The Interoperability Journey*

NETTAB Workshop on Clinical Bioinformatics
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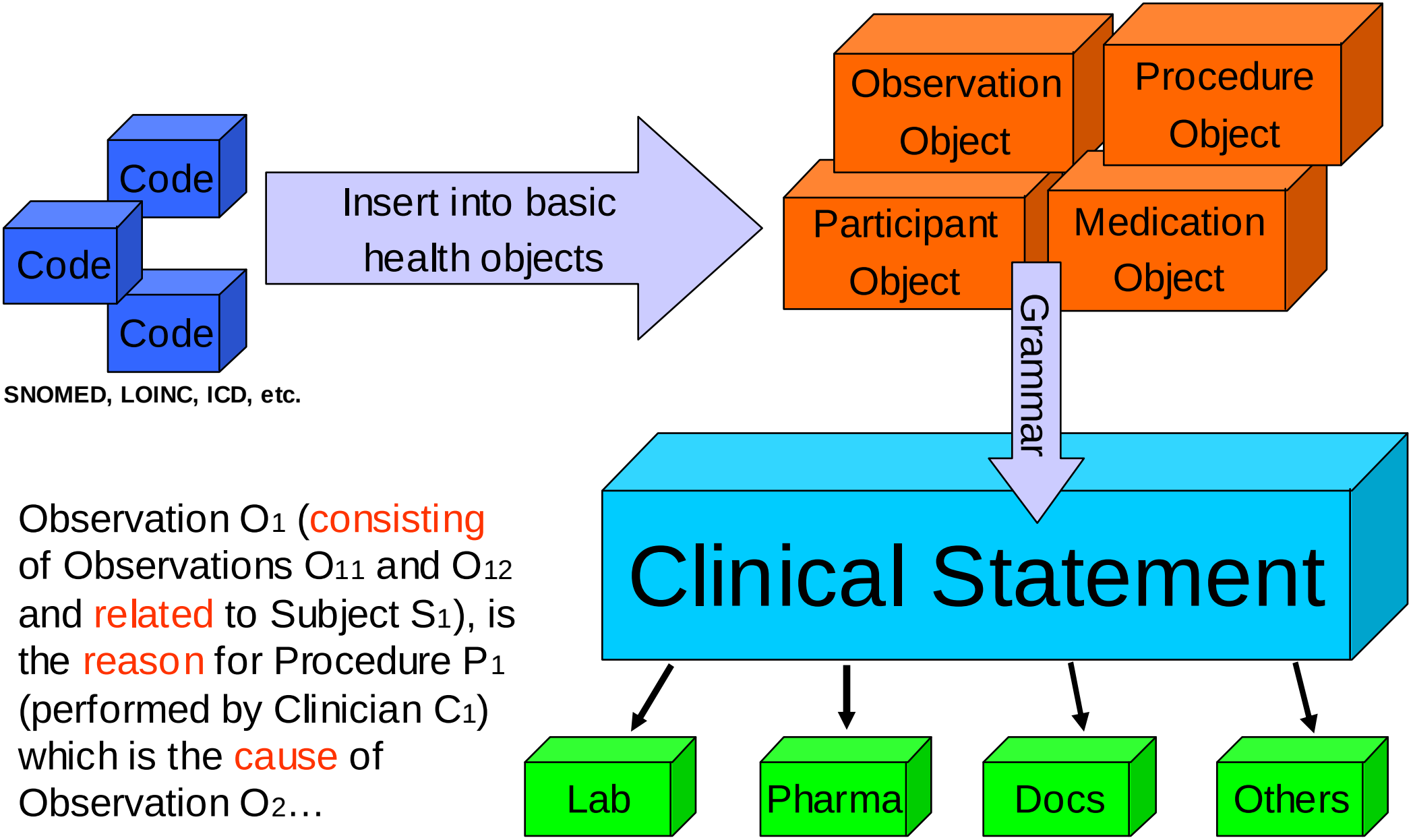
* The presentation is based on key slides from my NETTAB Special Session talk on interoperability.

Challenges

- Interoperability Foundations
- Key Standards
  - Clinical Genomics
  - CDA
  - Family History
- The EHR
- IHRB

