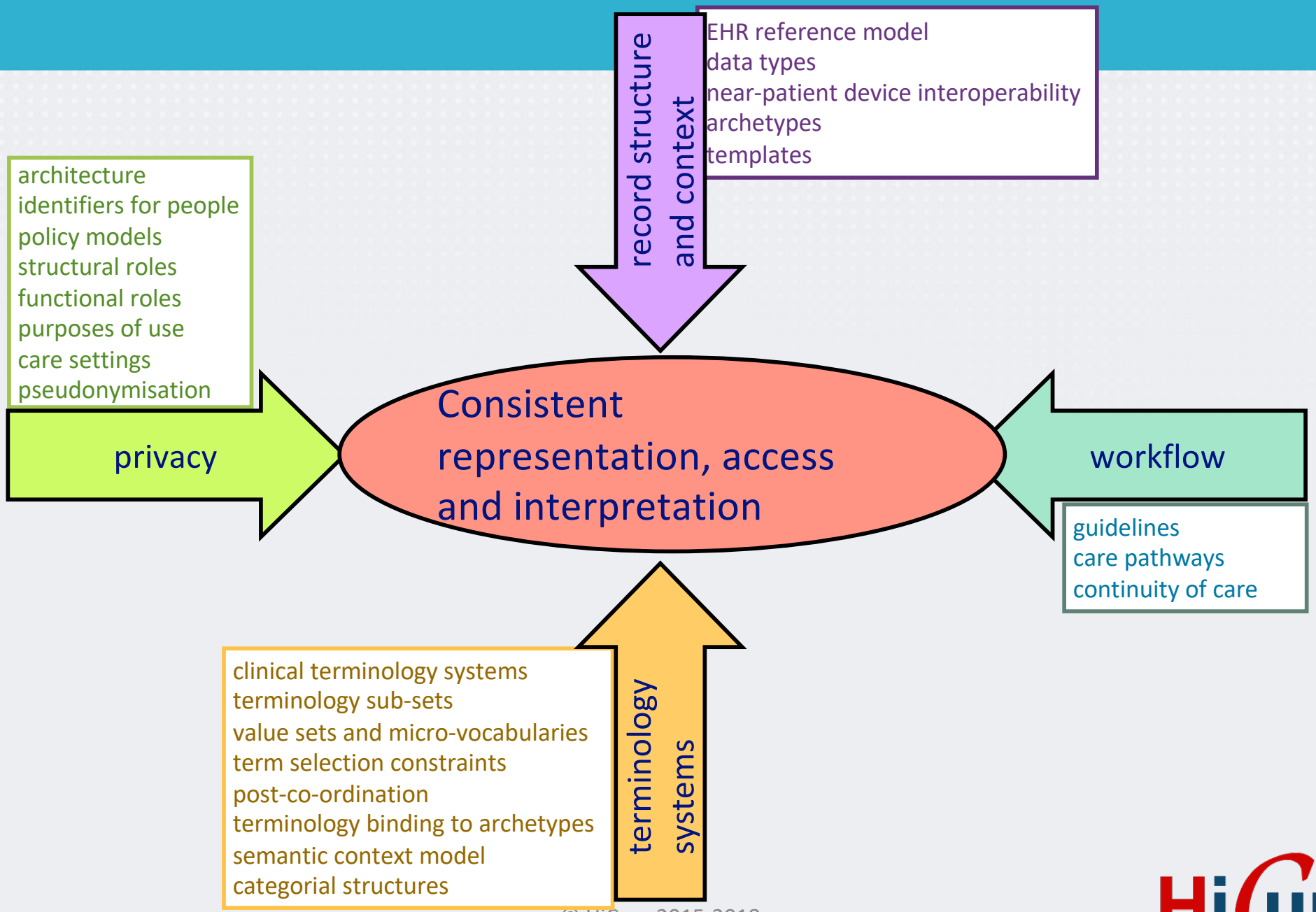
Clinical Information and Processes



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Standards relevant to the EHR

