

COMP3342: Health Systems Interoperability and Integration

Electronic Health Records and Related Standards

Time: **Monday+ Wednesday: 14:00-15:20**

Location: **Masri304**

Section: **1**

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Excellence in Health Informatics Integrated Curricula

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Medical Terminologies: Coding Standards

Learning Objectives:

1. Understand healthcare environment elements, clinical care processes and workflows,
2. Understand EHRs objectives, EHR requirements and the difference between different EHR standards
3. Understand EHRs structural/framework standards.
4. Identify and understand the purpose EHR related standards and their purpose:
 1. CEN 13940
 2. openEHR and CEN 13606

RECALL: Types of Health Standards

1. Medical terminology/vocabulary or coding standards

- Define standard code-sets for generally used concepts, terms, entity names, disease names, procedures, laboratory tests, observations, clinical findings, body structure names, etc.
- e.g. ICD9/10, SNOMED-CT etc.

2. Electronic Health record or Data–model standards

- Define system modules and module structures, the interfaces between modules, and operations/processes
- **openEHR/CEN 13606**, etc.

3. Health data exchange or messaging standards

- Provide a comprehensive framework for **exchange, integration, sharing, and retrieval** of electronic health information
- E.g. **HL7 v2.x/v3.0**, ISO/HL7 27931 etc.

RECALL: Types of Health Standards

4. Architecture or Model-oriented System standards

- Define elements of a health system architecture to support different health functions
- e.g. ISO 12967, ISO 10781, ENV 12443, etc.
- **e.g. CDA: Clinical Document Architecture**

5. Data formats standards

- Define data formats for different types of health data for laboratory data, medical images
- e.g. DICOM etc.

6. Workflows and Process-oriented standards

- describe the semantics of **clinical concepts & processes** to support **continuous care** of an individual within an organization and Across organizations
- **CEN 13940** etc.

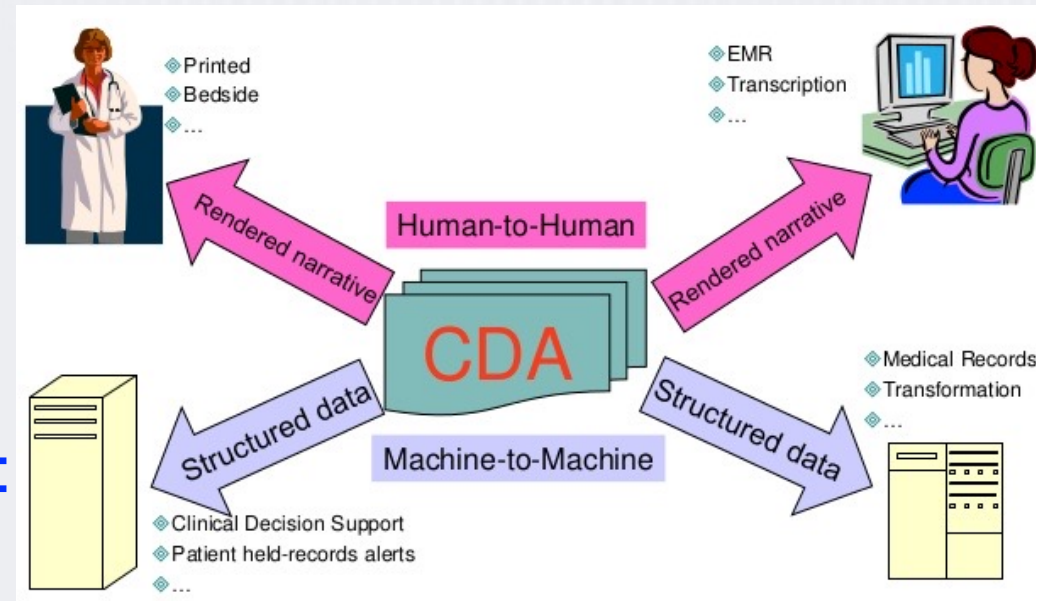
RECALL: Clinical Data Terminology/Vocabulary/Coding Standards

- Controlled Medical Terminology/Vocabulary:
 - ICD9/ICD10 (International Classification of Diseases, ver. 9/ver. 10)
 - SNOMED -CT (Standardized Nomenclature of Medicine, Clinical Terms)
 - LOINC (Logical Observation, Identifiers, Names and Codes) – Lab results
 - RxNorm (normalized naming system for generic and branded drugs)
 - RCT (Read Codes Terms, ver. 2.x, ver. 3.x) – specific to the UK
 - NLM UMLS (Unified Medical Language System): inclusive of all coding systems, and mapping between them



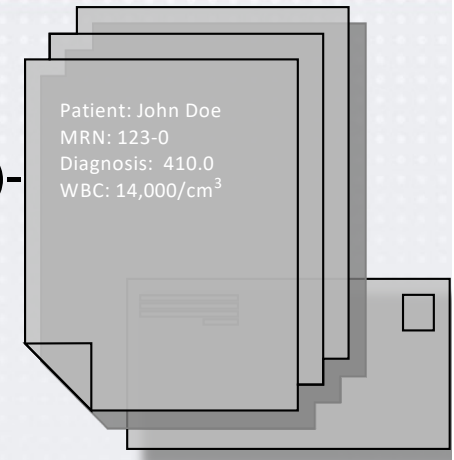
RECALL: Clinical Data model and exchange Standards

- Data-model and Architectural standards:
 - **CDA** (Clinical Document Architecture)
 - **CEN 13606** [~openEHR] (EHR communication standard)
- Data Exchange standards:
 - **HL7** (Health Level 7, v 2.x, v 3.x)
 - **CCR** (Continuity Care Records)