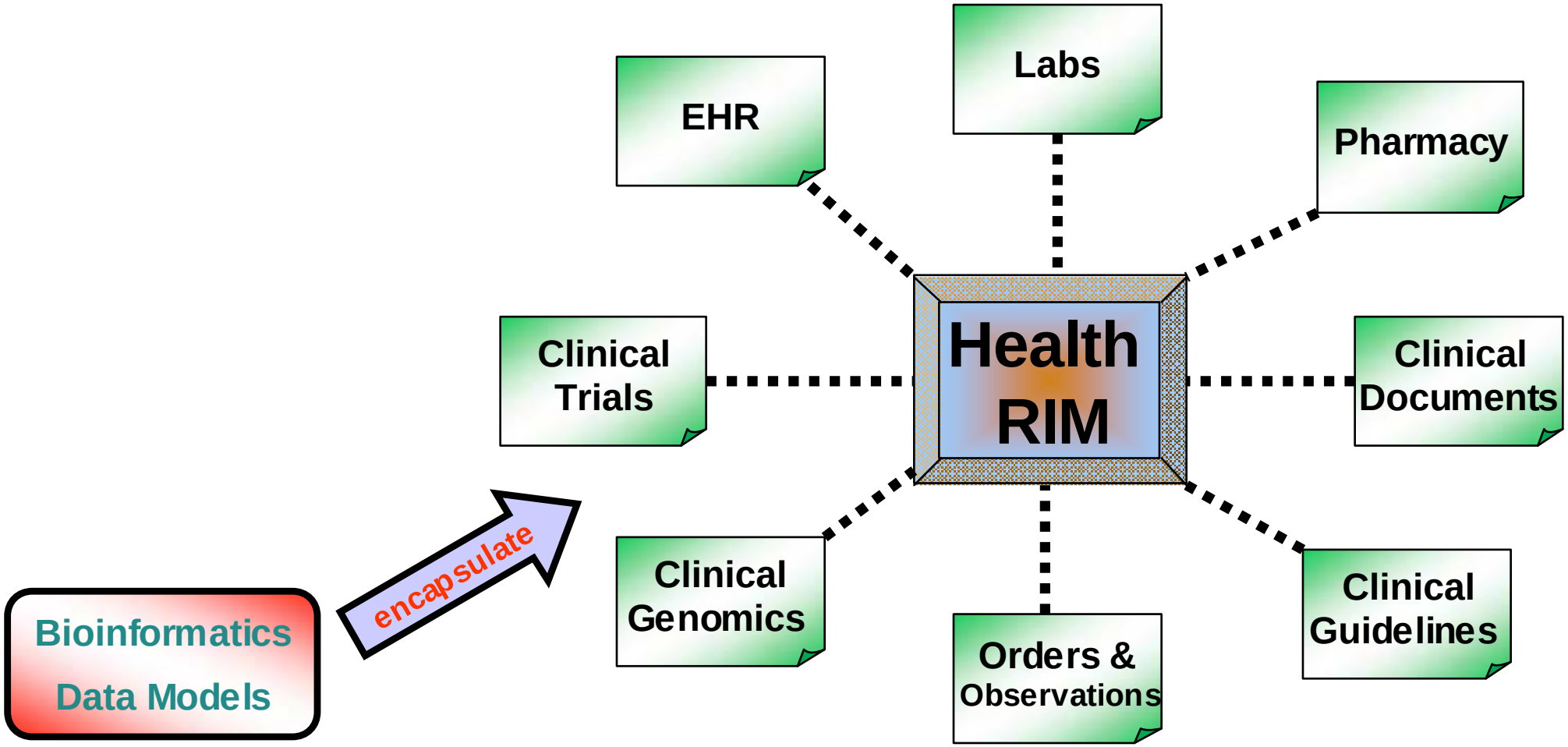
Universal Exchange Language? The New Generation of Standards!



Observation O_1 (consisting of Observations O_{11} and O_{12} and related to Subject S_1), is the reason for Procedure P_1 (performed by Clinician C_1) which is the cause of Observation O_2…

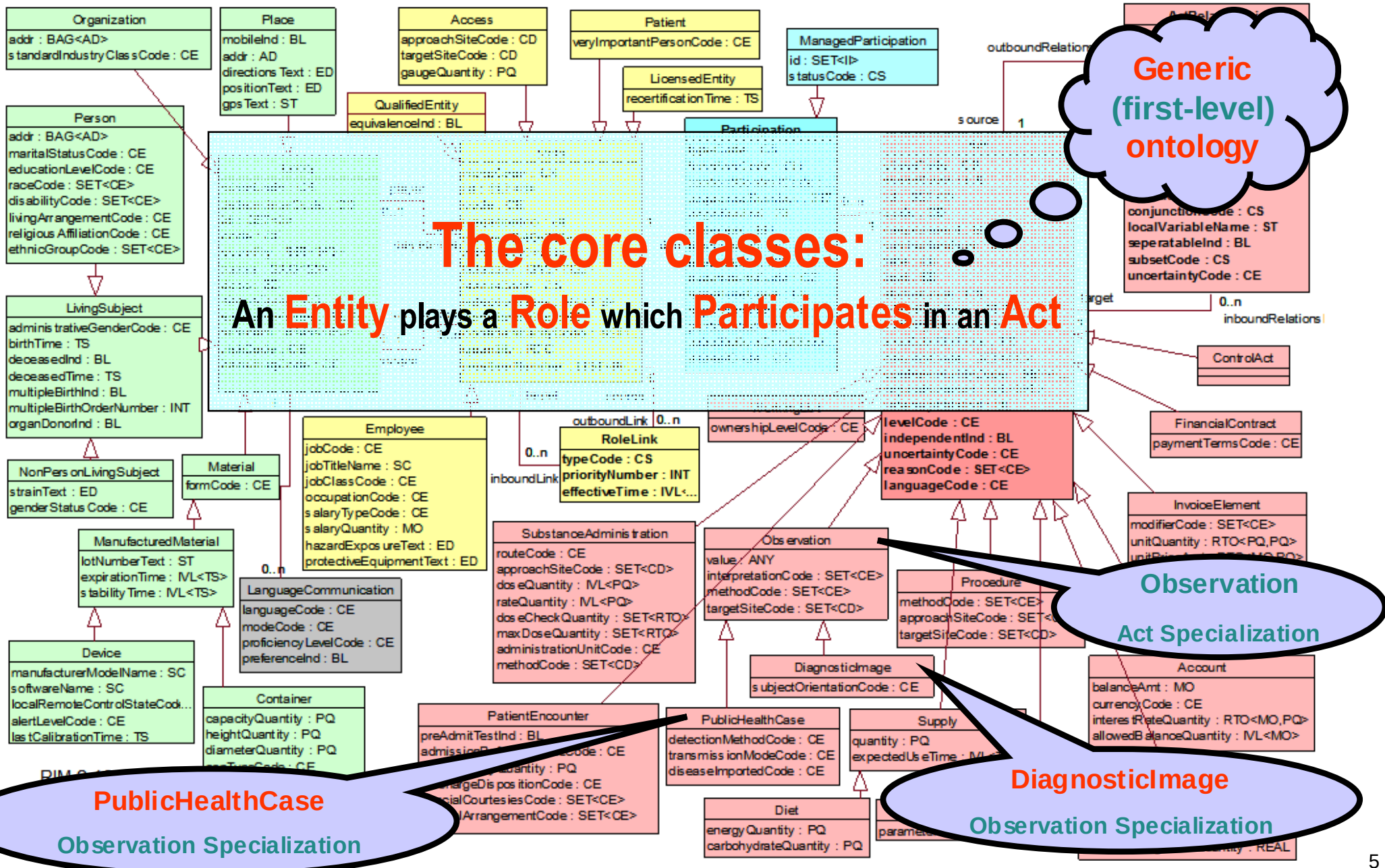
To Achieve Semantic Computation & Interoperability…

