Advanced Aspects of Hospital Information Systems

EHR- and related Standards

DI Harald Köstinger
(harald.koestinger@inso.tuwien.ac.at)

INSO - Industrial Software
Institut für Rechnergestützte Automation | Fakultät für Informatik | Technische Universität Wien

Agenda

- Defacto industry EHR standards and their architectures/implementations

    - HL7 and its revisions
        - v2.x
        - v3
        - CDA
        - RIM

    - CEN EN-13606

    - openEHR

    - the relationship of those standards

and its versions 2, 3, RIM and CDA

HL7 – HEALTH LEVEL 7

Health Level 7

- the standard is being developed by Health Level Seven International, a **non-profit organization** in the USA

- They are now focusing on **providing a framework** and related standards for:

  - **exchanging, integrating and sharing** EHR information
  - and health services for **management and evaluation** of such information

- Earlier, they focused on **defining messaging standards** and their **interfaces between healthcare enterprises**

- Vision: developing the best and most widely used standard in the world

HL7 – Version 2.x

- formally "Application Protocol for Electronic Data Exchange in Healthcare Environments"

- is the "*most widely used protocol*" for **exchanging messages** between different health care providers and medical systems

- **was not developed systematically** and is therefore lacking of consistency but allows big flexibility

- is **NOT** based on any underlying reference model

  - this leads to **inconsistent implementations**

  - → applications exchanging information have to **rely on additional agreements** in order to ensure interoperability

A. Begoyan. *An overview of interoperability standards for electronic health records*, Integrated Design and Process Technology, June 2007

- **solves most problems** of v2 and comes with new features

- is based on an object-oriented modeling approach resulting in the *v3 Message Development Framework*

- v3 includes an **interoperability specification** defining communications produced and received by different computer systems

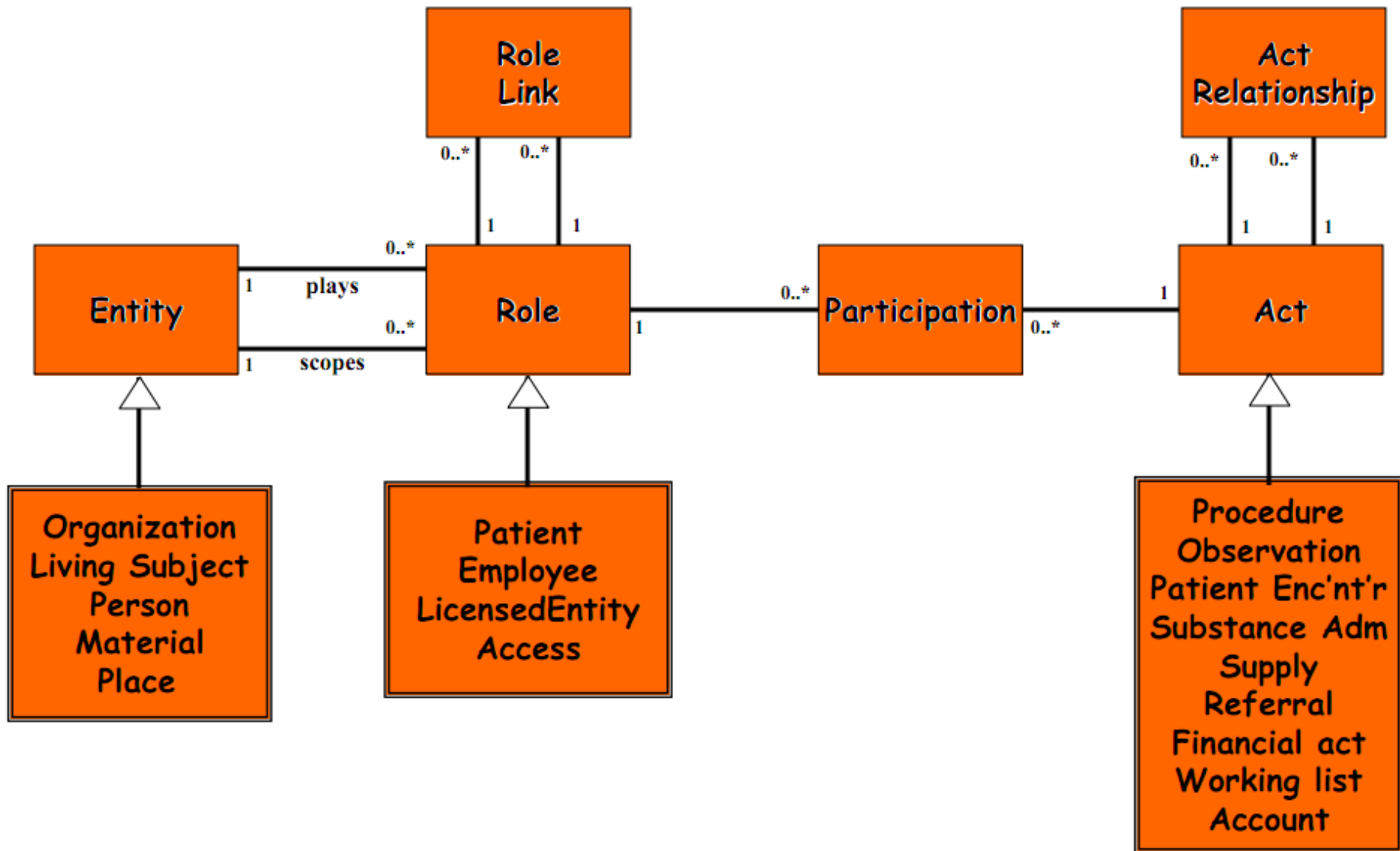- Key feature of v3 is the newly introduced

  Reference Information Model (RIM)