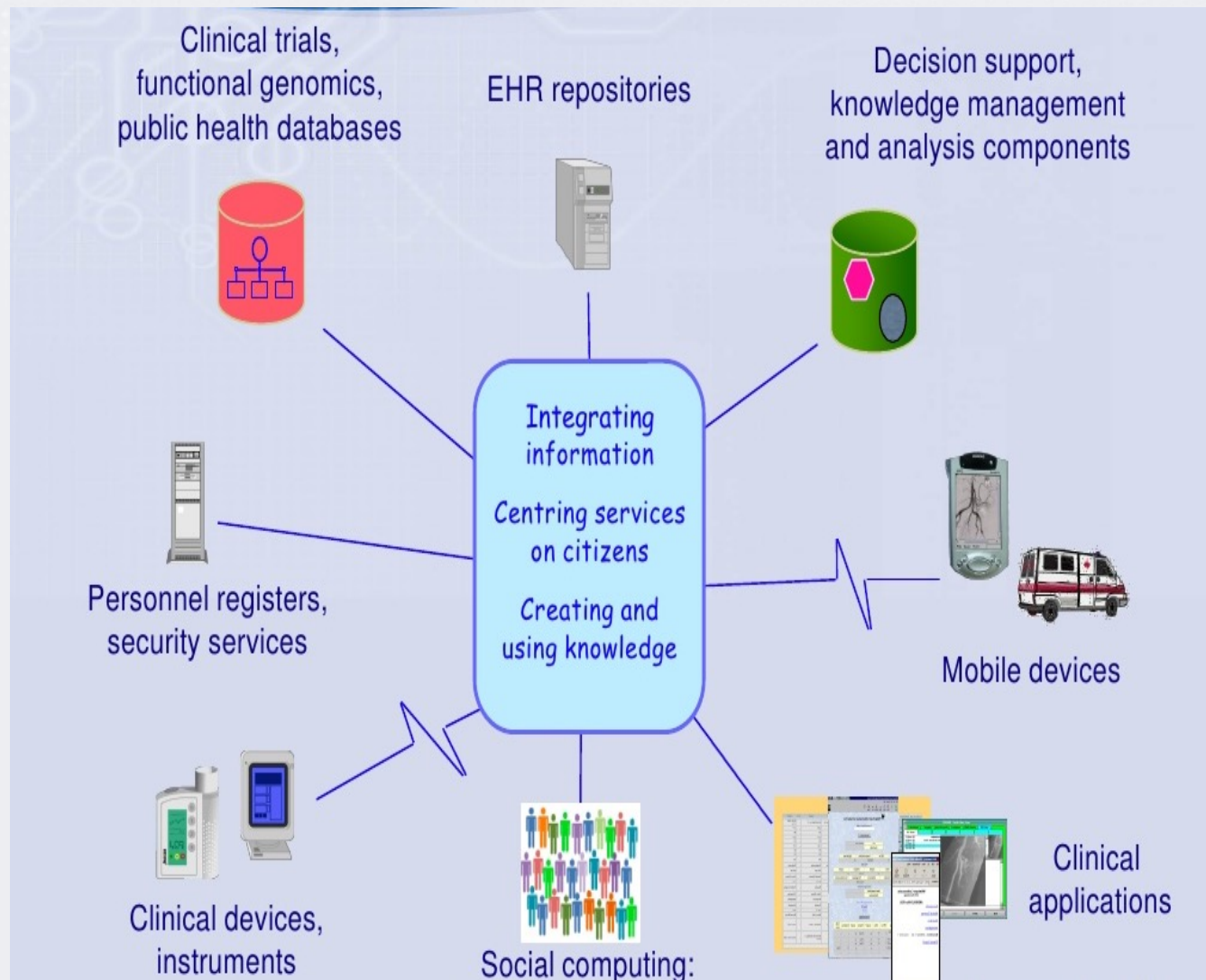


RECALL: Clinical Data format and Privacy Standards

- **Data Format standards:**
 - DICOM (Digital Imaging and Communications in Medicine)- messages for images
- **Privacy and Confidentiality:**
 - **HIPPA** (Health Insurance Portability and Accountability Act)



Electronic Health Records Land escape



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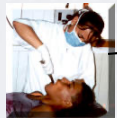
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RECALL: EHR System objectives

- The EHR should enable the [consistent](#) capture, processing, retention, protection and communication of health information such that [interoperability](#) is achieved in support of shared care, improved quality of care, effective resource management, providing evidence of actions taken in health(care), and in support of the uses of anonymised information for health system management.
- The EHR should enable authorised users to [access health information](#) that is relevant, intact, appropriate to their permissions and within a timeframe that is appropriate to the context.
- The EHR should enable the [communication \(or exchange\) of all health information](#) between care settings, subject to appropriate consent and access rights, to a sufficient quality to support safe shared clinical care.

[ISO 18308]



STANDARDS

DATA

Analysis

Statistics

Research

Clinical Trials

Surveillance

Patient Safety

Quality

Low cost

Accessible

KNOWLEDGE

PROCESS

Public/Private Partnership

Vendor/Provider Partnership

Privacy, Security, Trust, Integrity

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 *openEHR*
EHR interoperability Reference Model ISO/EN 13606-1
HL7 Clinical Message Interoperability
HL7 Clinical Document Architecture (CDA)
Clinical content model representation *openEHR* 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.

