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# EHR STANDARDS

# STANDARDS FOR ELECTRONIC HEALTH RECORD

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## ISO 13606

- The overall goal of ISO 13606 is to define a rigorous and stable information architecture for communicating part or all of the Electronic Health Record (EHR) of a single subject of care (patient).

**Model for data exchange, not for a full EHR system**

## CEN 14822

- This European Standard specifies General Purpose Information Components to be used in standards for information exchange and information models supporting various health specific business requirements. The components defined in this standard are the most commonly needed basic building blocks for such standardization but these components may require further specialisation and be complemented by other objects required for specific purposes not met by these generally useful components.

**Model for creating components to exchange**

## OpenEHR

- Technology for e-health, consisting of open specifications, clinical models and software that can be used to create standards, and build information and interoperability solutions for healthcare. The various artefacts of openEHR are produced by the openEHR community and managed by the openEHR Foundation, an international non-profit organisation established in the year 2003.

**Model for a full EHR**

# ISO 13606

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INTERNATIONAL STANDARD

**ISO 13606-1**

FIrst edition
2008-02-15

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**Health informatics — Electronic health record communication —**

# EN 13606



## Part 1 – Reference Model

- Comprehensive model for exchanging part of an EHR or an entire EHR among heterogeneous systems

## Part 2 – Archetype interchange specification

- Definition of clinical "business objects" based on the reference model (adopted from OpenEHR)

## Part 3 – Reference archetypes and term list

- Inter-reference model conversion –> maps to OpenEHR and HL7v3 RIM
- Term list for Part 1

## Part 4 – Security features

- Measures and models to share access control and content auditability

## Part 5 – Exchange model

- Message and service interfaces to enable EHR and archetype communication

# THE DUAL MODEL APPROACH



- **The Reference Model** represents the global characteristics of health record components:
  - how they are aggregated
  - the context information required to meet ethical, legal and provenance requirements.
  - the set of classes that form the generic building blocks of the EHR.
- **An Archetype** is the formal definition of prescribed combinations of the building-block classes defined in the Reference Model for particular clinical domains or organizations. An archetype is a formal expression of a distinct, domain-level concept, expressed in the form of constraints on data whose instances conform to the reference model.

# EN 13606 REFERENCE MODEL



## EXTRACT PACKAGE

- Describes the root class of the reference model
- Describes the structure of the EHR content

## DEMOGRAPHICS PACKAGE

- Provides the minimal dataset to define the entities (person, device, organization, etc) that are referenced in the EHR_EXTRACT

## ACCESS CONTROL PACKAGE

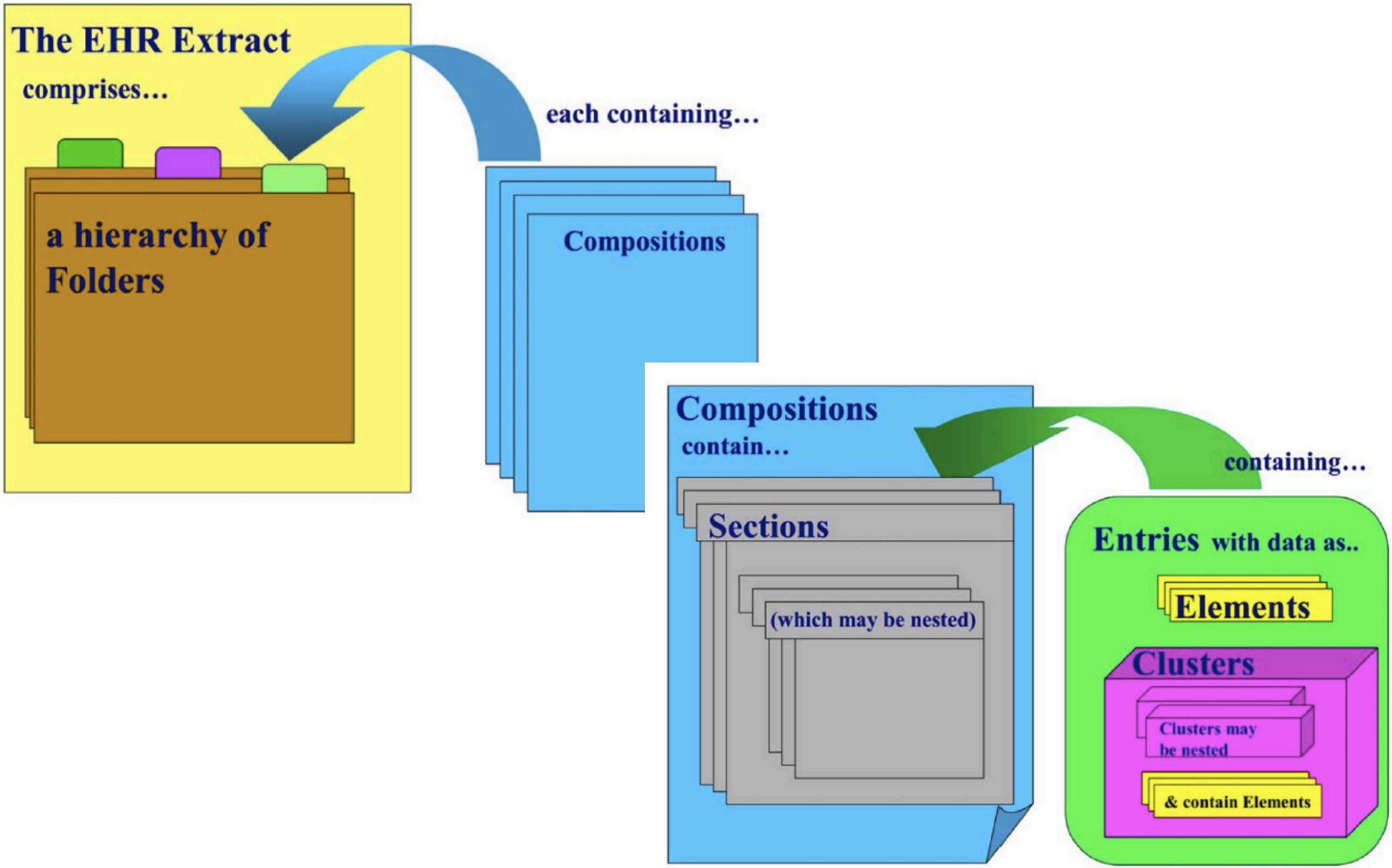
- Defines a representation for EHR access policies