…all standards need to derive from a Central Health RIM:



Central Health RIM (e.g., an extended HL7 V3 Reference Information Model):
Bio & medical-informatics standard specs are derived from the same RIM

The HL7/ISO RIM (Reference Information Model)



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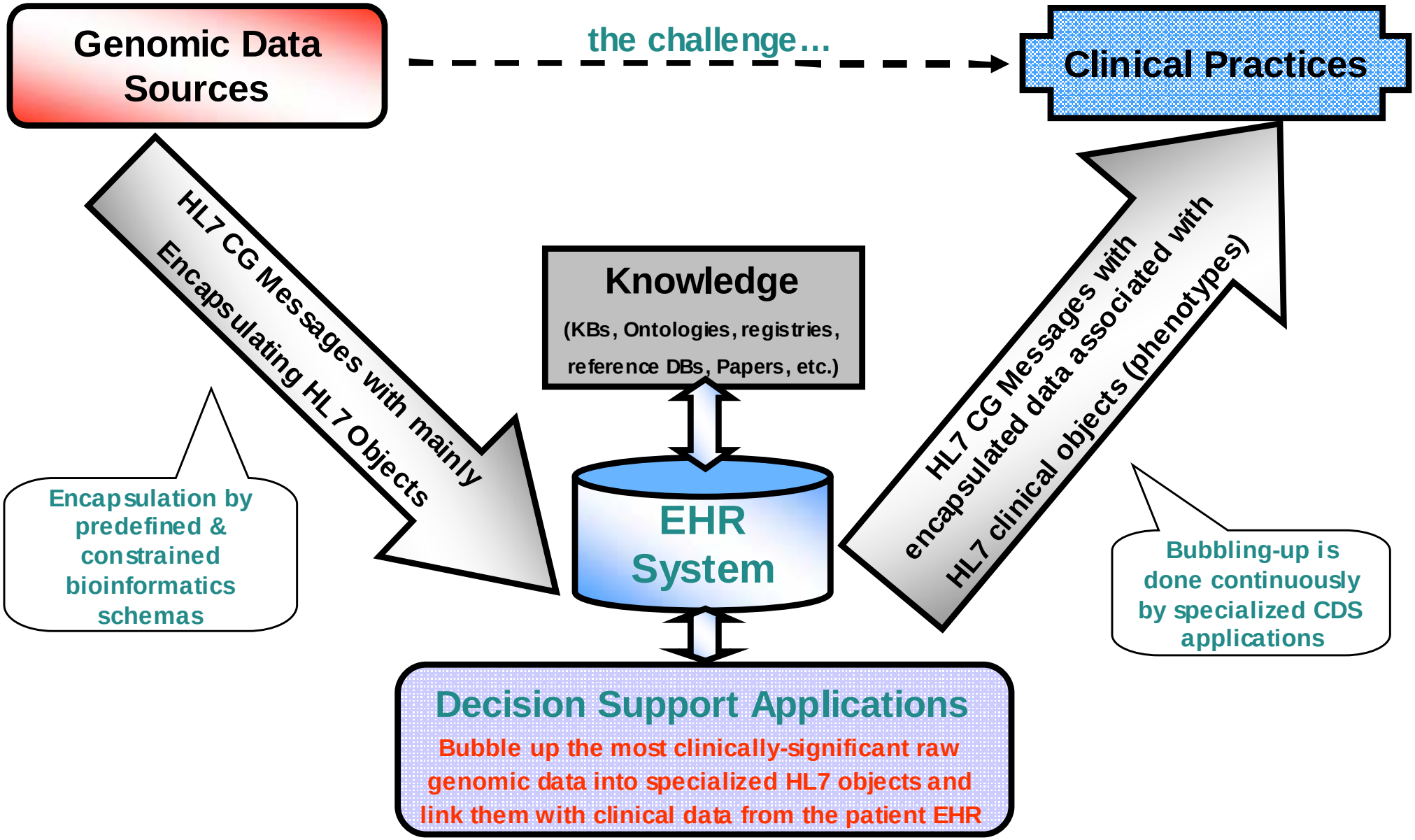
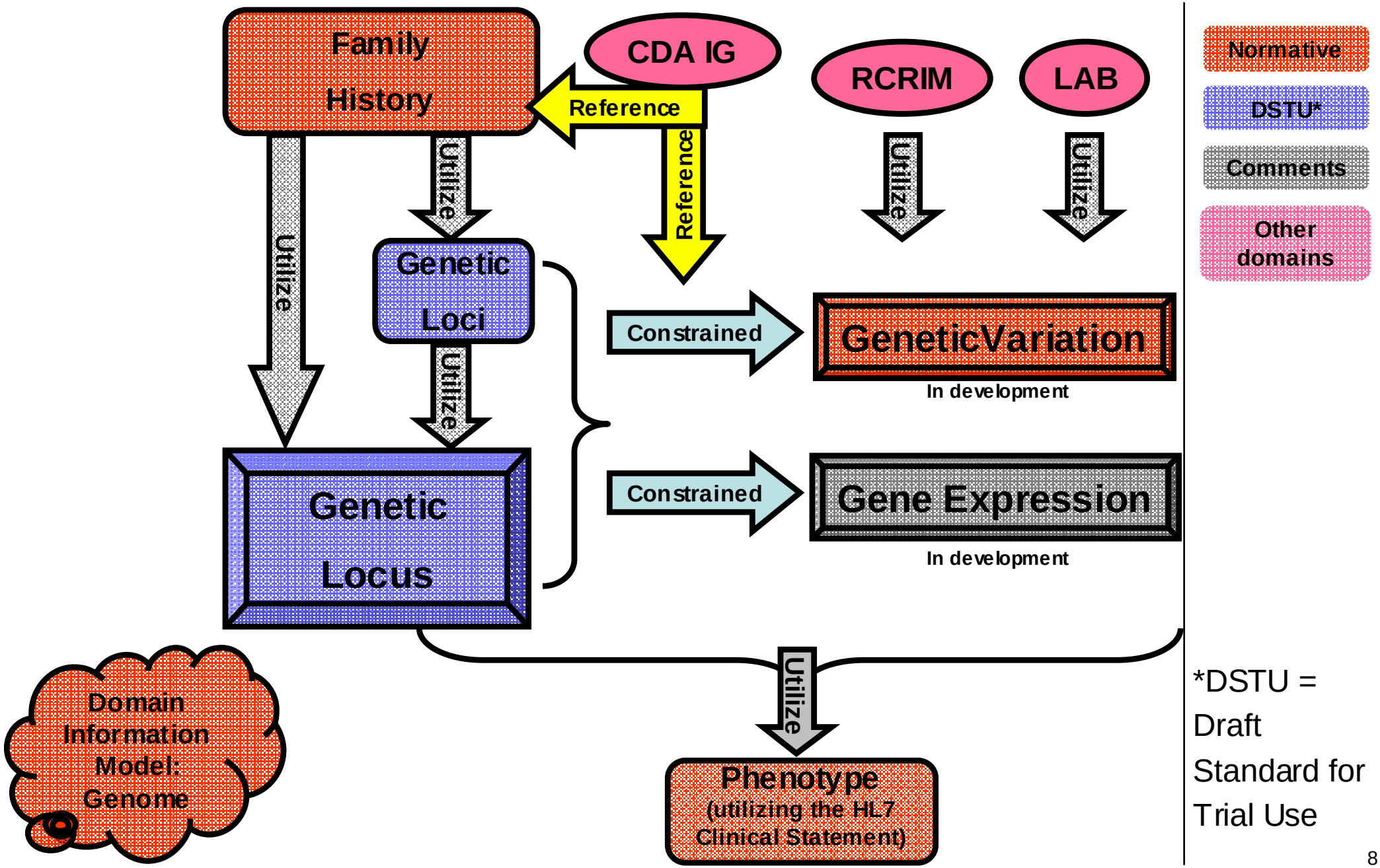
HL7 Clinical Genomics Data Standards: Encapsulate & Bubble-up



HL7 Clinical Genomics v3 Static Models



*DSTU = Draft Standard for Trial Use

HL7/ISO CDA (Clinical Document Architecture)