CEN/TC EN 13940

Standardisation of Clinical Processes and Workflows

Defines System of Concepts to Support Continuity of Care

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CEN/TC EN 13940

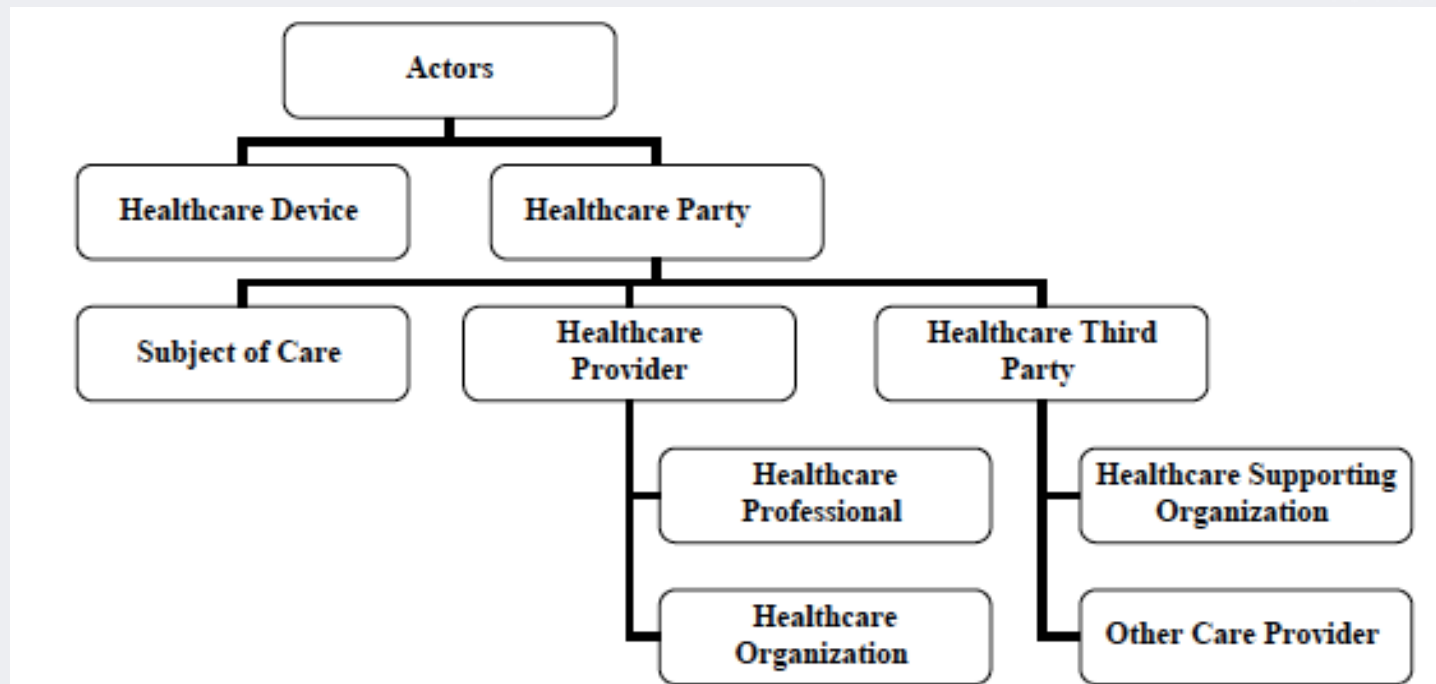
- **CEN 13940** standard describes the semantics of **clinical concepts & processes** to support **continuous care** of an individual/patient within an organisation and across organisations
 - CEN 13940 main goals:
 - Standardisation of **concepts, processes, & workflows** in healthcare
 - Facilitate **interoperability** between health Information systems used in organisations.
- CEN/TC standard has two parts:
 - **Part 1 (EN 13940-1)**: describes the **basic concepts** within healthcare settings
 - **Part 2 (EN 13940-2)**: describes various **core processes** involved in healthcare as well as **process workflows** for different scenarios.

CEN/TC EN 13940-1: Basic Concepts

- The basic concepts of **CEN/TC EN 13940-1** consists of the following:

1. Actors in continuity of care

- Entities involved in healthcare activities
- Actor might be a **healthcare device** or **healthcare Party**



CEN/TC EN 13940-1: Basic Concepts

2. Health issues and their management

- Refers to **health problem** of a subject of care (**patient**) identified by a **healthcare party** (**doctor or hospital**).
- The **interpretation** of health issues can change over time depending on **efforts/actions** taken to solve these issues.
 - Health issues can be referred to in none or many health situations and have different interpretations
 - Example
 - “**An accident**” issue can further be interpreted as “**fracture**” in diagnosis process.

CEN/TC EN 13940-1: Basic Concepts

3. Concepts related to **health mandates**

- **Health mandate** → The authorisation given to a healthcare provider for treating a health issue of a patient.
- Health mandates are categorised into:
 - **Demand mandate** → a patient has demanded the care
 - **Care mandate** → the authorisation given to a healthcare provider for being responsible for care of the patient
 - **Mandate to export personal data** → the authorisation of sharing patient's data with other healthcare providers during the care process
 - **Continuity facilitator mandate** → the authorisation to provide continuous sharing of information for supporting continuity of care to a patient

CEN/TC EN 13940-1: Basic Concepts

4. Time-related concepts in **continuity of care**

- Refers to **timeframes** of interactions among the involved **actors** that take place for treating a **patient**.
 - **Period of care**
 - Duration of clinical activities that are performed for **multiple** health issues
 - **Contact (i.e. encounter)**
 - A meeting between a patient and a healthcare professional for addressing one or more health issues
 - **Episode of care**
 - **Collection** of contact (i.e. encounters) elements for **one** particular **health issue**
 - An episode of care is usually divided into multiple sub-episodes
 - each **sub-episode** of care is aimed at achieving a **specific goal** for the care of the patient.

CEN/TC EN 13940-1: Basic Concepts

5. Concepts related to **knowledge, activities, & decision support**
- Activities preformed in healthcare during the treatment of a patient includes:
 - **Healthcare activities such as**
 - Provider activity
 - Self-care activity
 - Contributing activity
 - Automated activity
 - **Clinical guidelines and protocols**
 - Generic clinical guidelines that are followed when healthcare activities are performed by provider for treating patients
 - **Programs of care and care plans**
 - Protocols followed within a health care organization by its **multiple Health care professionals** in the care process of a patient.
 - A **Program of care** can have a number of **Care plans**

CEN/TC EN 13940-1: Basic Concepts

6. Health data management

- Concepts related to management of **health data** is detailed in a **hospital** and including **sending it to another hospital**.
- Health data management deals with assuring **correctness** of such data generated by means of clinical devices
- Clinical record data in electronic form should also be stored in a **shared repository** after **verification and approval by clinician**
- The standards also deals with **access rights verification**
 - All access information should be logged in the EHR of a patient

CEN/TC EN 13940-2: Clinical Process & workflow

- **EN 13940-2** describes the usability aspects of the concepts defined in **Part 1** in terms of:
 - **Processes and entities** involved in the processes
 - **Workflow** for various scenarios in hospitals.
 - Each process has one **refinement object**
 - Converts **input** into **output** with a defined **objective**.
- Example:
 - *A clinical process* deals with a patient's conditions
 - *Refinement object* → **curing** the patient is the objective to this process.