## MESSAGE PACKAGE

- Defines the attributes required to communicate EHR_EXTRXT to a requesting process via message or other form

# THE EHR EXTRACT





# THE EHR EXTRACT DATA MODEL

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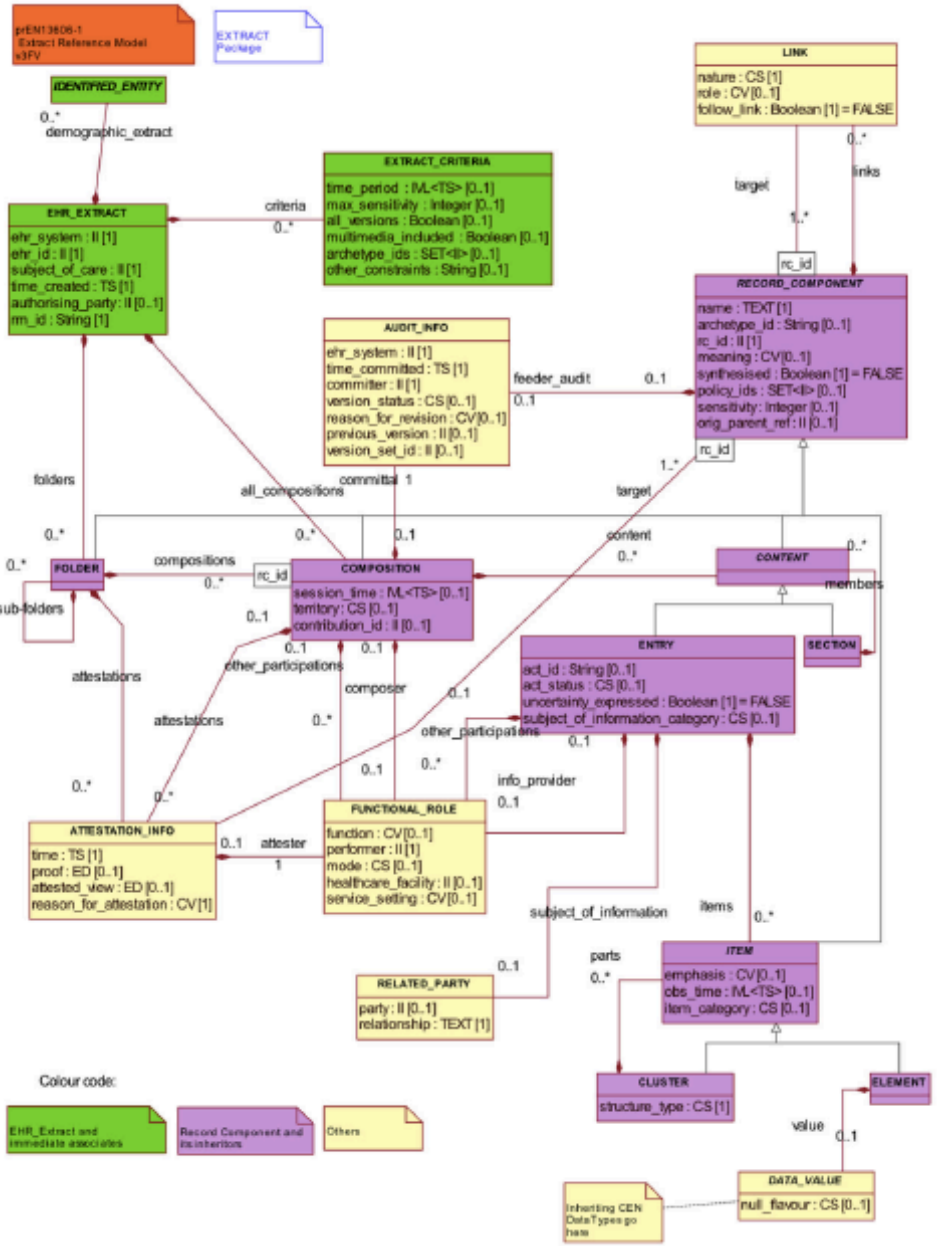