- Printed
- Bedside
- …

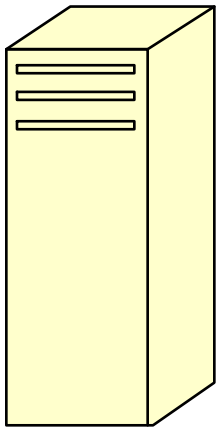
- EMR
- Transcription
- …

Rendered narrative

Human-to-Human

Rendered narrative

CDA

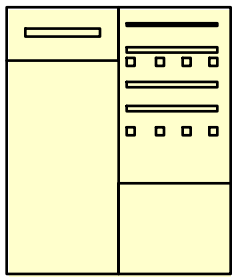


Structured data

Machine-to-Machine

Structured data

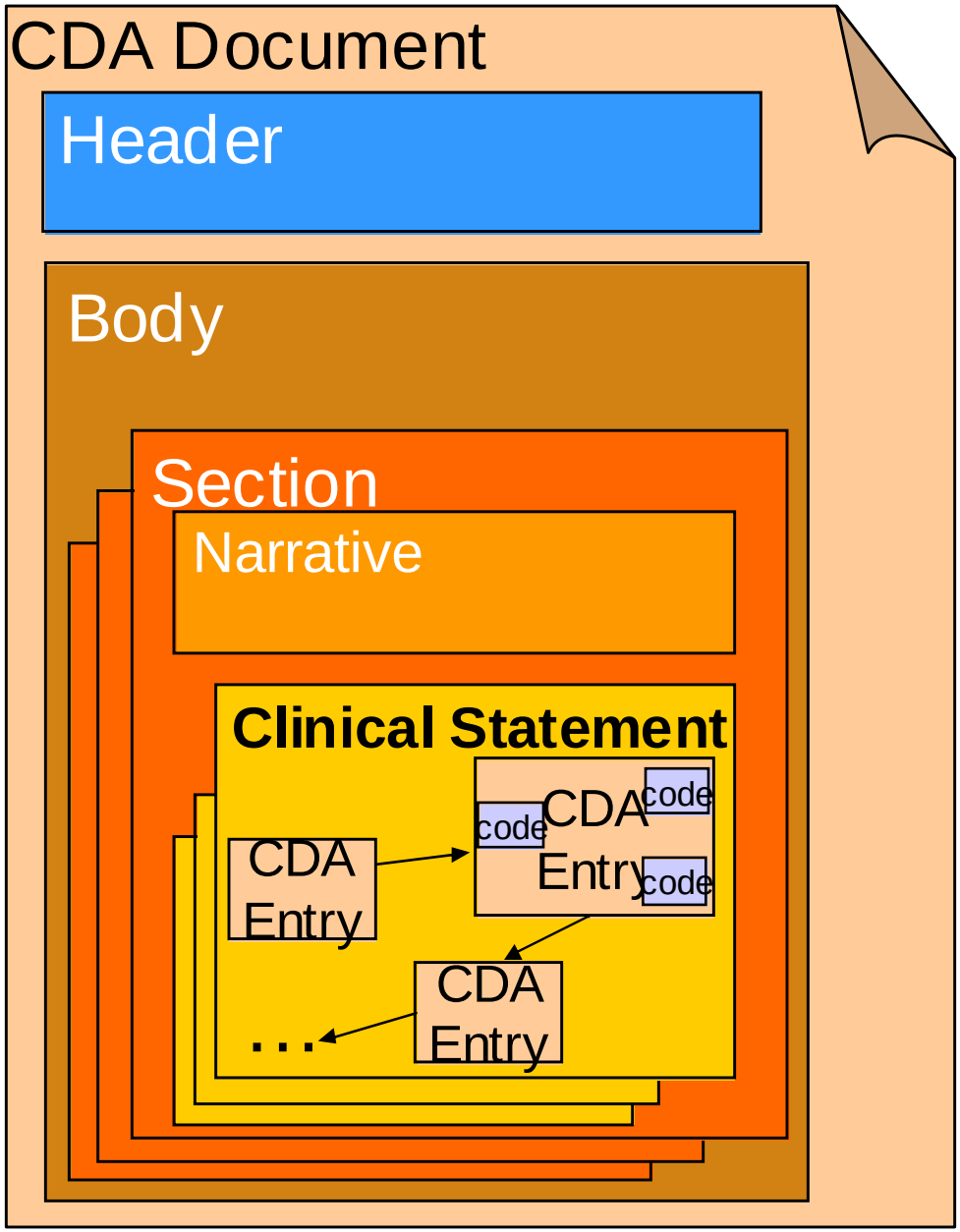
- Medical Records
- Transformation
- …



- Clinical Decision Support
- Patient held-records alerts
- …

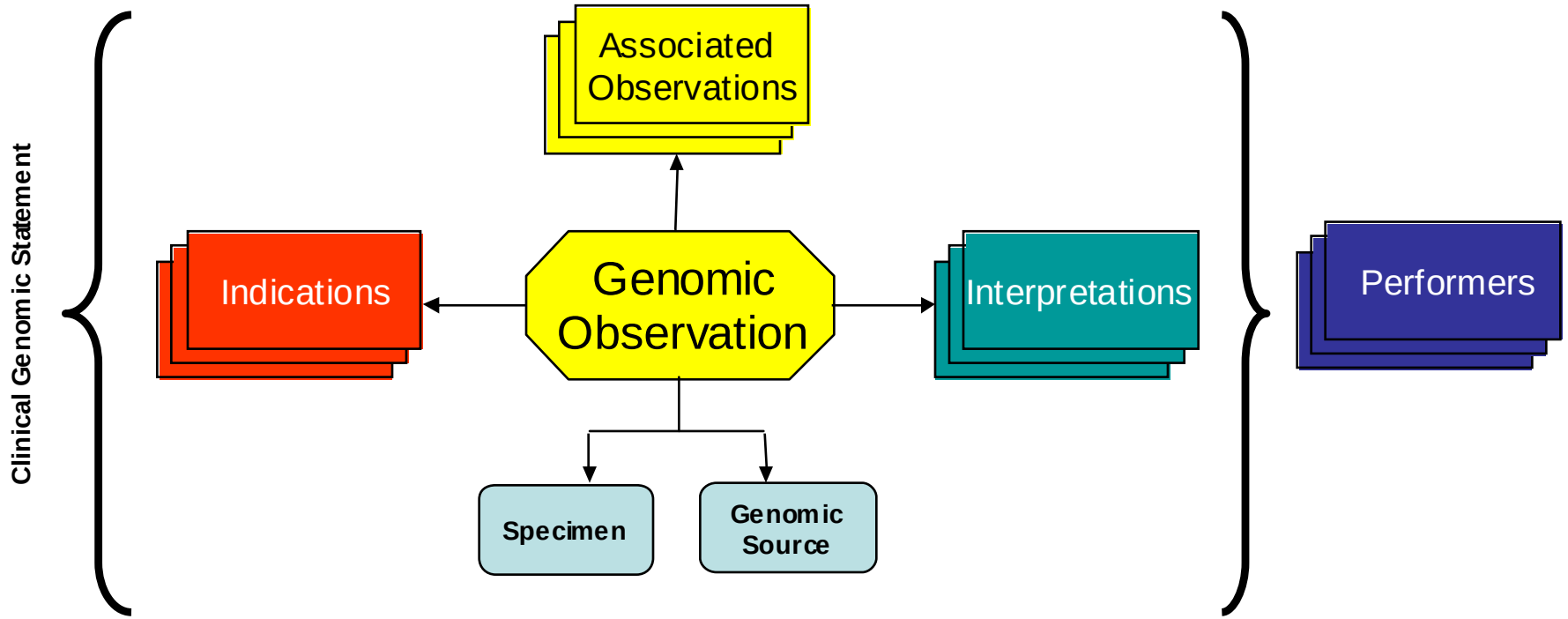