- **it is NOT a full specification of an EHR system!**

George W Beeler. HL7 Version 3 - An object-oriented methodology for collaborative standards development. International Journal of Medical Informatics, 48(1):151–161, February 1998.
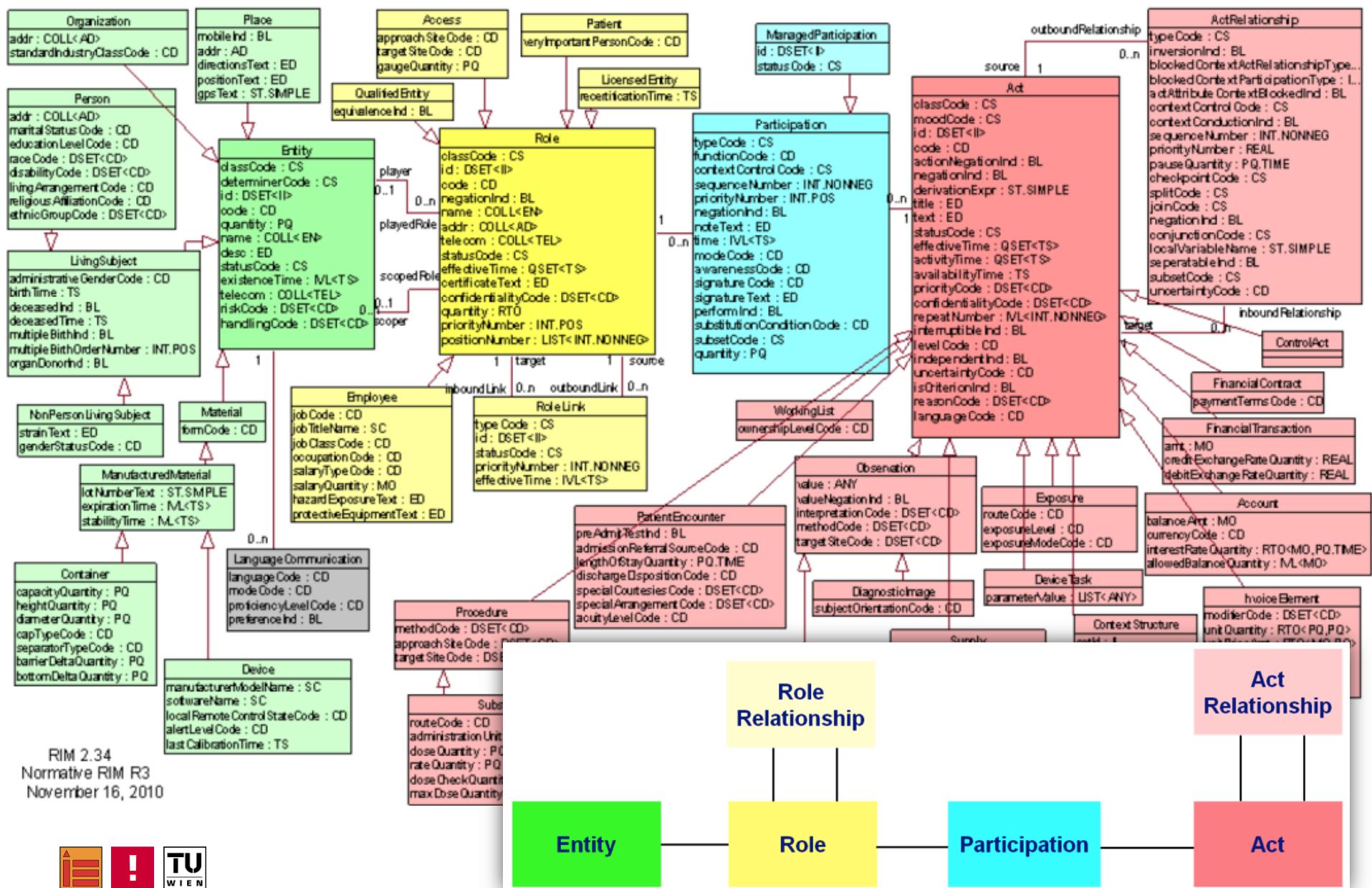
HL7 – Version 3 and v3 RIM (ii)

- the RIM is the **object-oriented core** of the standard represented as classes and attributes, used by messages defined in the standard

- the RIM is a **one model approach**, meaning:

  - it is **defining all classes and their attributes**
    - thus not flexible if classes/attributes change over time

  - and it is **hard to extend the model** itself
    - thus applications are hard to maintain

S. Gaion, S. Mininel, F. Vatta, and W. Ukovich. Design of a domain model for clinical engineering within the HL7 Reference Information Model. Health Care Management (WHCM), 2010 IEEE Workshop, pages 1–6, Feb 2010.

HL7 – Clinical Document Architecture (CDA) (i)

- in contrast to the aforementioned messaging standards, CDA **provides medical documents with structure and semantics**

- it defines **how documents are exchanged** by the use of classes from the RIM thus it ensures interoperability

- by the use of **XML schemas**, a CDA document structures as:

  - a *header*, containing information about the **identity** of the CDA document, **the actual subject of care** and the involved **providers** and some more information

  - a *body*, containing the actual report wrapped in sections

- it defines three compliance levels:

  - *Level 1:*
    simplest one, requires only a **valid document header** and a body containing any clinical data.

  - *Level 2:*
    observations and instructions are defined in the header and it **constrains the structure of the document**. It increases interoperability.

  - *Level 3:*
    completely structured entries and full compliance to the RIM. Validation against the schemas is performed.

- → Advantage: the implementer can choose the "amount" of implementing the standard

Oliver Johannes Bott. "The" Electronic Health Record: Standardization and Implementation. pages 57–60, Berlin, Germany, 2004. 2nd OpenECG Workshop.

HL7 CDA Sample document

```xml
<ClinicalDocument>
  ... CDA Header ...
  <structuredBody>
    <section>
      <text>(a.k.a. "narrative block")</text>
      <observation>...</observation>
      <substanceAdministration>
        <supply>...</supply>
      </substanceAdministration>
      <observation>
        <externalObservation>...
        </externalObservation>
      </observation>
    </section>
    <section>
        <section>...</s
    </section>
  </structuredBody>
</ClinicalDocument>
```

```xml
<section>
  <code code="8716-3" codeSystem="2.16.840.1.113883.6.1"
   codeSystemName="LOINC"/>
  <title>Vital Signs</title>
  <text>Temperature is 36.9 C</text>
  <entry>
    <observation classCode="OBS" moodCode="EVN">
      <code code="386725007" codeSystem="2.16.840.1.113883.6.96"
       codeSystemName="SNOMED CT" displayName="Body temperature"/>
      <statusCode code="completed"/>
      <effectiveTime value="200004071430"/>
      <value xsi:type="PQ" value="36.9" unit="Cel"/>
    </observation>
  </entry>
</section>
```

Robert H Dolin, Liora Alschuler, Sandy Boyer, Calvin Beebe, Fred M Behlen, Paul V Biron, and Amnon Shabo. HL7 Clinical Document Architecture, Release 2. Journal of the American Medical Informatics Association, 13(1):30–39, Jan / Feb 2006.