| Inner elements |
|---|
| **Name** |
| ATTESTATION_INFO |
| AUDIT_INFO |
| CLUSTER |
| COMPOSITION |
| CONTENT |
| EHR_EXTRACT |
| ELEMENT |
| ENTRY |
| EXTRACT_CRITERIA |
| FOLDER |
| FUNCTIONAL_ROLE |
| ITEM |
| LINK |
| RECORD_COMPONENT |
| RELATED_PARTY |
| SECTION |

# GENERAL PURPOSE INFORMATION COMPONENTS (EN 14822)

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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

**EN 14822-1**

October 2005

ICS 35.240.80

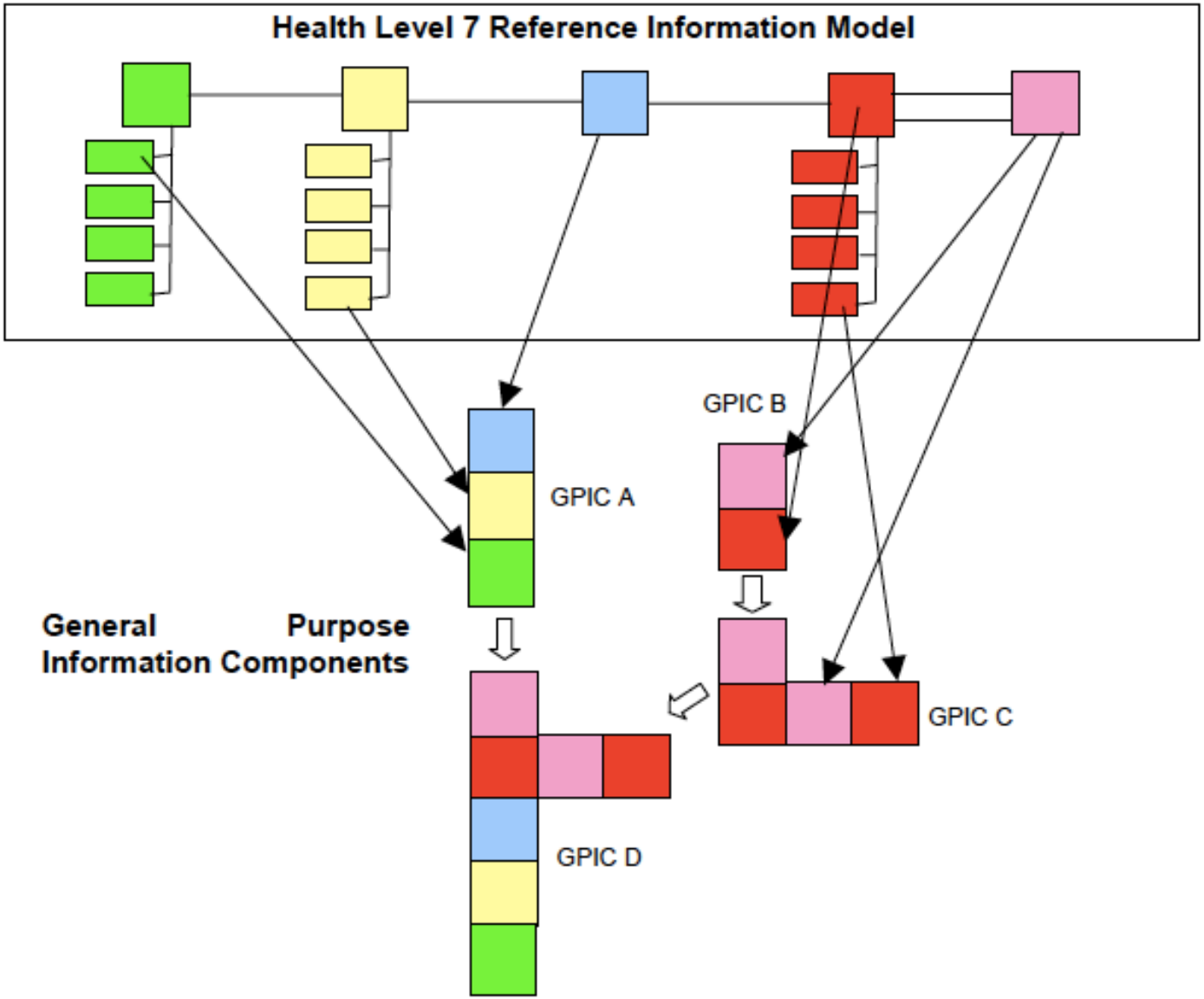
English Version

## Health informatics - General purpose information components - Part 1: Overview

**3.1**
**General Purpose Information Component**
**GPIC**
commonly useful information component that is a specialisation of classes in an international reference information model which is intended to be used in the specification of an information service for health or of a communication between health information systems

