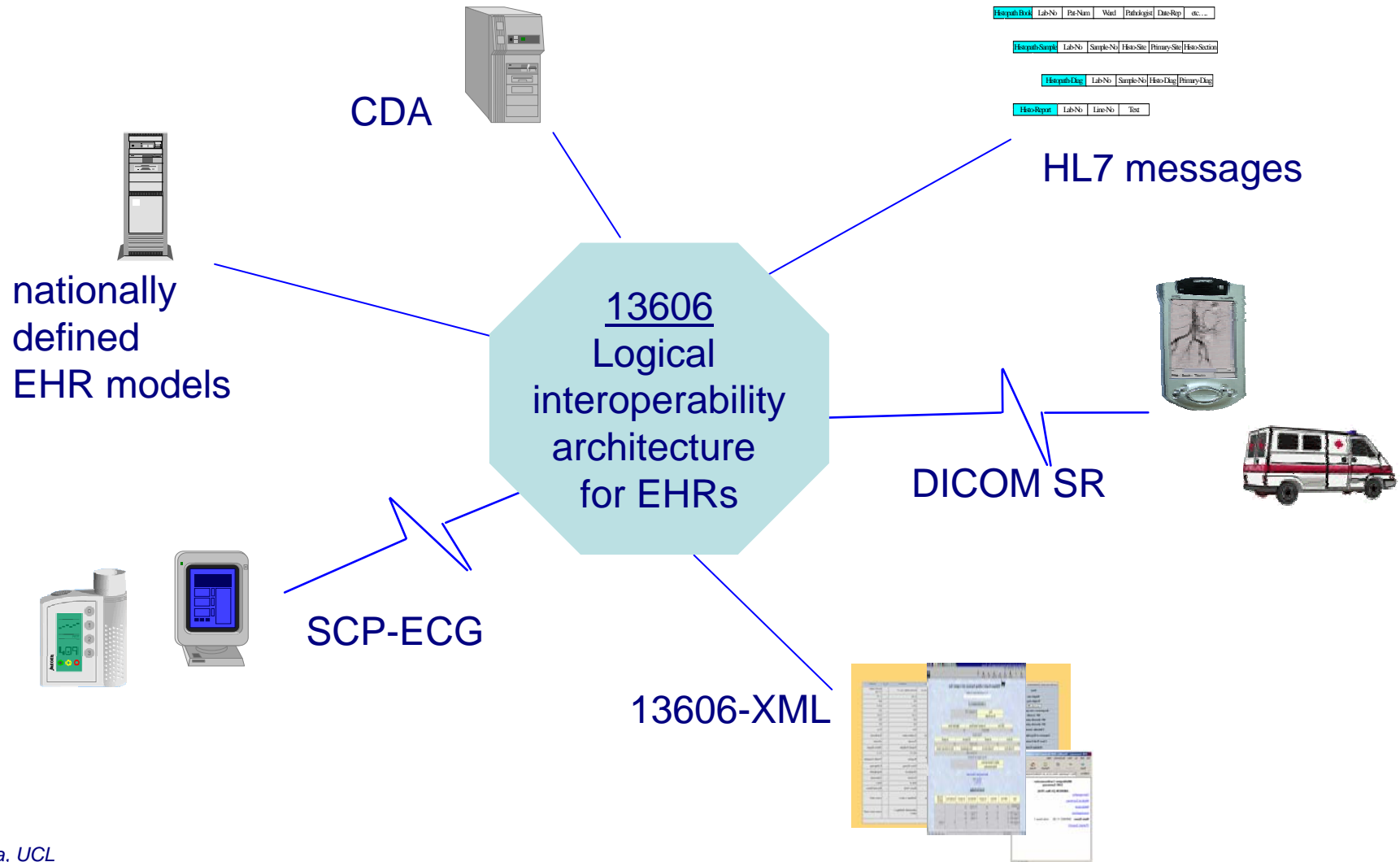
- Recursive containment of context, risking ambiguous interpretation e.g. handling of negation or subject of information
- Data types are complex, covering too many use cases, somewhat undisciplined and differ from other industry standards

# Harmonisation in practice

- everyone wants a single standard to exist for each distinct purpose
- everyone wants standards to work cleanly together
- everyone wants to minimise vendor migration costs
- everyone wants multivendor products to be interoperable
- everyone hopes this can be achieved simply:
  - “lets all adopt CEN standards”
  - OR
  - “lets all adopt HL7 standards”

**But this simplicity is a myth**

# A generic logical EHR reference model is needed



# Fitness for purpose v harmonisation

- Health care is a diverse and complex informatics field
  - and continually evolving
- Best practice in clinical information management, sharing, and exploitation is still not established
  - i.e. it is largely validated at a theoretical level, in small demonstrators, or is not yet known

There is much about the wide-scale adoption of the EHR that we don't know yet

## from Rector A, Berg M, Tange H, Kalra D and others (summarised from several publications)

- There are limitations to the idealised image of medical practice as a strictly cognitive process involving gathering observations, testing hypotheses and logically deducing treatments
- New health data can often undo the reasoning of previously solid historical "facts":
  - the clinical picture of a patient is constantly being reconstructed, with no predictable and reproducible basis for weighting one kind of fact over another

## from Rector A, Berg M, Tange H, Kalra D and others (summarised from several publications)

- A medical record may at times need to be seen as a comprehensive, accurate and legal "log" of healthcare activities, and at times will document hypotheses and filtered abstractions of the healthcare process to support the reasoning of the clinician
- The medical record is often not an accurate mirror of the consultation nor an actuarial document, but itself provides a means for organising ideas and contributes to the work of communicating, decision making and sharing with patients

## from Rector A, Berg M, Tange H, Kalra D and others (summarised from several publications)

- Records contain much reiteration, not because facts are not found elsewhere but to summarise the current focus of thinking.
- Many entries are brief, concise, and are understood by those who are familiar with the context of that recording. Such entries often only note exceptions and emphasised information, and may even omit the routine. Such brevity allows the record to highlight what needs to be known rather than to document all that is known

## from Rector A, Berg M, Tange H, Kalra D and others (summarised from several publications)

- Secondary uses assume that healthcare data are utilities or commodities that can be extracted, and often aggregated, if their input has been structured and/or coded
- Patient data entered exclusively into highly structured forms can easily be misinterpreted out of context, especially when inferring the meaning of unfilled sections

# The EHR Reference Model

- aims to capture as much as possible of the relevant context to make subsequent interpretation as safe as possible
- cannot in itself guarantee semantic interoperability
- archetypes help with semantic interoperability
- formalising the relationships between record structures, archetypes, message models and terminology models is an important area of ongoing research