The European approach

CEN EN-13606

CEN EN-13606 – "One standard to rule them all…"

- first official version published in 1999-2000

- the pre-standard was hard to implement → **2006 release of full standard**

- " … designed to achieve **semantic interoperability** in the electronic health record communication"

- → not a full standard for EHR systems: **specification for EHR extracts only**

> "*The overall goal of this standard 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). This is to support the **interoperability** of systems and components that need to communicate (access, transfer, add or modify) EHR data via electronic messages or as distributed objects:*
>
> • *preserving the **original clinical meaning intended by the author**,*
> • *reflecting the **confidentiality** of that data as intended by the author and patient.*"

CEN EN-13606: Dual Model Architecture

- defines a separation between **information** on the one hand and **knowledge** on the other hand

  - *Information*: the actual information about a certain case which is stored in basic entities build and structured through the **Reference Model (RM)**

  - *Knowledge*: based on so called **archetypes**, knowledge is the formal representation of the clinical concepts. e.g. a glucose measurement, a family history, etc.. Archetypes are built by the formal and structured valid and constrained combinations of entities of the RM using the **Archetype Model (AM)**. (somehow a semantic meaning for the RM)

(more on this at the openEHR standard)

CEN EN-13606: Parts of the standard

- Part 1: Reference Model:
  Scalable generic information model used to communicate the actual health information of any patient. (generic building blocks for EHRs)

- Part 2: Archetypes Interchange Specification:
  Definitions of archetypes and their language. Definitions for constraints and legal combinations of RM objects.

- Part 3: Reference Archetypes and Term Lists:
  Basic set of standard archetypes and terms. Data objects for describing rules for distributing EHRs.

- Part 4: Security:
  Suitable interaction with **security components**, data safety, …

- Part 5: Messages for Exchange / Exchange Models:
  basics for the **message based communication** (under development)

CEN EN-13606: EHR Extract Record Hierarchy

- mostly **reflects the structure** and organization of files and medical records **in the original documents**

- sub-elements may have simple or complex inner structure
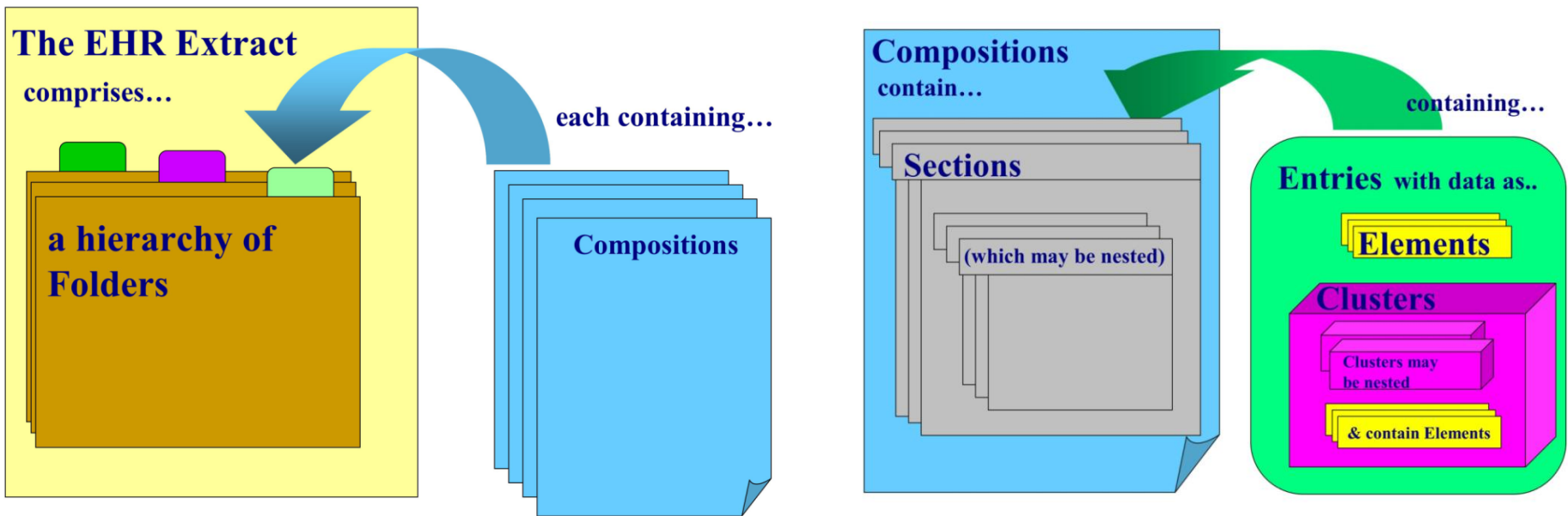
And now: the openEHR Foundation

OPENEHR

openEHR: The Beginnings

- is being developed by

  - the **openEHR Foundation**: independent, non-profit organization and community founded in 2000 by OceanInformatics

  - and the **University College London (UCL)**

- **"the most complete and validated EHR architecture worldwide"**

- Aims:
  "an **open**, **interoperable** health computing platform, of which a major component is a **clinically effective and interoperable** electronic health care record (EHR)"

D. Kalra. Electronic Health Record Standards. In IMIA Yearbook of Medical Informatics, pages 136–144. IMIA and Schattauer GmbH, 2006.

openEHR: Requirements (i)

- recording *clinical information*, workflow-based instructions, imaging data, diagnoses and many more

- **archetype- and template-enabling** of all clinical systems, allowing professionals to actually define and model clinical content, the semantics and user-interfaces → two model approach

- supporting **terminology systems to integrate**, such as the *Systematized Nomenclature of Medicine – Clinical Terms (SNOMED-CT), International Classification of Diseases (ICD), Logical Observation Identifiers Names and Codes (LOINC)*

P. Schloeffel, S. Heard, D. Kalra, D. Lloyd, and T. Beale. OpenEHR – Introducing openEHR, 2006.

- allowing the systems to be able to **communicate via messaging systems** such as **HL7v2** or Electronic Data Interchange For Administration, Commerce and Transport (**EDIFACT**) → interoperability!