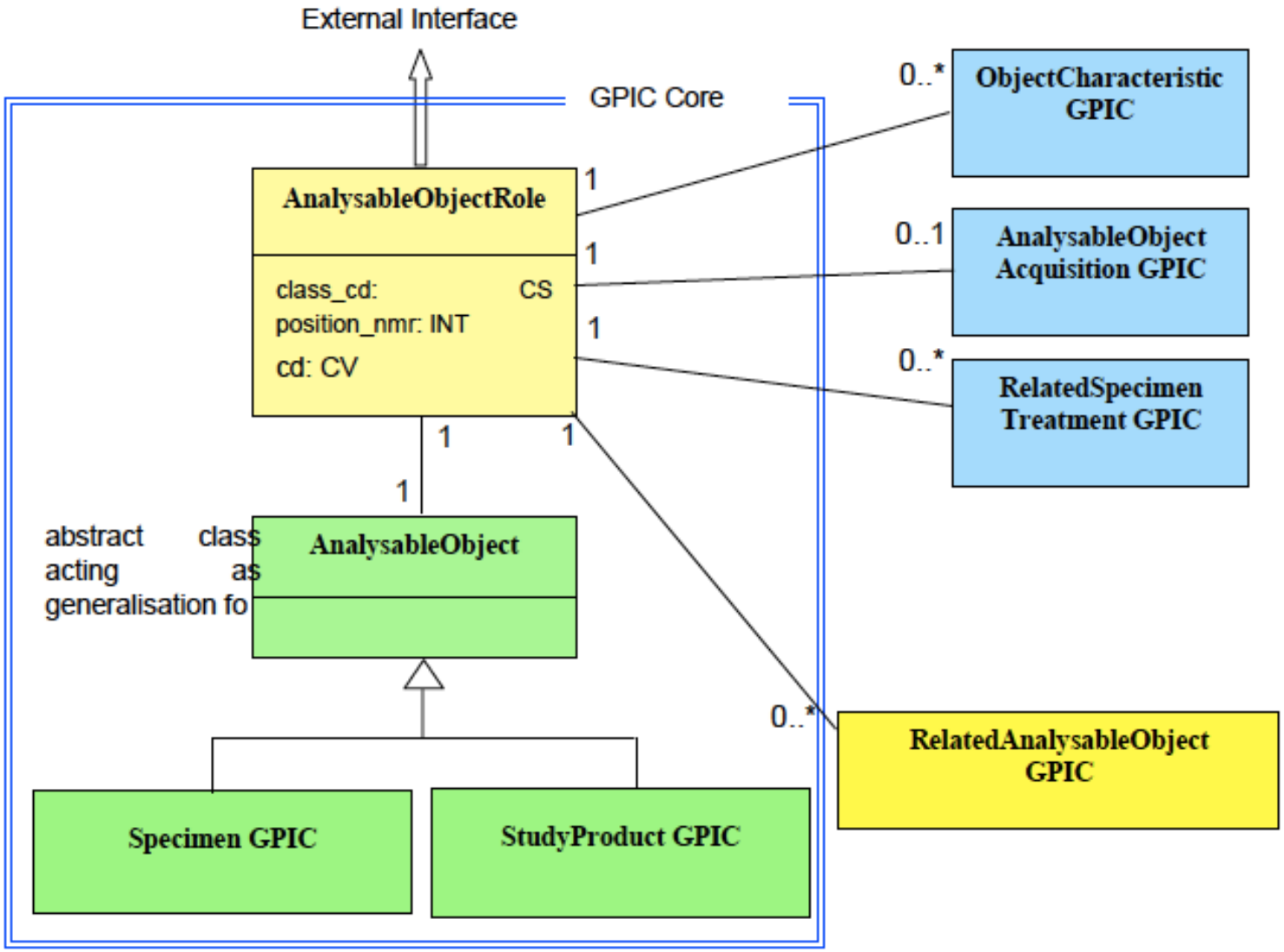
# GPIC AND HL7v3 RIM





# EXAMPLE




External Interface
GPIC Core
AnalysableObjectRole
class_cd: CS
position_nmr: INT
cd: CV
1
1
1
1
1
1
abstract class
acting as
generalisation fo
AnalysableObject
Specimen GPIC
StudyProduct GPIC
0..*
ObjectCharacteristic GPIC
0..1
AnalysableObject Acquisition GPIC
0..*
RelatedSpecimen Treatment GPIC
0..*
RelatedAnalysableObject GPIC

# OpenEHR AND ARCHETYPES



- Each archetype is a computable definition, or specification, for a single, discrete clinical concept.
- It includes all data elements that make clinical sense about that concept and designed for all imaginable clinical situations.