CDA Overview

- **CDA – a generic specification**
- **Could be used to represent various types of documents:**
  - **Consultation note**
  - **Visit / progress note**
  - **Referral letter**
  - **Discharge summary**
  - **Operative note**
  - **…**
- **A document type is also called ‘template’ or ‘implementation guide’**

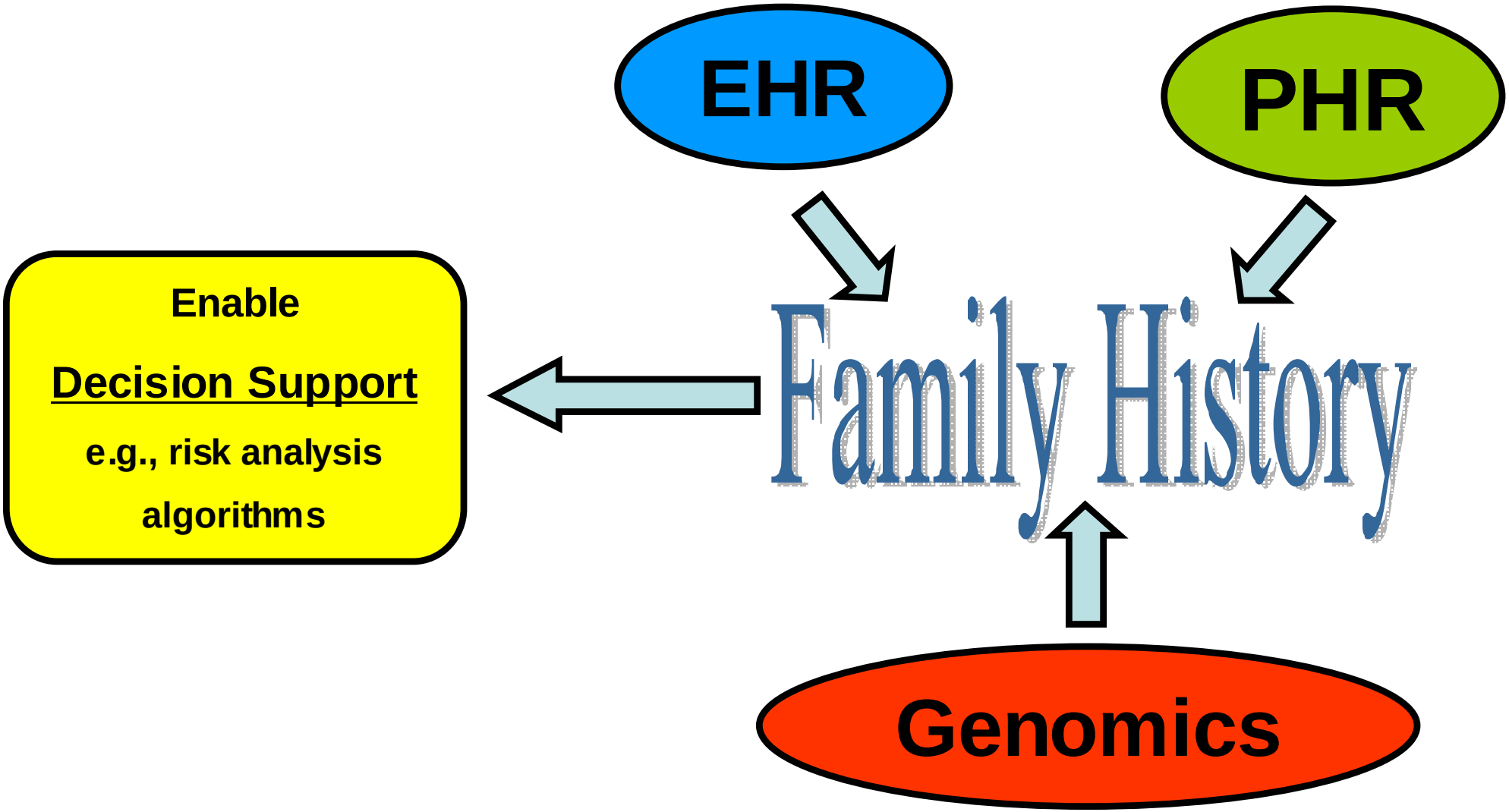


CDA Template for Genetic Testing Report (GTR)