CEN/TC EN 13940-2: Clinical Process & workflow

- **EN 13940-2** describes the following types of processes:
 - **Healthcare Process** (Core clinical process)
 - Consists of **clinical**, **resource management**, and **clinical management processes**.
 - **Healthcare Provider Research Process**
 - Improving **clinical knowledge of healthcare professionals**
 - **Healthcare Provider Educational Process:**
 - Improving **skills** of healthcare professionals
 - Enabling healthcare professionals to learn the **practical implementation** of the **clinical knowledge** related to patient's care
 - **Healthcare Administrative Process**
 - Used to **control and support** the healthcare process

CEN/TC EN 13940-2: Clinical Process & workflow

- **Healthcare Process workflow**
 - A clinical process is started through a **demand of care** and go through the following steps:
 - **Initial contact of the patient**
 - The first encounter for **health issue** showing the process for demand of care
 - **Change of Health Conditions**
 - The **activities** that contribute to any change in health condition of the patient.
 - **Program of Care**
 - Healthcare **workflow** with healthcare resources for multiple health issues and health issue threads.
 - **Healthcare activities**
 - Decision, diagnostic activities, plans, etc., and their relationship with other objects such as, **mandate, health condition**, etc.

Concepts/Coding Standards

CEN/TC EN 13940 - Online

ISO 13940:2015(en) Health informatics — System of concepts to support continuity of care

Buy

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Available in: [en](#) [fr](#)

0 Introduction

0.1 General

The purpose of this International Standard is to define the generic concepts needed to achieve continuity of care. Continuity of care is an important aspect of quality and safety in healthcare and semantic interoperability is a basic requirement for continuity of care. The concepts that are needed for these should represent both the content and context of the healthcare services.

Healthcare is provided through activities in healthcare and clinical processes. These types of processes reflect the interaction between a subject of care and healthcare professionals. A clinical process provides continuity from the subject of care's perspective. To complete the concepts representing continuity of care, a number of basic premises for management, resource handling and administration are also needed.

The system of concepts for continuity of care defined in this International Standard is based upon the clinical perspective with the clinical process as focus, it defines its component concepts and their descriptive terms regarding all types of healthcare and especially considering patient-centred continuity of care. This International Standard will establish a common conceptual framework across national, cultural and professional barriers.

0.2 Aims for this International Standard

The general aim for this International Standard is to provide a comprehensive, conceptual basis for content and context in healthcare services. It should be the foundation for interoperability at all levels in healthcare organizations and for development of information systems in healthcare.

The concepts aim to support the continuity of care in healthcare with clinical processes as the focus, enabling the use of healthcare information for other purposes such as secondary use for follow-up and knowledge management. The core business in healthcare is the interaction between subjects of care and healthcare professionals, such interactions occur in healthcare and clinical processes and are the justification for the process approach of this International Standard. To be able to represent both clinical content and clinical context, this International Standard is based upon the clinical perspective and has focus upon the clinical process as a main concept for achieving continuity of care.

EHR Information Model Standards

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EHR Key Aims

- To create a shared EHR that provides a **central point** of shared health data
- To support the process of **continuity of care**
- To support a **longitudinal** patient record
- To support a real world health **environment**
- To provide targeted **decision** support
- To support the functions of **clinical research** to improving medical knowledge

A view of the healthcare world

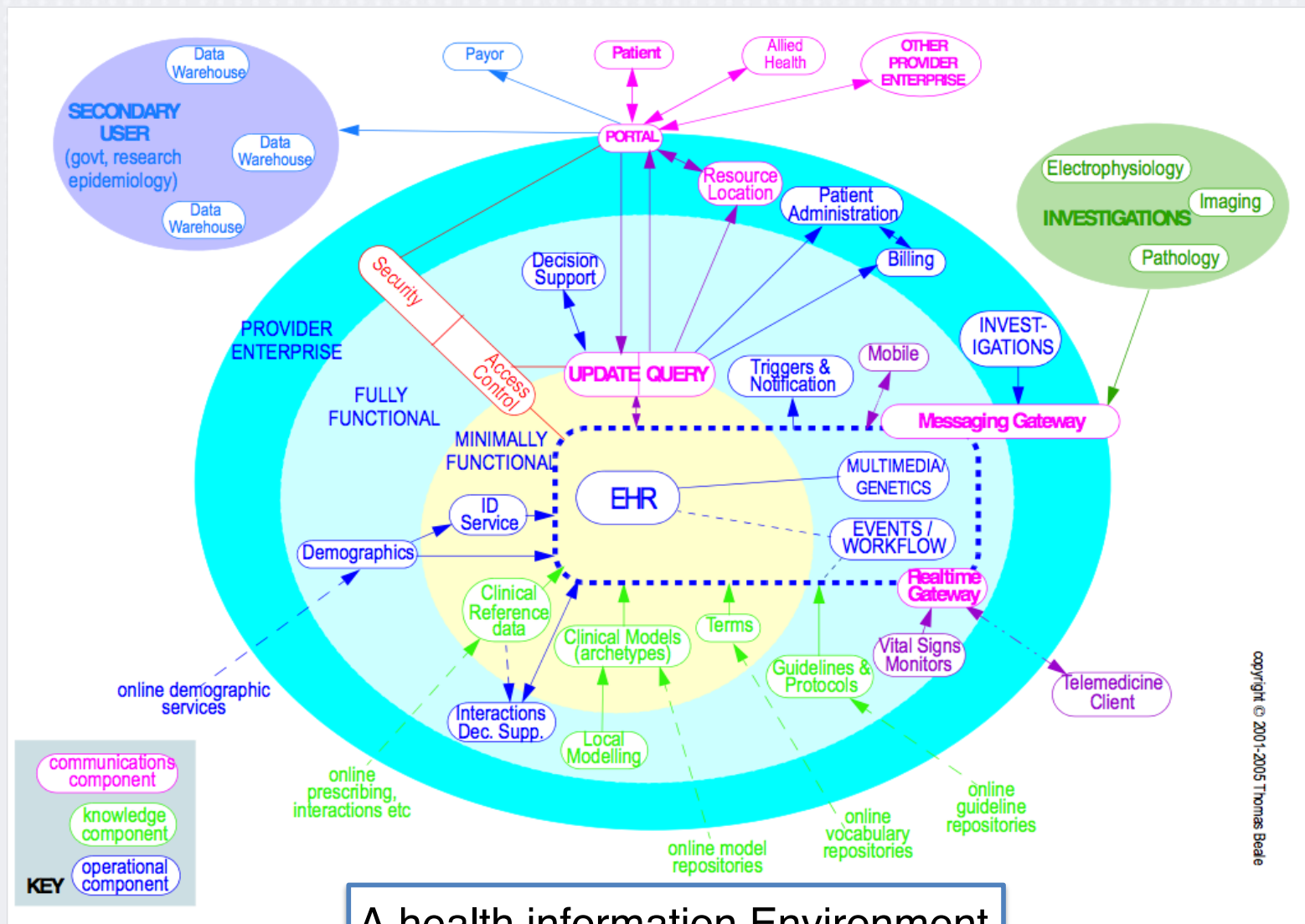
Genomic Medicine	Preventive Care			Acute Care						Chronic Care							
	Data			Data						Data							
	Normal	Concern	Abnormal	Symptoms	Diagnoses	Treatment	Outcomes	Intensive	Hospital	Emergency	Specialty	Outpatient	Nursing Homes, etc.	Home Care	Performance	Control	Treatment
	Decision Support			Decision Support						Decision Support							