- The definition is kept broad and constraints minimal in order to maximise interoperability by being able to share and re-use the archetype across many types of healthcare and the broadest range of clinical scenarios.
- **Archetype Definition Language (ADL):** ISO standard that specify the definition of archetypes.
- By design, they provide structure and specify content which means that archetypes can be both clinically meaningful AND interpretable by EHR systems.

# ARCHETYPES CONCEPTS

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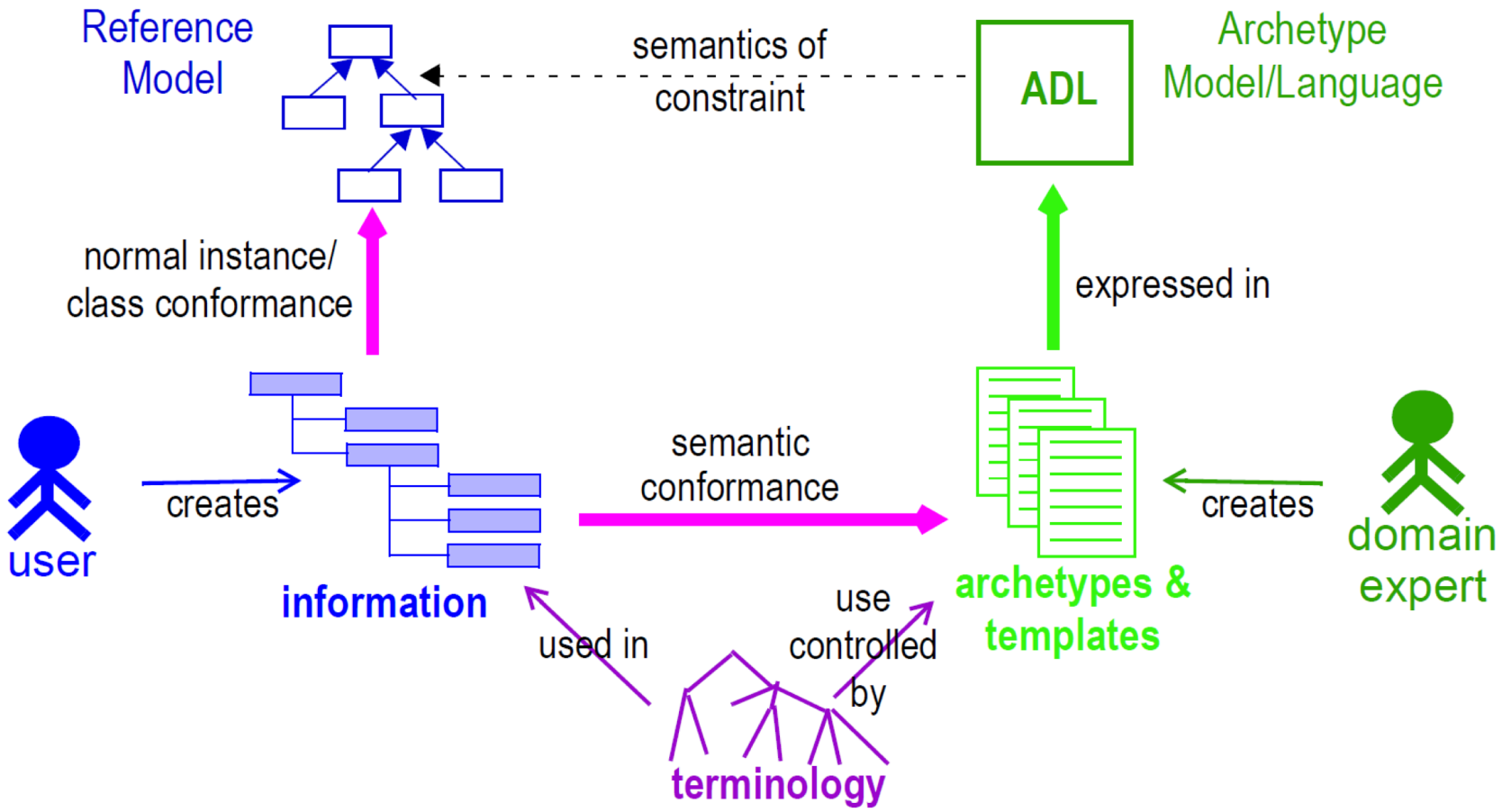