Business requirements	**ISO 18308 EHR Architecture Requirements** HL7 EHR Functional Model ISO EN 13940 Systems for Continuity of Care ISO EN 12967-1 HISA Enterprise Viewpoint
Information models	**EHR system reference model *open*EHR** **EHR interoperability Reference Model ISO/EN 13606-1** **HL7 Clinical Message Interoperability** **HL7 Clinical Document Architecture (CDA)** **Clinical content model representation *open*EHR ISO/EN 13606-2 archetypes** ISO 21090 Healthcare Datatypes ISO EN 12967-2 HISA Information Viewpoint
Computational services	EHR Communication Interface Specification ISO/EN 13606-5 ISO EN 12967-3 HISA Computational Viewpoint HL7 SOA Retrieve, Locate, and Update Service DSTU
Security	EHR Communication Security ISO/EN 13606-4 ISO 22600 Privilege Management and Access Control ISO 14265 Classification of Purposes of Use of Personal Health Information
Clinical knowledge	Terminologies: SNOMED CT, etc. Clinical data structures: Archetypes etc.

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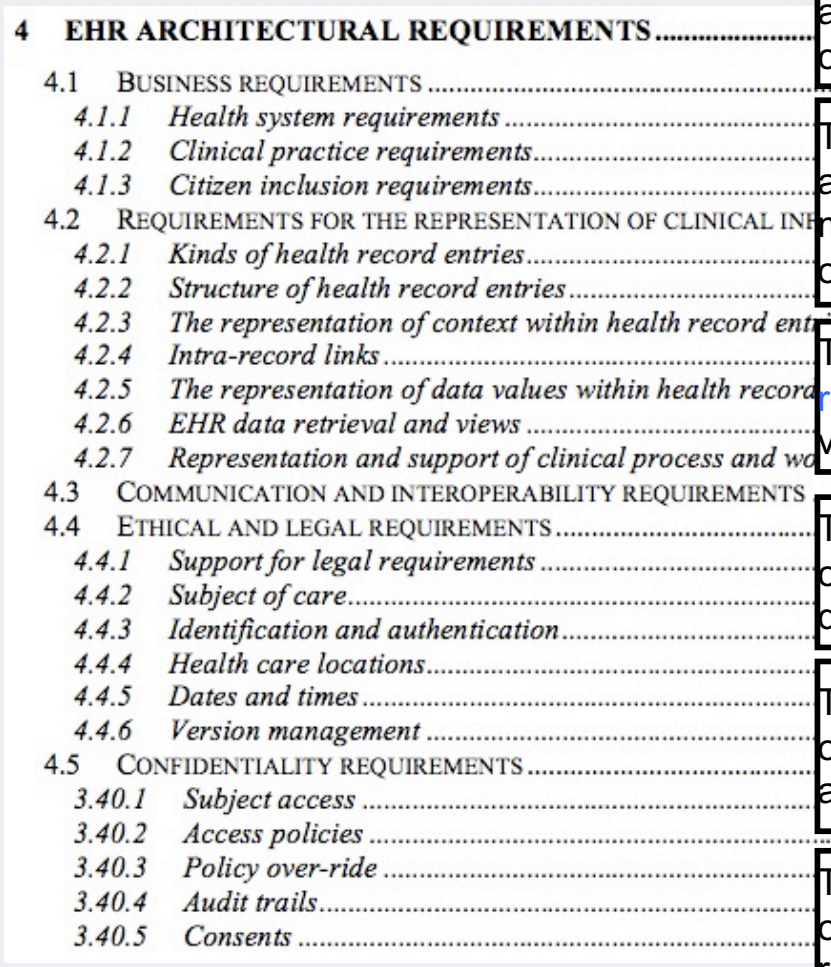
Requirements the EHR must meet: ISO 18308