- making it easier to **integrate** with an existing Hospital Information System (HIS) → open and defined interfaces

- providing an **Application Programming Interface (API)**

- allowing of **distributed versioning** of EHR data

P. Schloeffel, S. Heard, D. Kalra, D. Lloyd, and T. Beale. OpenEHR – Introducing openEHR, 2006.

openEHR: The Approach

- same as for the EN-13606, openEHR uses **a two-model approach,** the "two level methodology"

  (in fact, the CEN EN-13606 is a **complete subset** of the openEHR standard)
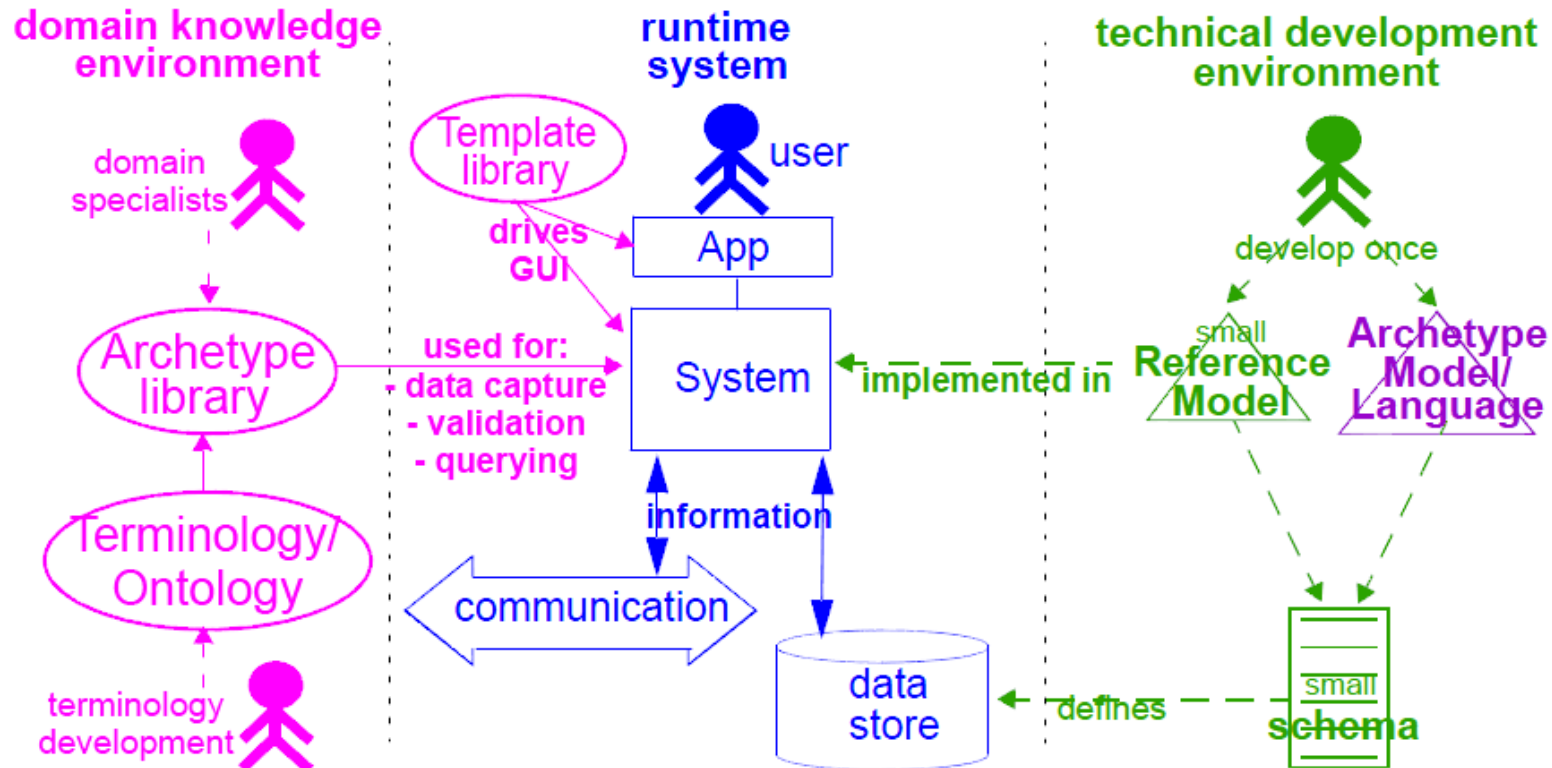
Based on the RM in the middle, openEHR is built upon archetypes constructed using the **Archetype Model (AM).** Integration with other systems is done within the **Service Model (SM).**
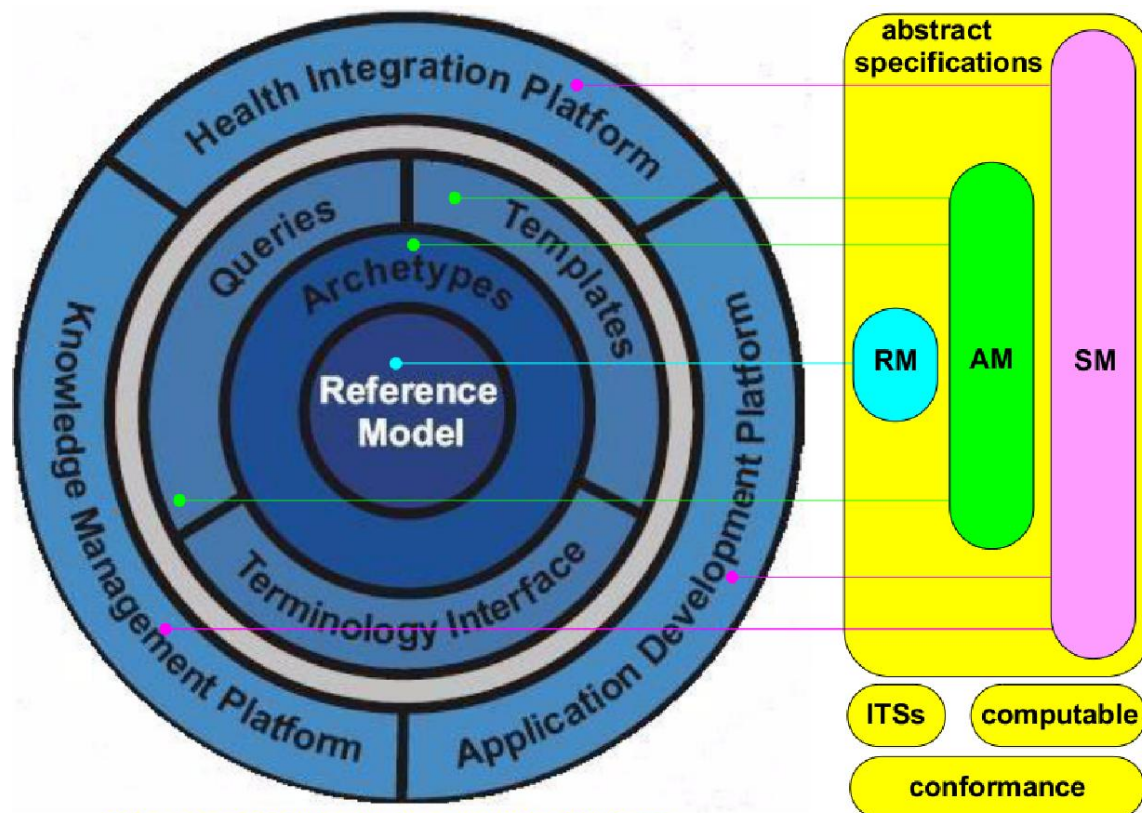
The openEHR Health Computing Platform