- ”Data" as we know it in normal information systems (blue) conforms in the usual way to an object reference model.
- Runtime data conform semantically to archetypes as well as concretely to the reference model.
- All archetypes are expressed in a generic Archetype Definition Language (ADL).

# ARCHETYPE CLASSES



## COMPOSITION

- Container class: all information stored within the EHR is contained within a Composition.
- Compositions correspond to commonly used clinical documents or events
- Examples: Discharge Summary, Antenatal visit, Operative Notes or Prescription.
- Compositions can contain SECTIONs

## SECTION

- Organising class, usually contained within a COMPOSITION.
- Correspond to the headings that you might find on a blank piece of paper usually with no semantic meaning
- most commonly used to provide a framework in which to place the smaller Entry and Cluster class archetypes which hold most of the detailed clinical content

## ENTRY

- A standalone 'semantic unit' of information.
- The information within an Entry will mean the same thing no matter where it is used
- Examples: Blood pressure - systemic arterial blood pressure; Intravascular pressure - pressure at a point within the vascular system; Weight - the weight of the whole body; ECG measurement; Pulse; Medication order; Diagnosis

## CLUSTER

- Reusable archetypes for use within any ENTRY or other CLUSTER, and are particularly of value where recursiveness is important.

# ARCHETYPE CLASSES

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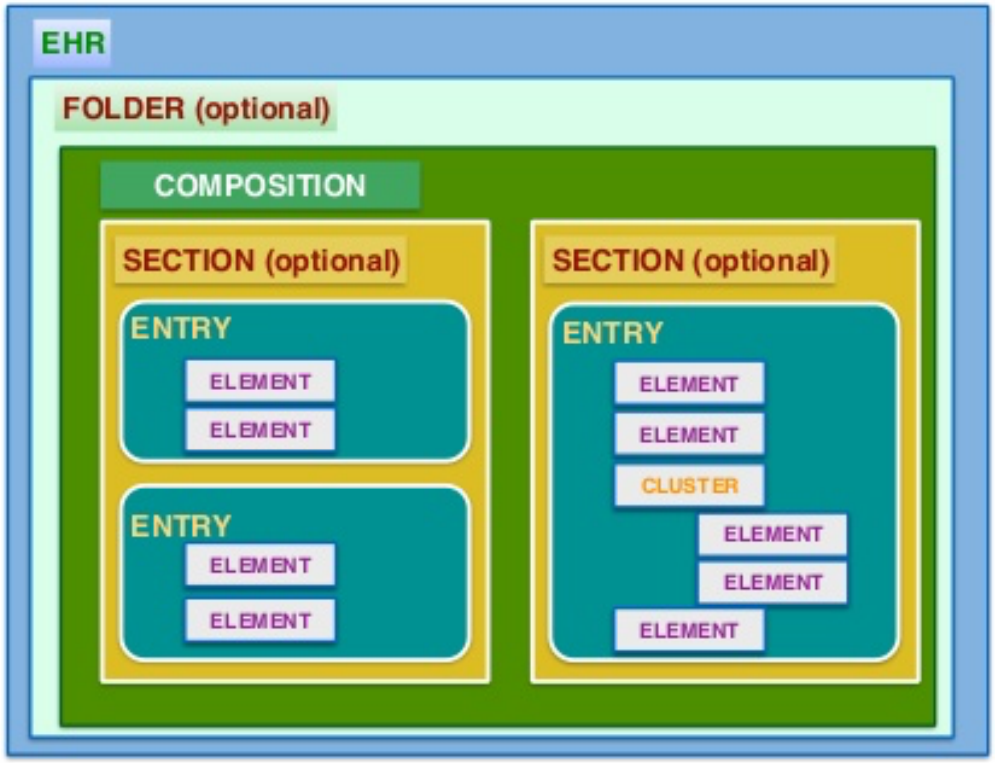
## Generic RM Classes