Clinical Information Models: aims

- Formally models **clinical domain concepts**
 - e.g. “smoking history”, “discharge summary”
- Encapsulate **evidence** and **professional consensus** on how clinical data should be represented
 - published and shared within a clinical community, or globally
 - imported by vendors into EHR system data dictionaries
- Support **consistent** data capture, adherence to guidelines
- Enable use of **longitudinal** EHRs for individuals and populations
- Define a systematic EHR target for **queries**: for decision support and for research

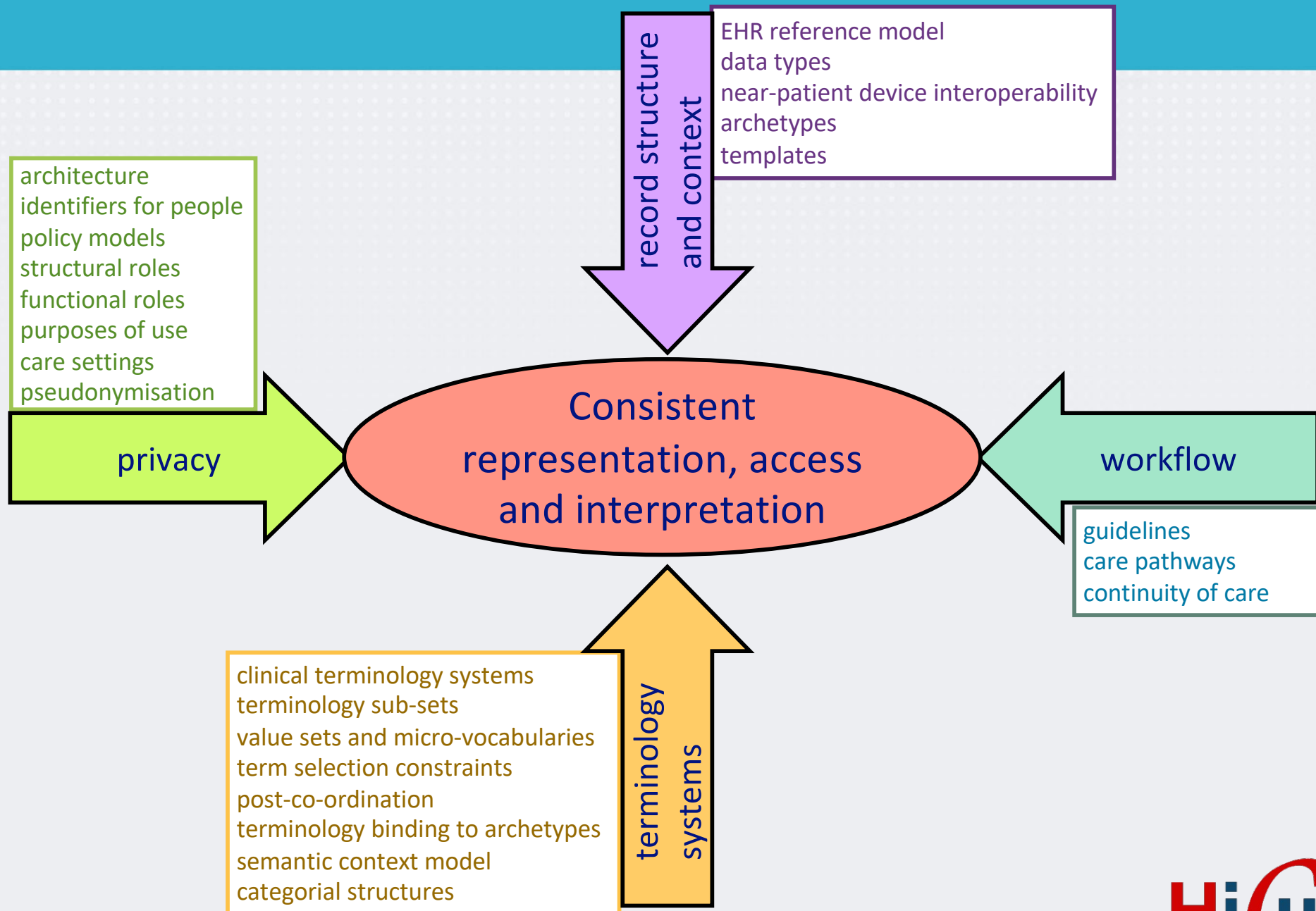
=> **Archetypes (openEHR and ISO 13606-2)**

Health Information Environment



A health information Environment

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

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ISO 14265 Classification of Purposes of Use of Personal Health Information

Clinical knowledge

Terminologies: SNOMED CT, etc.

Clinical data structures: Archetypes etc.