4 EHR ARCHITECTURAL REQUIREMENTS .....
- 4.1 BUSINESS REQUIREMENTS .....
  - 4.1.1 *Health system requirements* .....
  - 4.1.2 *Clinical practice requirements* .....
  - 4.1.3 *Citizen inclusion requirements* .....
- 4.2 REQUIREMENTS FOR THE REPRESENTATION OF CLINICAL IN
  - 4.2.1 *Kinds of health record entries* .....
  - 4.2.2 *Structure of health record entries* .....
  - 4.2.3 *The representation of context within health record ent*
  - 4.2.4 *Intra-record links* .....
  - 4.2.5 *The representation of data values within health record*
  - 4.2.6 *EHR data retrieval and views* .....
  - 4.2.7 *Representation and support of clinical process and wo*
- 4.3 COMMUNICATION AND INTEROPERABILITY REQUIREMENTS
- 4.4 ETHICAL AND LEGAL REQUIREMENTS .....
  - 4.4.1 *Support for legal requirements* .....
  - 4.4.2 *Subject of care* .....
  - 4.4.3 *Identification and authentication* .....
  - 4.4.4 *Health care locations* .....
  - 4.4.5 *Dates and times* .....
  - 4.4.6 *Version management* .....
- 4.5 CONFIDENTIALITY REQUIREMENTS .....
  - 3.40.1 *Subject access* .....
  - 3.40.2 *Access policies* .....
  - 3.40.3 *Policy over-ride* .....
  - 3.40.4 *Audit trails* .....
  - 3.40.5 *Consents* .....

The EHR shall preserve any explicitly defined relationships between different parts of the record, such as links between treatments and subsequent complications and outcomes.

The EHR shall preserve the original data values within an EHR entry including code systems and measurement units used at the time the data were originally committed to an EHR system.

The EHR shall be able to include the values of reference ranges used to interpret particular data values.

The EHR shall be able to represent or reference the calculations, and/or formula(e) by which data have been derived.

The EHR architecture shall enable the retrieval of part or all of the information in the EHR that was present at any particular historic date and time.

The EHR shall enable the maintenance of an audit trail of the creation of, amendment of, and access to health record entries.

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EHR Standards

ISO EN 13606

CEN 13606: standardisation of EHR functions

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CEN 13606: EHR standard

- CEN 13606
  - Electronic Health Record **international** & **European Standard**
  - Defines **information architecture** for communicating Electronic Health Record (EHR) of a single subject of care (patient). Standardisation of health **contents**
  - Established by CEN as a reference model, as a set of unified Modelling Language (UML) diagrams.
  - The outcome is a **hierarchical model** (a set of classes)
    - Which reflect the **hierarchical** nature of **real heath records**.

- CEN 13606 ➔ **Formal standardisation** of *Open*EHR initiative

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CEN 13606 EHR standard

- **Five** part EHR communication standard:
  - CEN 13606 Part 1 - The **Reference model (Information model)**-a scalable model for representing health information)
  - CEN 13606 Part 2 - **Archetype interchange**
  - CEN 13606 Part 3 - **Reference archetypes** and term lists
  - CEN 13606 Part 4 - **Security** (for specifying the privileges necessary to access the EHR data)
  - CEN 13606 Part 5 - **Exchange models** (to describe the messaging model to enable the exchange of EHR data)

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CEN 13606 EHR standard

- ***CEN 13606-1***
  - **Reference model (or information reference model)** supports the exchange of EHR information
  - CEN 13606 represents EHR data as a set of unified Modelling Language **(UML) diagrams**.
  - **Reference model diagrams** is composed of a number of classes which build on each other to provide the representation of an **EHR data:**
    - **EHR Extract Class:** specifies what health data extract and for who
    - **Recorded Components class:** includes the structure of the extracted health data as a hierarchy.
  - Output ➔ **hierarchical models** that reflect the hierarchical nature of real EHR data