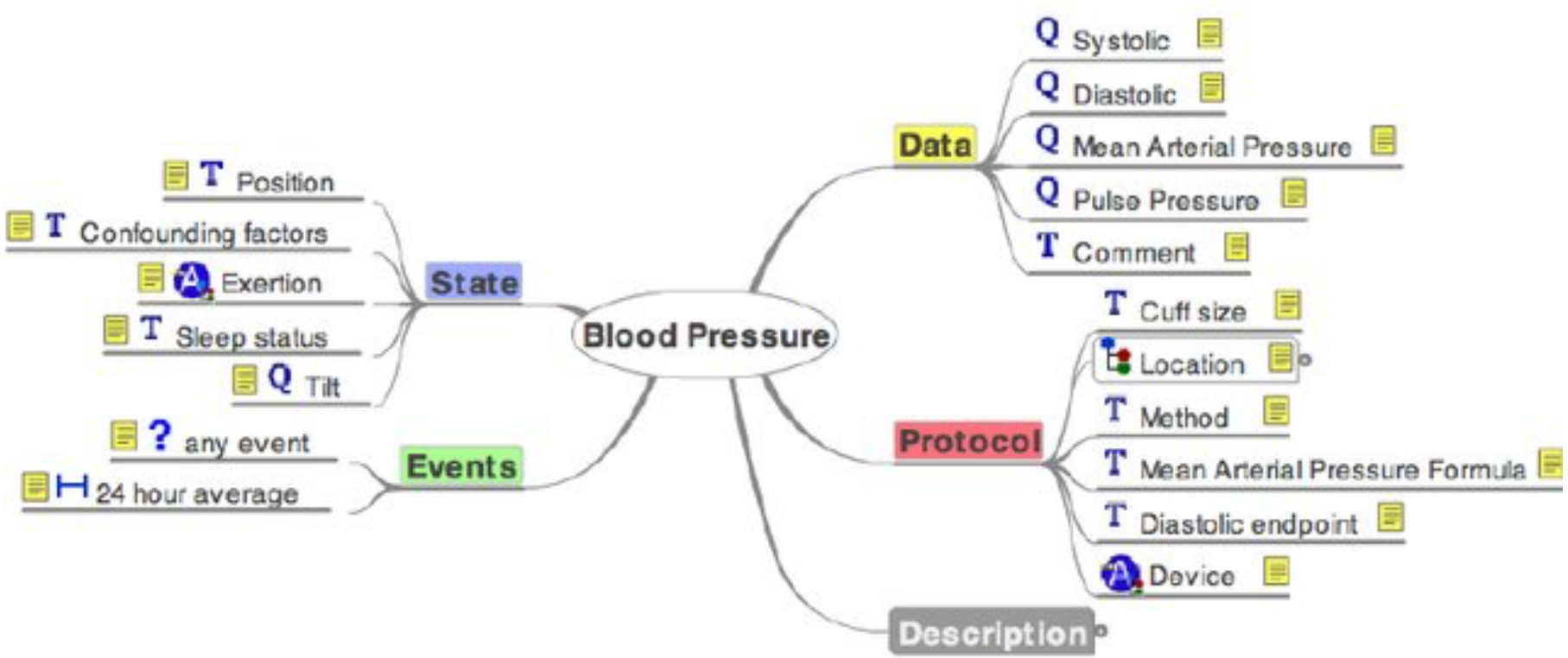



freshEHR
Clinical Informatics

openEHR

# EXAMPLE: ENTRY ARCHETYPE





# ENTRY SUBCLASSES



## OBSERVATION

- Observations are the 'uninterpreted' or raw information - ie the clinical observations or 'the evidence' –
- Includes anything reported by the patient as a symptom, event or concern; examination findings; and measurements/test results.
- used when the information is derived from a direct observation, measurement, or experience of the patient or data subject.
- Observations contain:
  - a DATA part which contains the core information (value of blood pressure)
  - a STATE part which contains information about the subject of data at the time the information was collected (the position of the patient at the time of measuring a blood pressure)
  - a PROTOCOL part which contains information on how the information was gathered or measured
  - a HISTORY part which contains information about the timing of the observation and the 'width' of the information.

## EVALUATION

- used to capture and record clinically interpreted findings, opinions and summary statements.
- They are 'meta-observations' - ideas, labels or views which arise within the clinician's mind, which involve interpretation of observations and formulation into a new form.