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 INFORMATION

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 entries

4.2.4 Intra-record links

4.2.5 The representation of data values within health record entries

4.2.6 EHR data retrieval and views

4.2.7 Representation and support of clinical process and workflow

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.

Standards relevant to the EHR

Business

ISO 18308 EHR Architecture Requirements

HL7 EHR Functional Model

ISO 15197-1 EHR Functional Model

regulatory

Information models

Information models

EHR system reference model *openEHR*

EHR interoperability Reference Model

ISO/EN 13606-1

Clinical content model representation

openEHR ISO/EN 13606-2 archetypes

Communication services

HL7 SOA Retrieve, Locate, and Update Service D310

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.

EHR Standards

ISO EN 13606

CEN 13606: standardisation of EHR functions

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 health records**.
- CEN 13606 → **Formal standardisation** of *OpenEHR* initiative

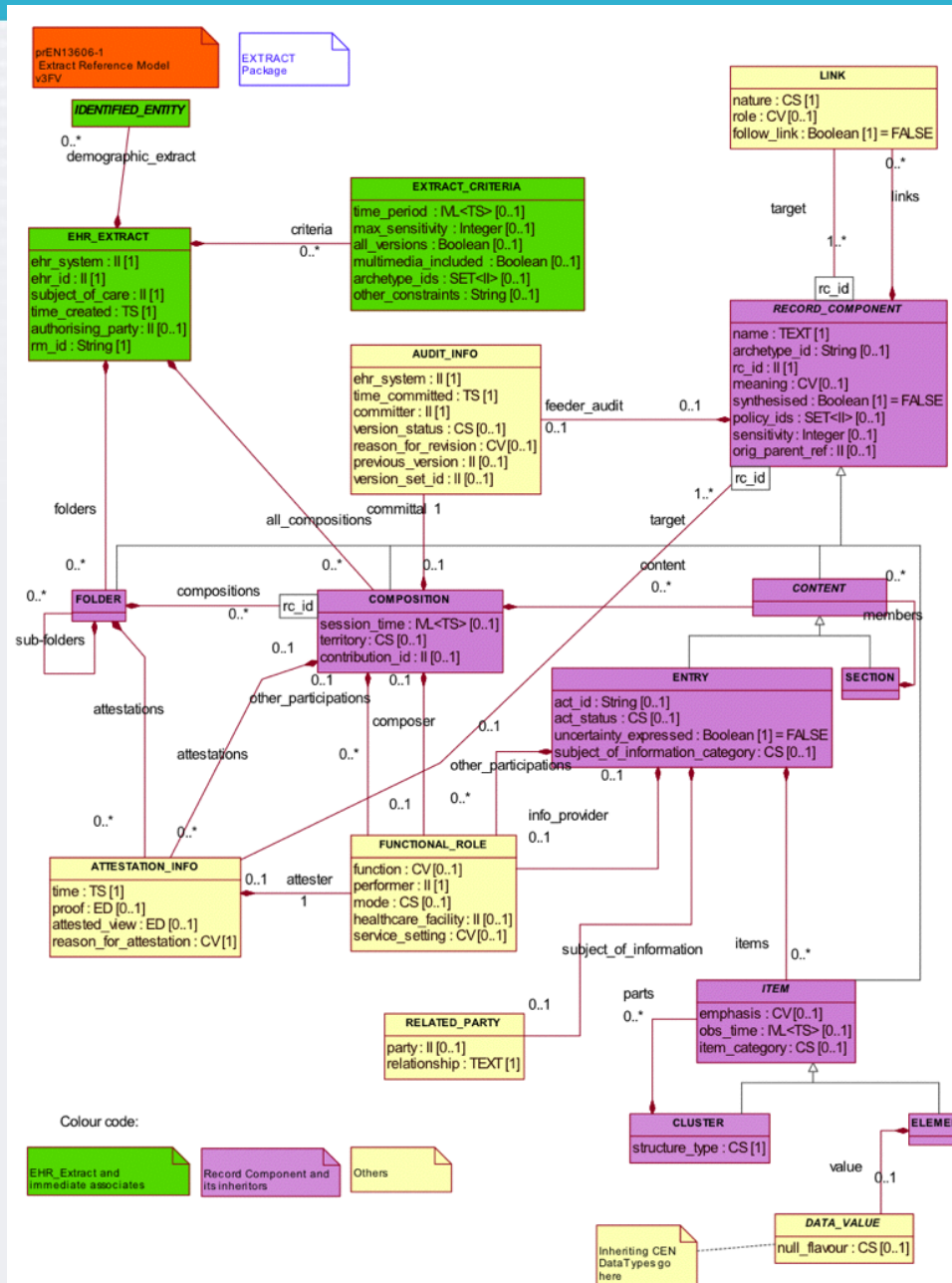
CEN 13606 EHR standard

- **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)

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

ISO EN 13606-1 Reference Model



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.

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

EHR Standards

*open*EHR

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Health Framework Standards

OpenEHR

- openEHR:
 - Virtual community working on means of **turning health data from the physical form into electronic form** and ensuring universal **interoperability** among all forms of electronic (health) data.
- Describes the **management, storage, retrieval and exchange** of health data in EHRs
- OpenEHR architecture
 - Consists of the following key elements:
 - Information models (also called Reference Model - RM)
 - The archetype formalism and the archetype query language (AM)
 - Service models (SM)