Relation of Archetypes and Templates
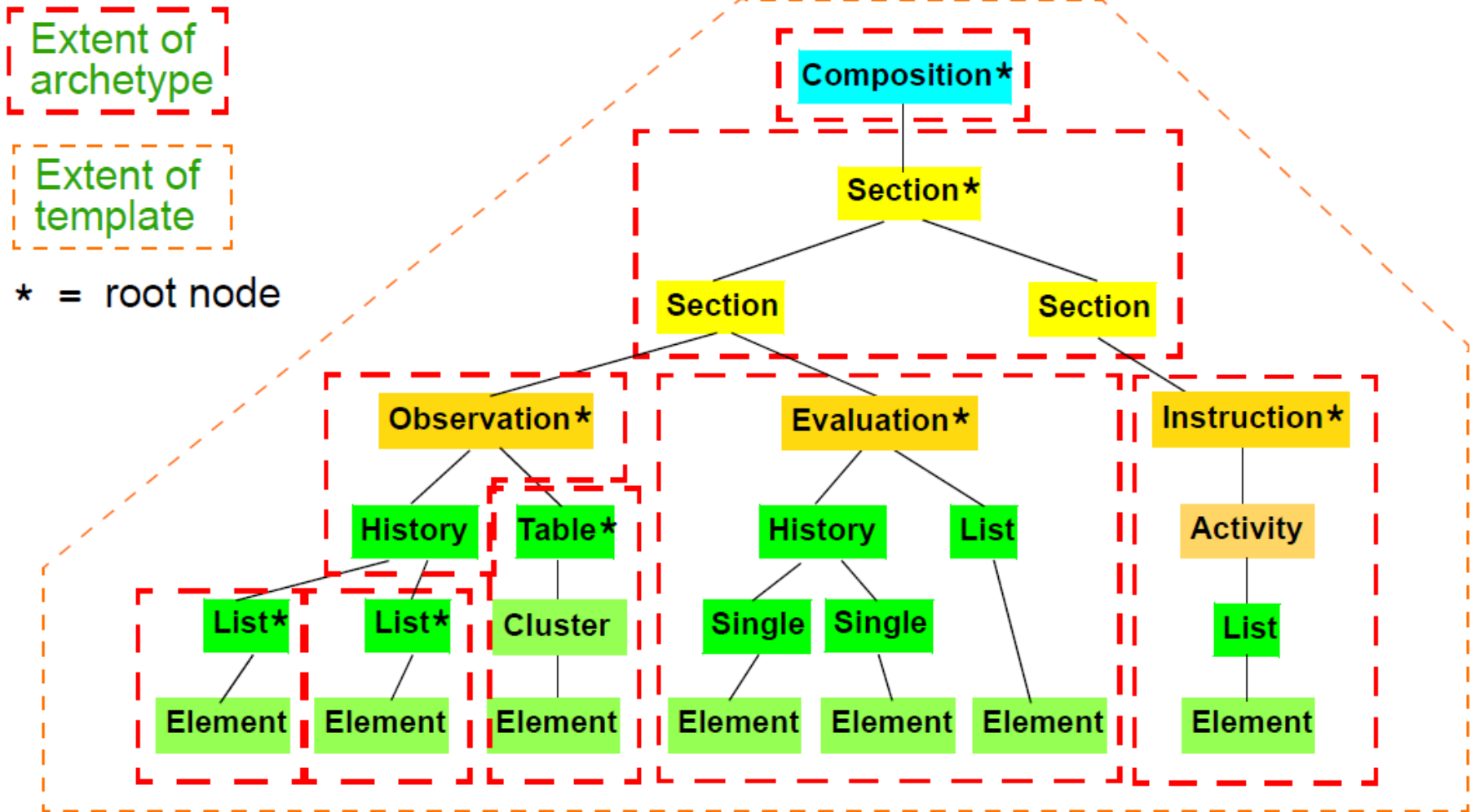
- by the use of the RM one can build instances for information

- the AM provides semantics and constraints for the RM

- the AM enables to build instances of archetypes
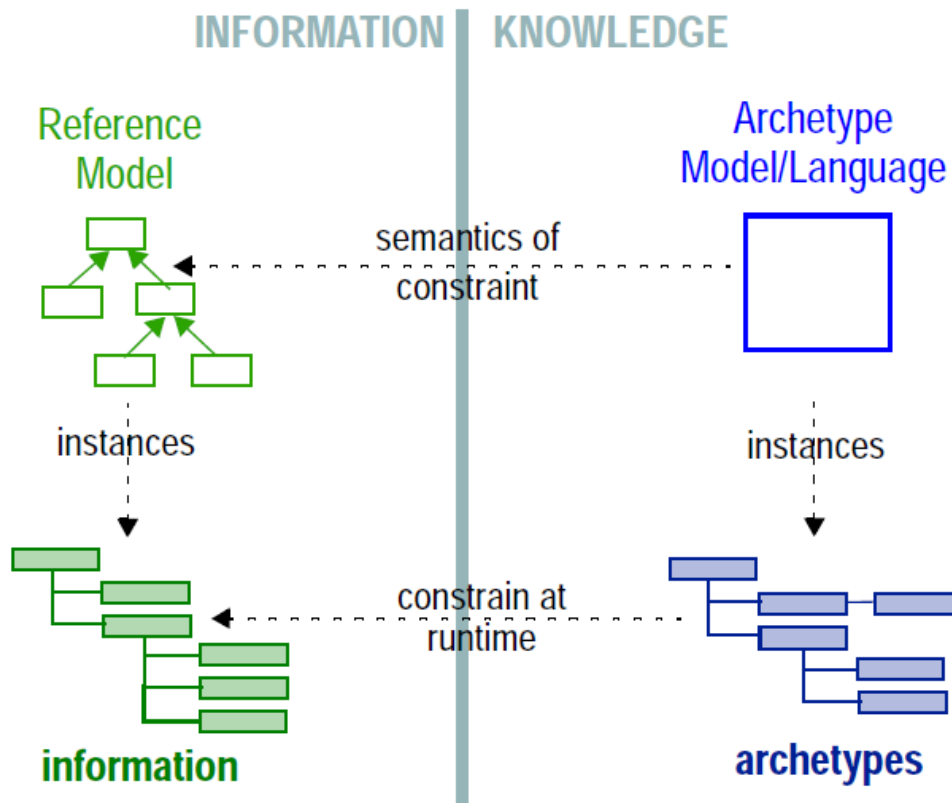
- Center piece of the openEHR design is the **EHR** class itself, having assigned a unique EHR_ID