## INSTRUCTION

- statements about what should happen in the future - such as clinical orders for care or the initiation of a workflow process, such as a medication order

## ACTION

- statements about what was actually done - they record clinical activities e.g. administration of the medication in the above Instruction

# THE RELATIONSHIP BETWEEN EHR STANDARDS

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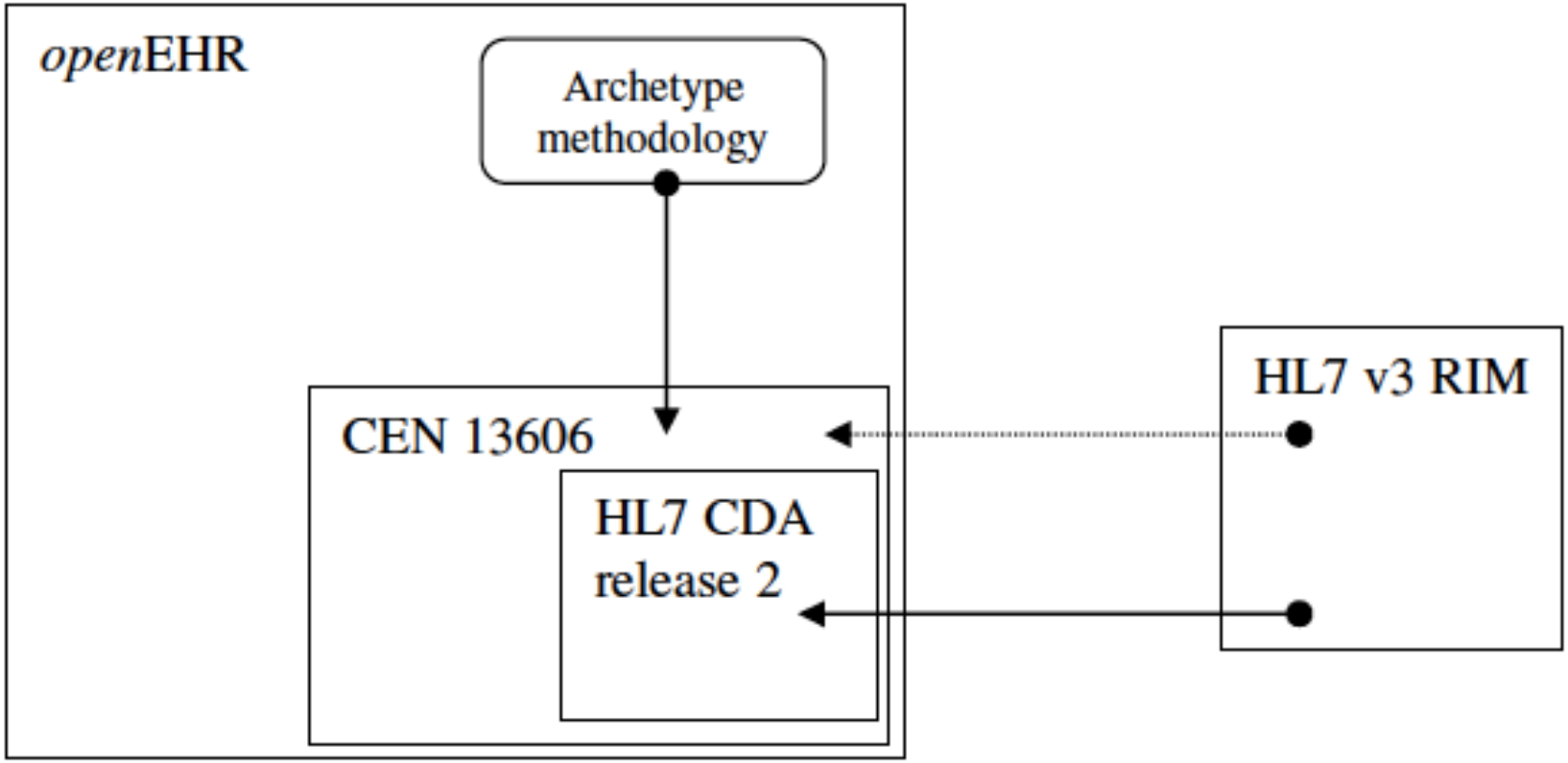


- HL7v2.x messaging is an appropriate standard for transmission of information from source clinical information systems to a Shared-EHR system. HL7 CDA may also be suitable for this purpose at some later stage.
- CEN EN13606 is an appropriate standard for the exchange of Shared EHR Extracts between different nodes of a multimode Shared-EHR system
- openEHR provides the archetype dual-mode methodology that enables this exchange