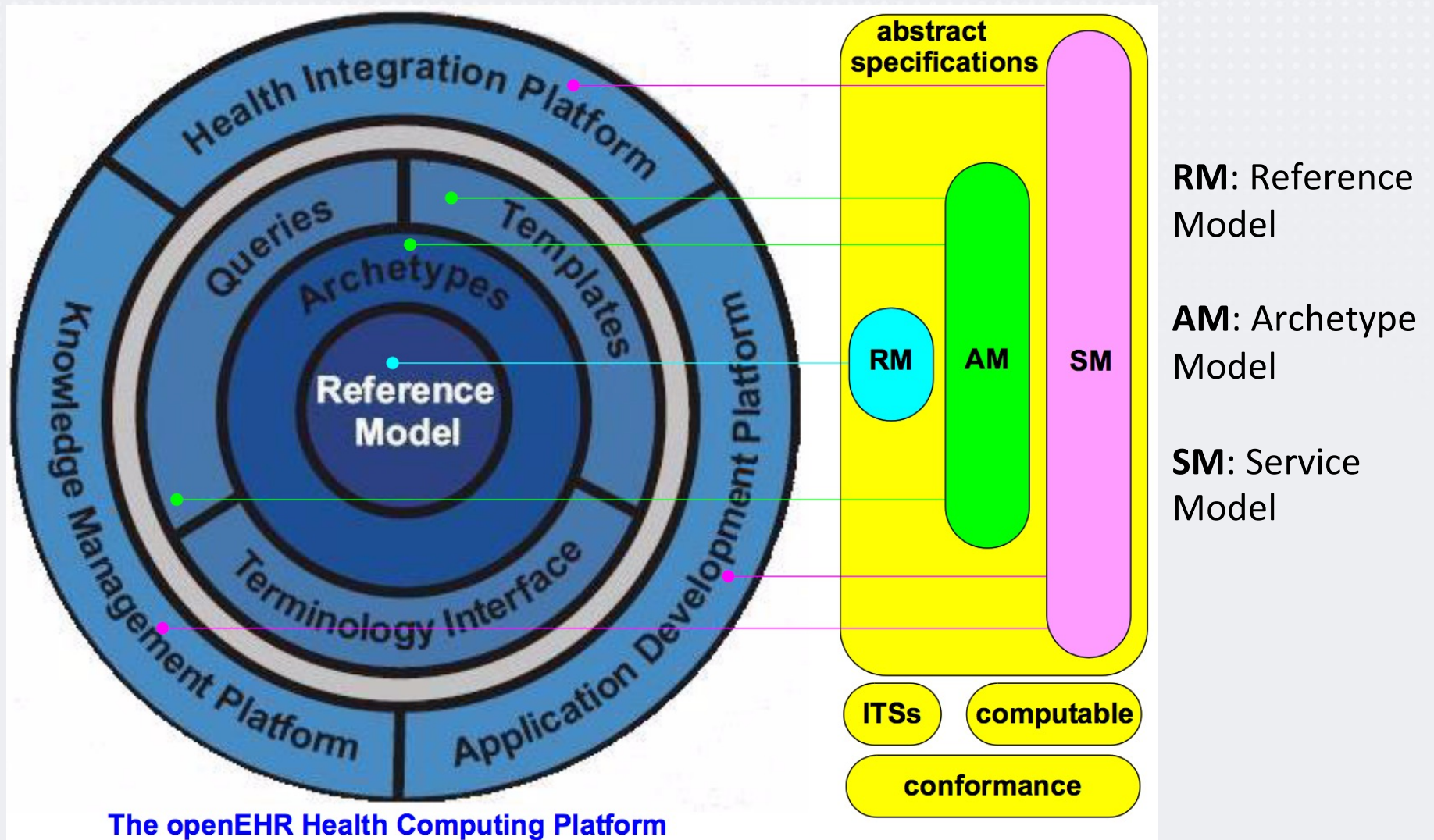
OpenEHR

- *OpenEHR* refers to both **foundation** and **specifications**
 - ***OpenEHR* Foundation**
 - Non-Profit organisation
 - Provides a membership to those who desires to contribute to the development & implementation of *OpenEHR* specifications.
 - **Vision** of *OpenEHR* Foundation: Enables healthcare sectors to obtains benefits from ICT:
 - Life-long **interoperable** electronic health records (EHRs)
 - Design EHRs to improve the **quality** of health care and clinical research.
 - More information about OpenEHR foundation:
 - <http://www.openehr.org/about/foundation>

*Open*EHR Specifications

- *Open*EHR Specifications
 - **Open** specifications for a health information model (opposed to proprietary closed specifications)
 - Capable of supporting an **open** platform health system
 - Vendor neutral
 - Technology neutral
 - Licensed to allow open and closed source business models
 - *Open*EHR specifications aim at:
 - Separating **clinical concepts** from the **EHR information model**
- *Open*EHR specifications include:
 - *Open*EHR Process Model (or workflow)
 - *Open*EHR Architecture