- openEHR as well uses **Compositions** to store the actual information

- other classes are stored to enable **security**, **versioning** and **workflow information** as well as a **hierarchical arrangement** of information
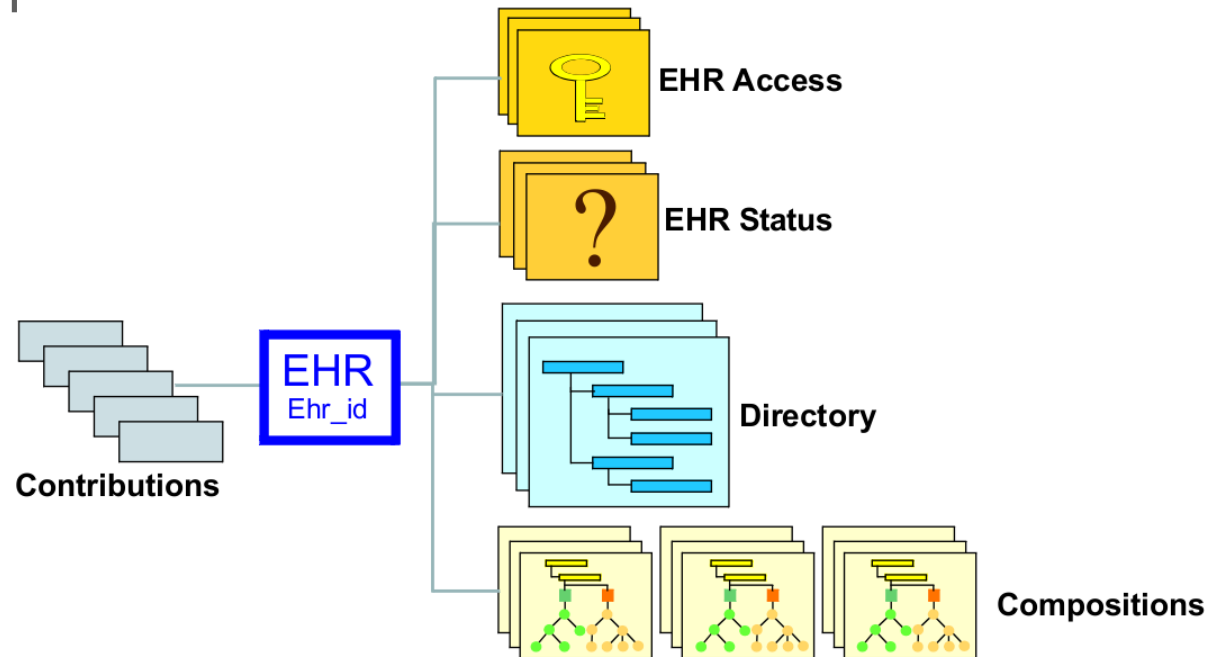
- information in openEHR is **ALWAYS versioned**!

- **Compositions** consist of sections which contain the actual information in form of

  - **Actions**
  - **Evaluations**
  - **Observations**
  - **Instructions**
  - and **Admin** entries

- they then store the inner structure and the single data items using the openEHR data types
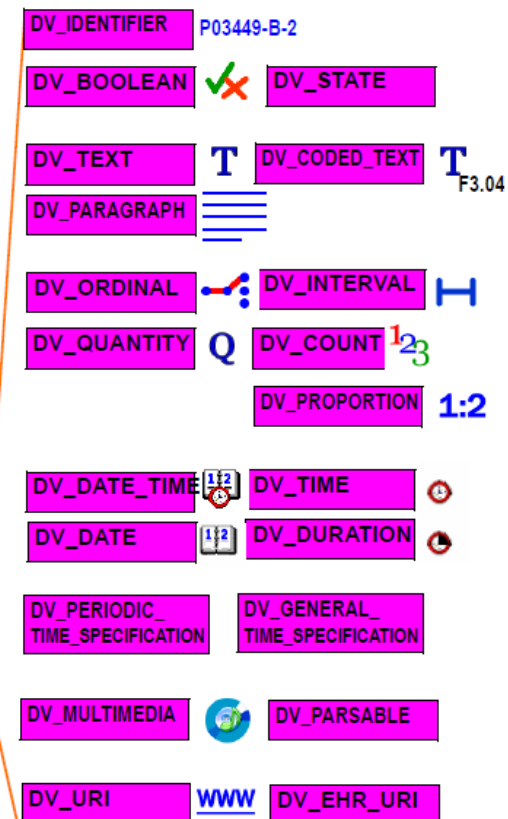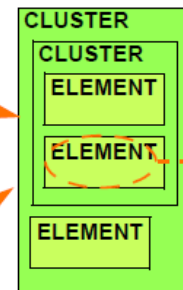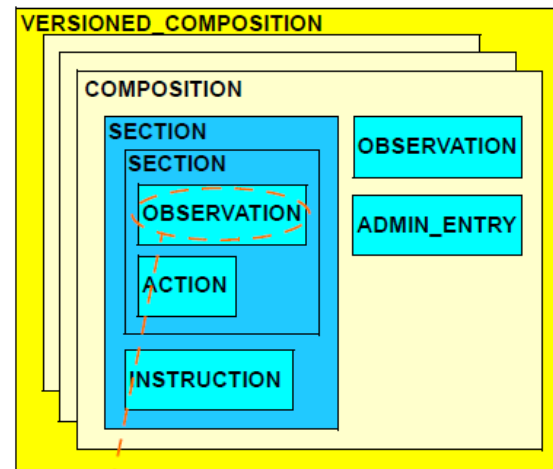
openEHR Data Types

- content is versioned throughout the whole life-time of a record!