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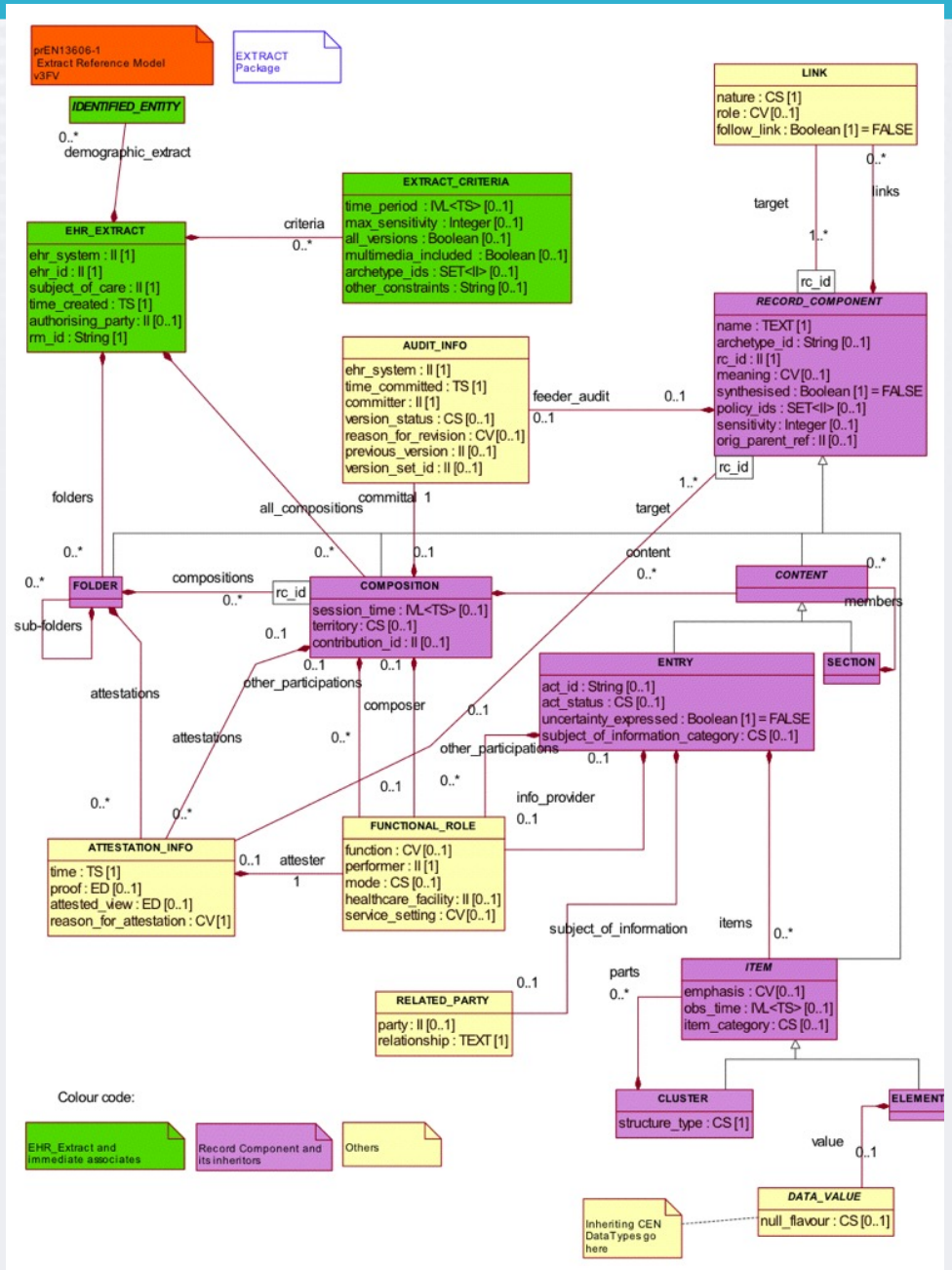
ISO EN 13606-1 Reference Model



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CEN 13606 EHR standard

- **EHR Extract class**
  - Identifies who the **data extract** is about
  - Which EHR system the extract has been extracted from
  - Demographics and access control policies
- **Recorded component**
  - This is a super class of other classes.
  - These record component classes build from *a simple element to more and more complex* structures
  - These classes include:
    - **Element** → a single value
    - **Item** → a single element, a list of elements, a cluster or a list of clusters. Item therefore allows the representation of a wide range of data structures.

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CEN 13606 EHR standard

- **Recorded component**:
  - These classes include:
    - **Entry** → items recorded for a single recording in the EHR (e.g. a single observation)
    - **Section** → entries grouped together
    - **Composition** → set of record components authored during a users clinical sessions and stored in the EHR (e.g. a progress note)
    - **Folders** → allows grouping of the record. Folders can include other folders, compositions or used to organize (selected subset) of the EHR extract.
    - Other classes such as audit, record linkages, access policy and message

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