*open*EHR Specifications



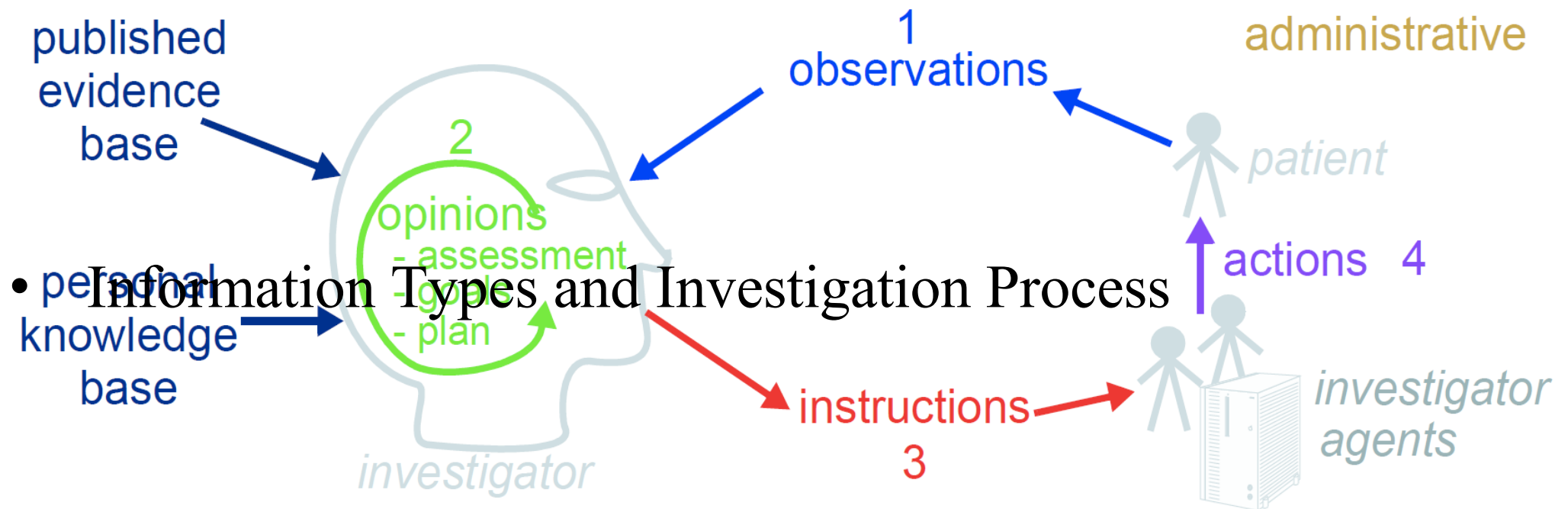
*Open*EHR Process Model

- OpenEHR is based on the problem-solving approach used in the "**Clinical Investigator Model**" or **CIM**.
- Clinical Investigator Model:
 - Includes **patient** & **care provider** as two participating entities
 - Based on **SOAP** (Subjective-Objective-Assessment-Plan) concept
 - During the clinical workflow, a set of clinical information is generated
 - The major types of **clinical information/statements** includes:
 - **Observations, Opinions, Instructions, Actions**
 - OpenEHR represents major types as **EHR_Entry** (discussed later)

*Open*EHR Process Model

- **Clinical Process or workflow (CIM)**
 - Starts from the patient's **observations** provided by care provider(s)
 - Then, care provider(s) provide
 - their **opinion(s)**
 - an **assessment** of the **current situation**,
 - **goals** for a future situation
 - Finally, **plans** for achieving the **goals**
- **Evidence and care providers' knowledge** always play an important part in this process
 - This leads to **instructions** designed to achieve the **planned goals**

OpenEHR Process Model

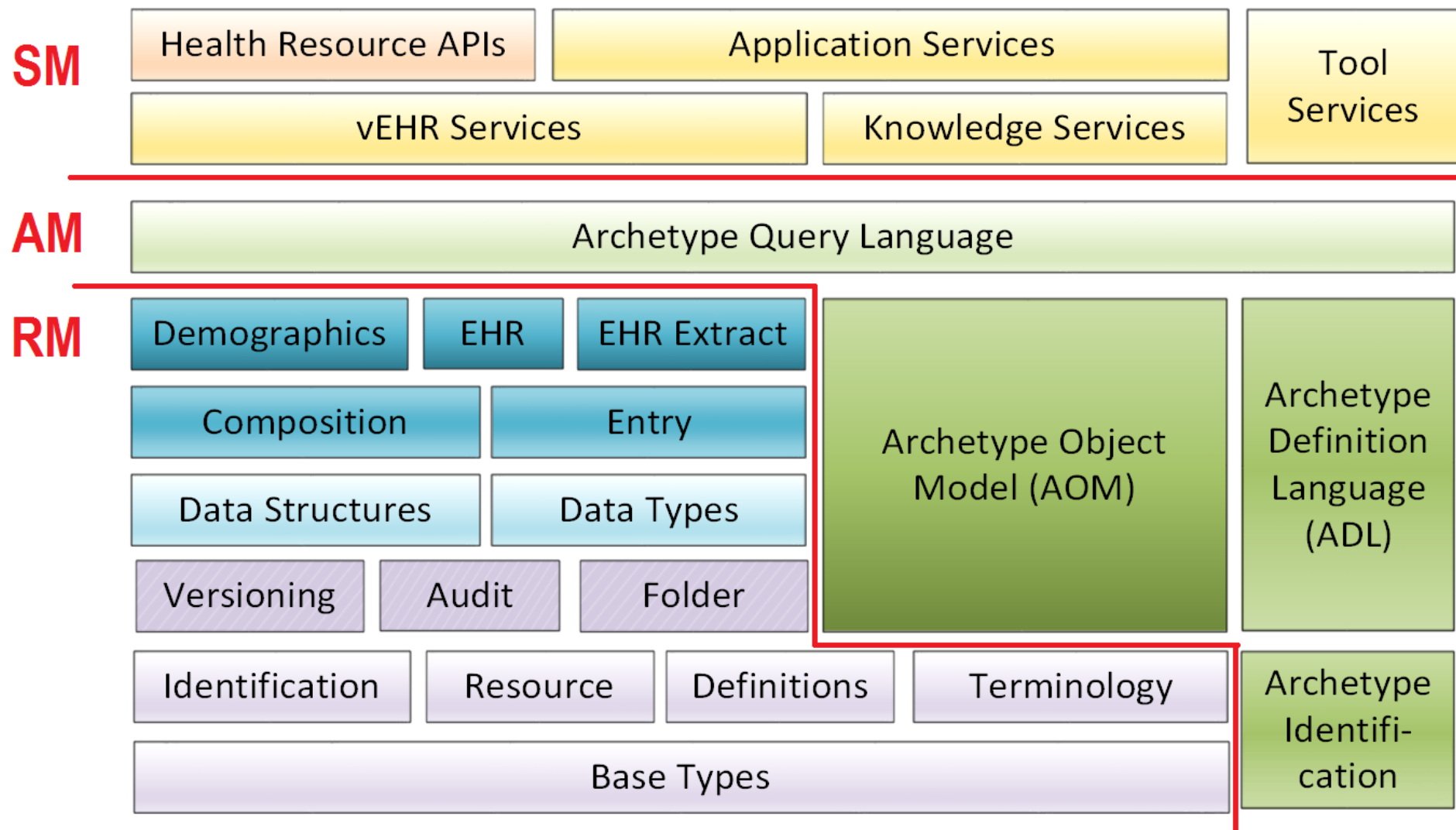


Clinical Investigator Model

*Open*EHR Architecture

- ***Open*EHR architecture :**
 - Is based on CEN/ISO 13606
 - Compliments other work developed by other standards organisations, including HL7 v3 & IHTDSO
- *Open*EHR architecture includes:
 - **Reference Model (RM)** – Information Model
 - **Archetype Model (AM)**
 - **Service Model (SM)**

OpenEHR Architecture



Dependency between components is from the bottom to top
All components use data types & data structures from RM