- it is an integral part of the architecture

- one of the most important features of EHRs in the field of medical information documentation!
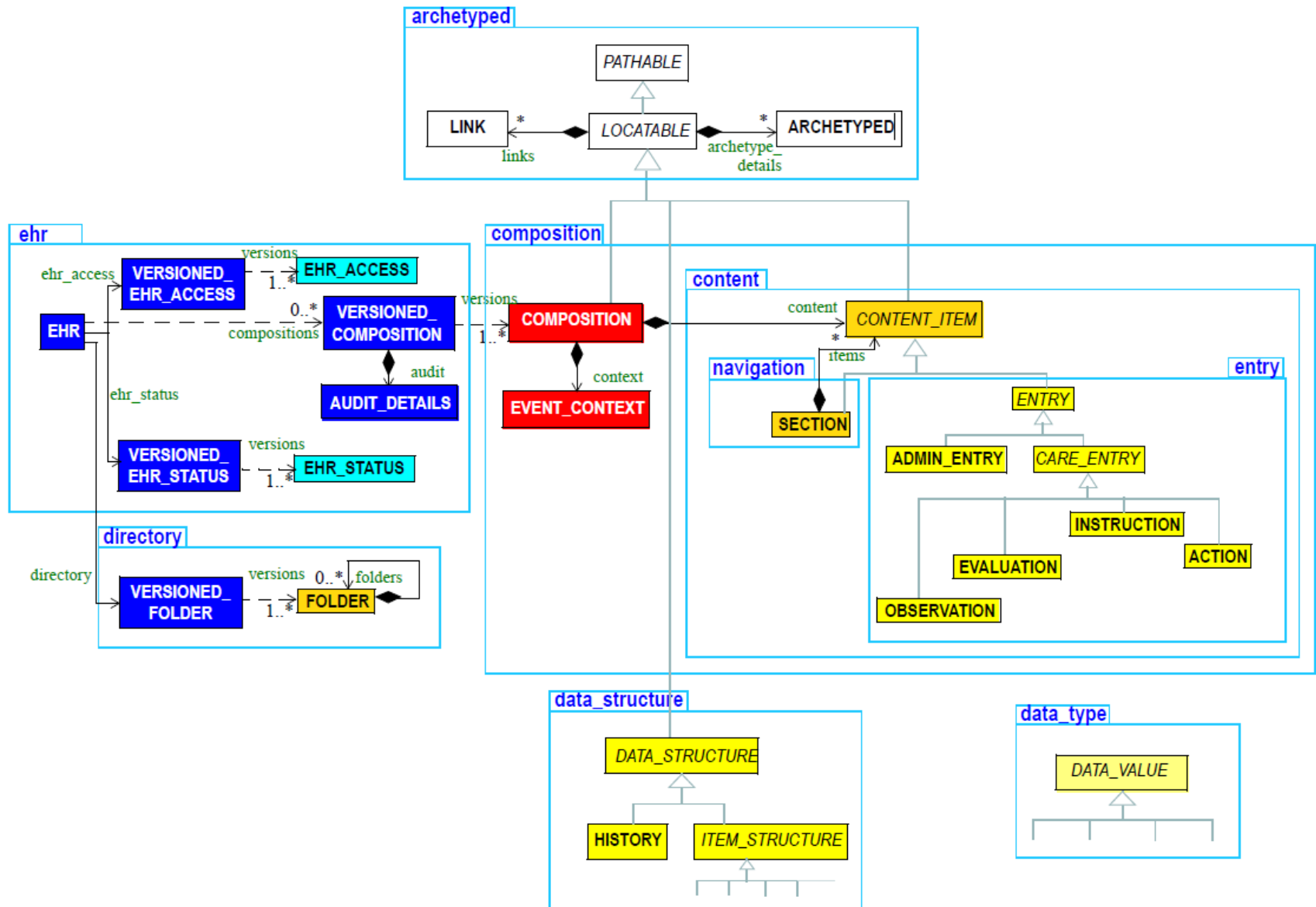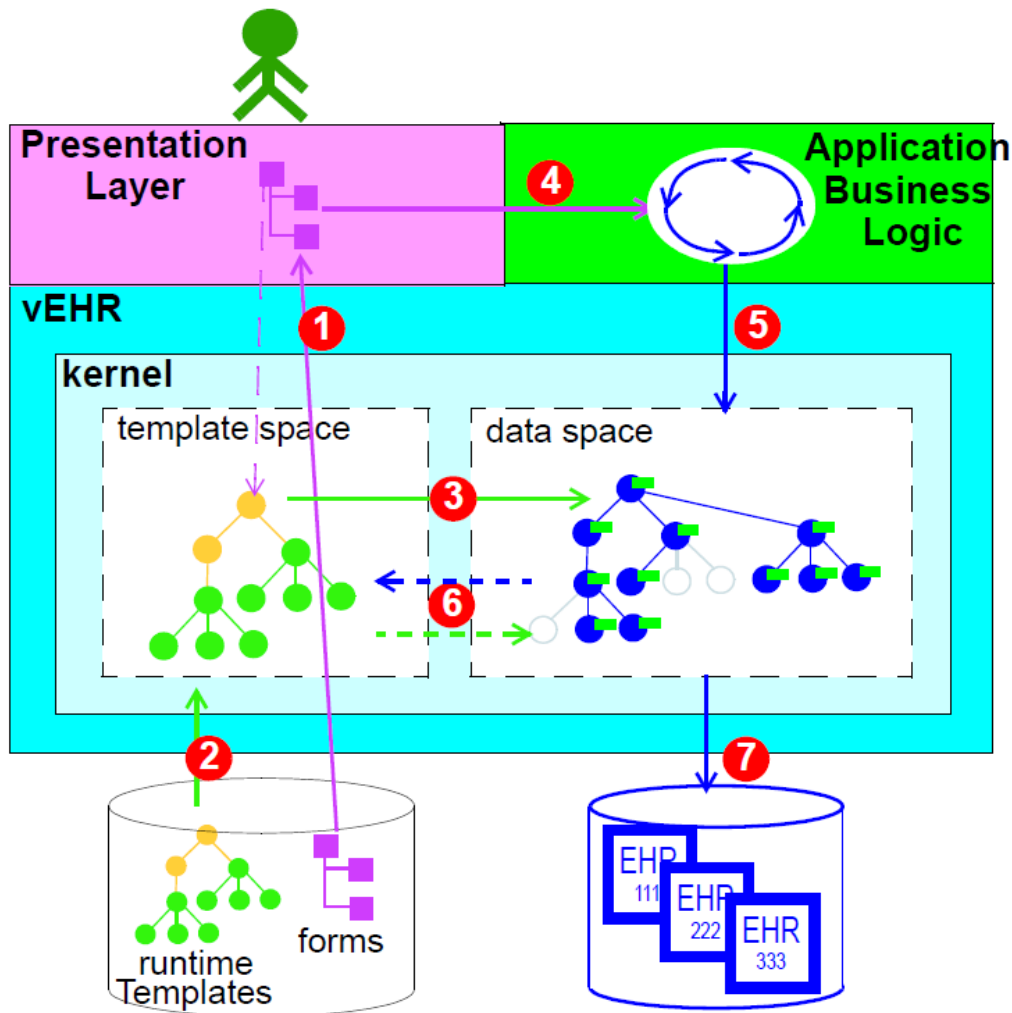

Versions
(VERSION class)

Version container
(VERSIONED_OBJECT class)

audit trail

a single Version

top-level content structure
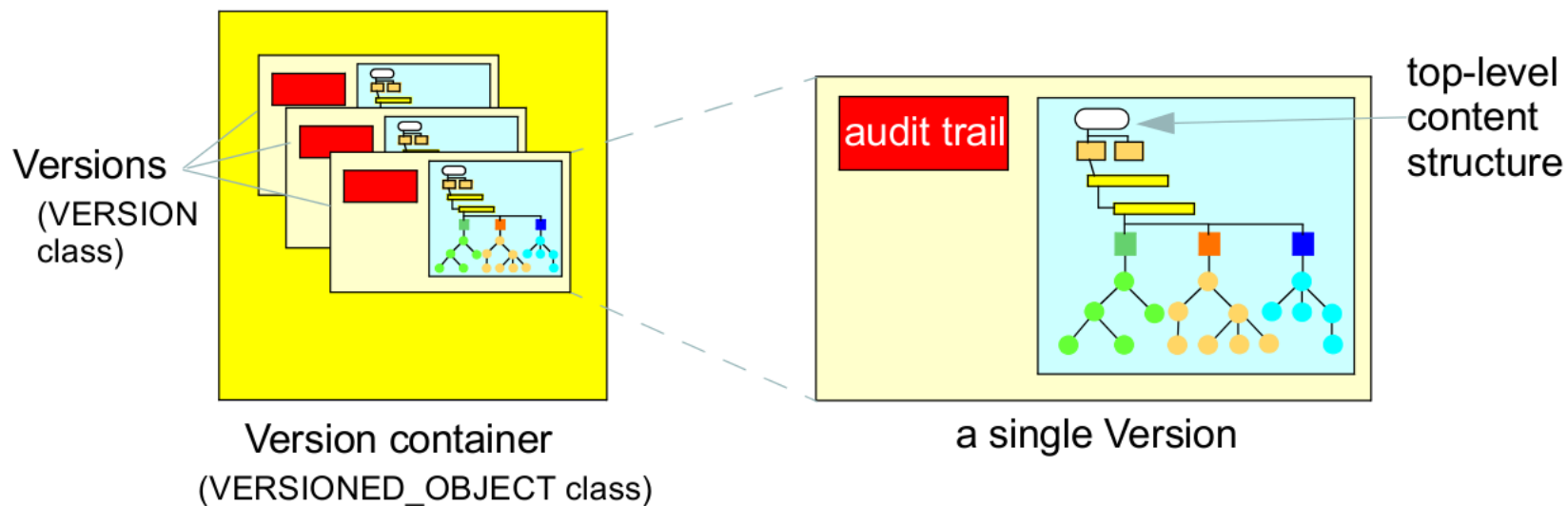
The openEHR Information Model (IM)

FIGURE 2 openEHR EHR Information Model Overview

FIGURE 33 Templated Archetypes at Runtime

Demonstration

- the Clinical Knowledge Manager
  http://www.openehr.org/knowledge/

  - Entry – Observation Archetype: Blood Pressure

    - what is and how does ADL look like?
    - how is an archetype defined?

  - Templates: Compositions

    - how does a template include archetypes?
    - how are constraints defined on archetypes?

The Relationships of Standards

- openEHR is the most influencing standard

- with the introduced archetype methodology, CEN and openEHR build upon a flexible two-level approach

- EHR extracts of CEN and openEHR can be transformed into CDA documents

- information being present as HL7 v3 RIM can be transformed into CEN and CDA data, but not vice-versa
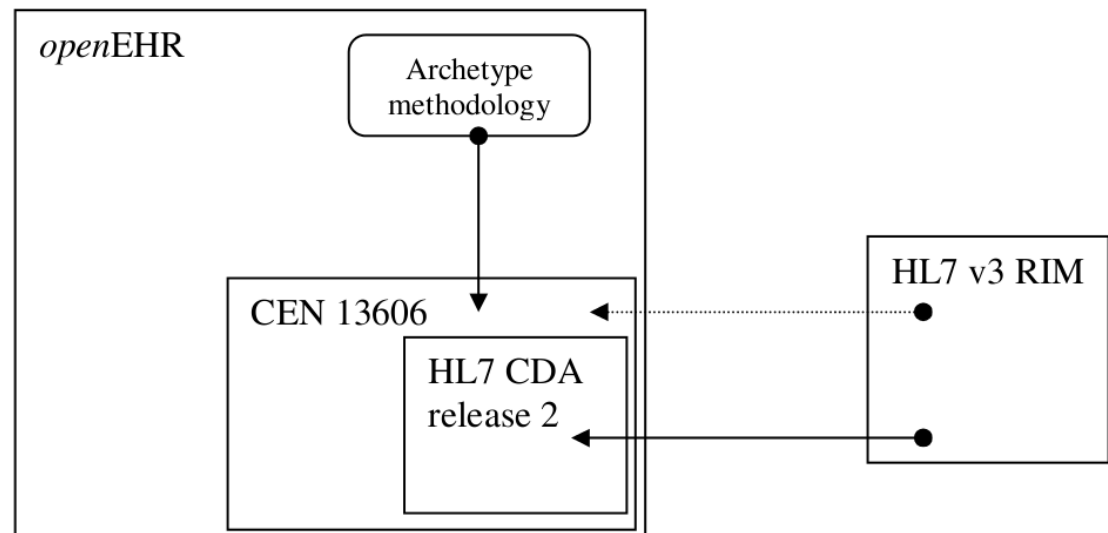
Sources and References

- HL7 and related:

    - http://www.hl7.org/ (10/2011)

    - http://www.hl7standards.com/, http://hl7book.net

- CEN EN-13606 (standard is available in the TU Library network for free)

    - http://www.cen.eu, http://www.en13606.org/ (10/2011)

- openEHR: all figures about it and cites (all specifications are available online for free)

    - http://www.openehr.org (10/2011)