- **An abstract Clinical Genomic Statement (CGS) template that**
  - **Has at its core a genomic observation (e.g., a DNA sequence variation)**
  - **If it's a reportable finding, then it should be associated with indications and interpretations, specimen and genomic source class**
  - **The major finding can be associated with associated observation (e.g., amino acid change)**
  - **Optionally, performers may be specified (overriding header performers)**
- **The CGS abstract template is instantiated by specialized CGS's, e.g., for genetic variations or cytogenetics**



Family History: PHR-EHR-GEN Convergence



Rich Expressiveness vs. Interoperability

- There's currently a tension between the two goals:
  The more expressive it is -
  the less interoperate it is

- Expressive structures lead to optionality
  - Possible solution: Constraints
    - Archetypes with EHR 13606 (European/ISO Standard)
    - HL7 Templates (no formalism has been agreed upon)
      - OCL is examined
      - GELLO (OCL-based) for clinical decision support
  - Public registries of templates
    - Need dedicated IT to provide registry services!

Template-based Information Model for HyperGenes

One instance per subject

CDA Template

Header

subject id

....

Body

reference1 to GV

reference2 to GV

reference2 to PD

....

clinical & environmental observations

GV Template

subject id

Genomic Observations

Phenotypes

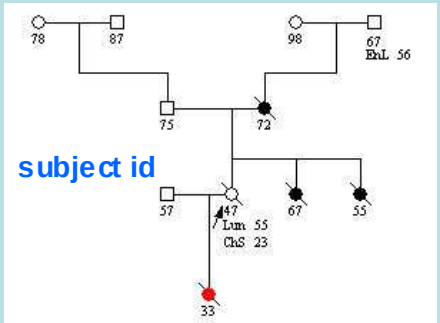
Encapsulation or referencing

Raw Genomic Data

subject id

or HapMap / BSML / MAGE Relational schemas optimized for persistency

Pedigree Template



Genotype

Phenotype

Observed

Interpretive

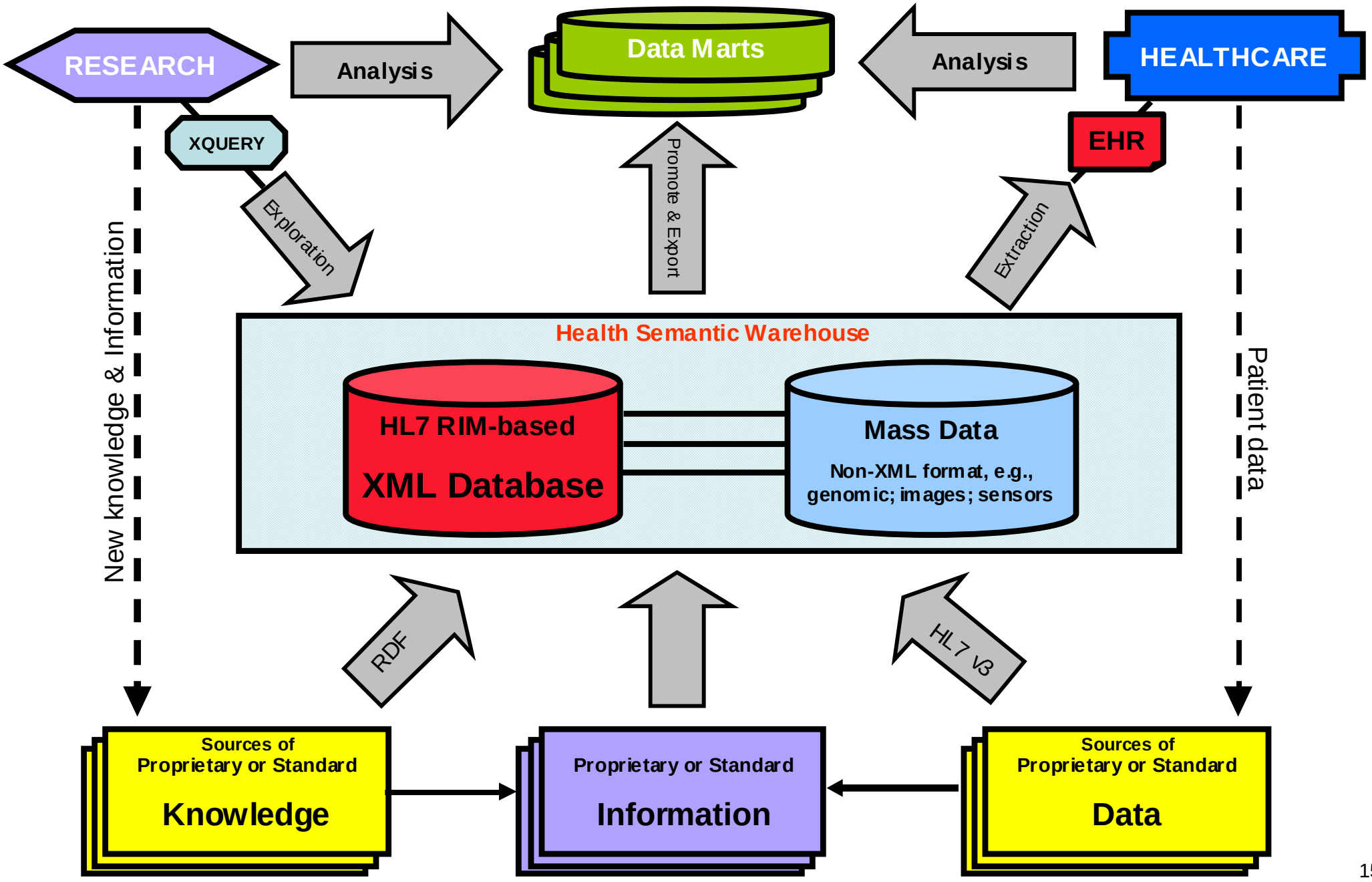
knowledge

Disease Model

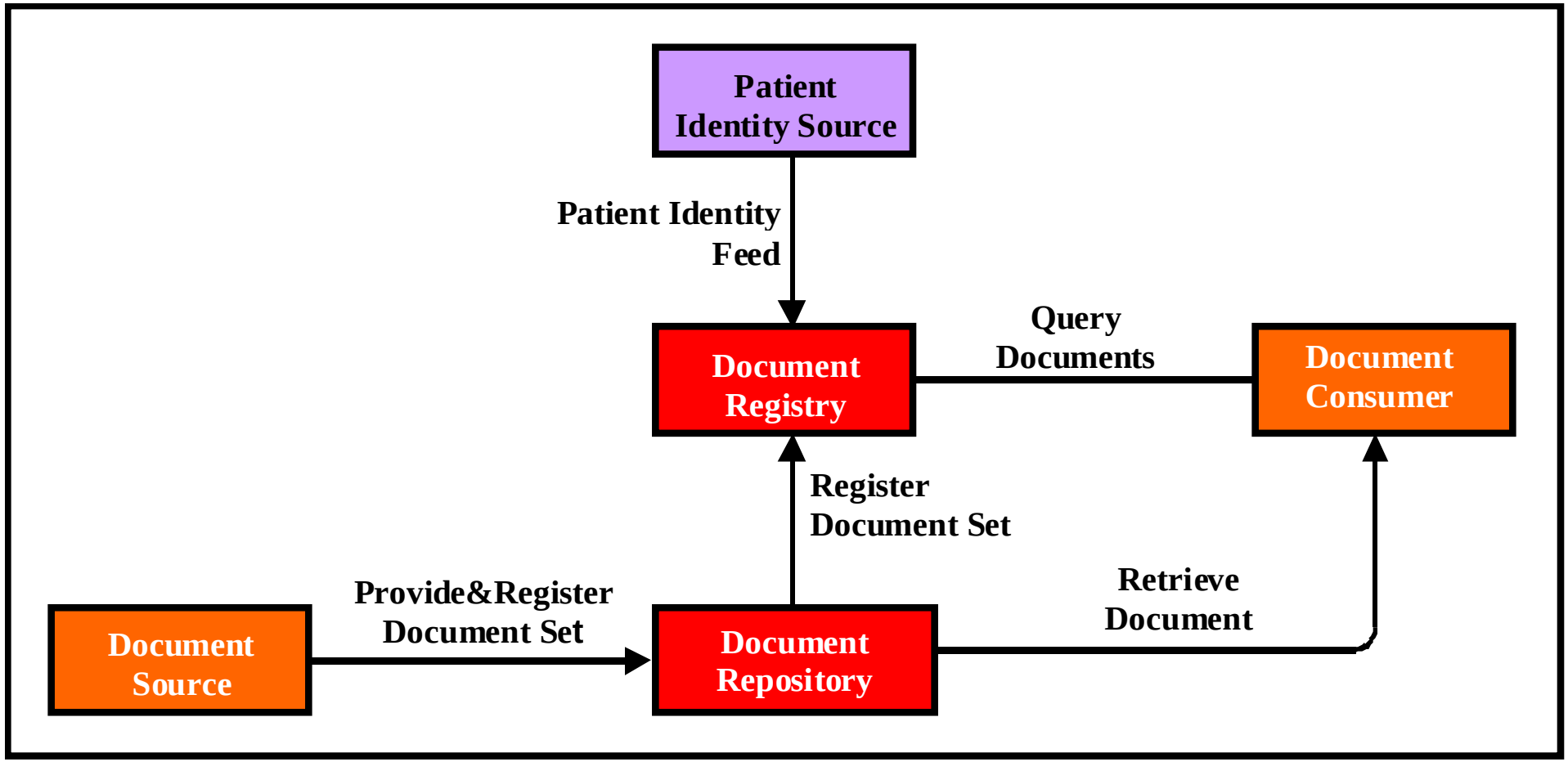
EHR

*Template (or profile) is a set of constraints specific to a project/solution

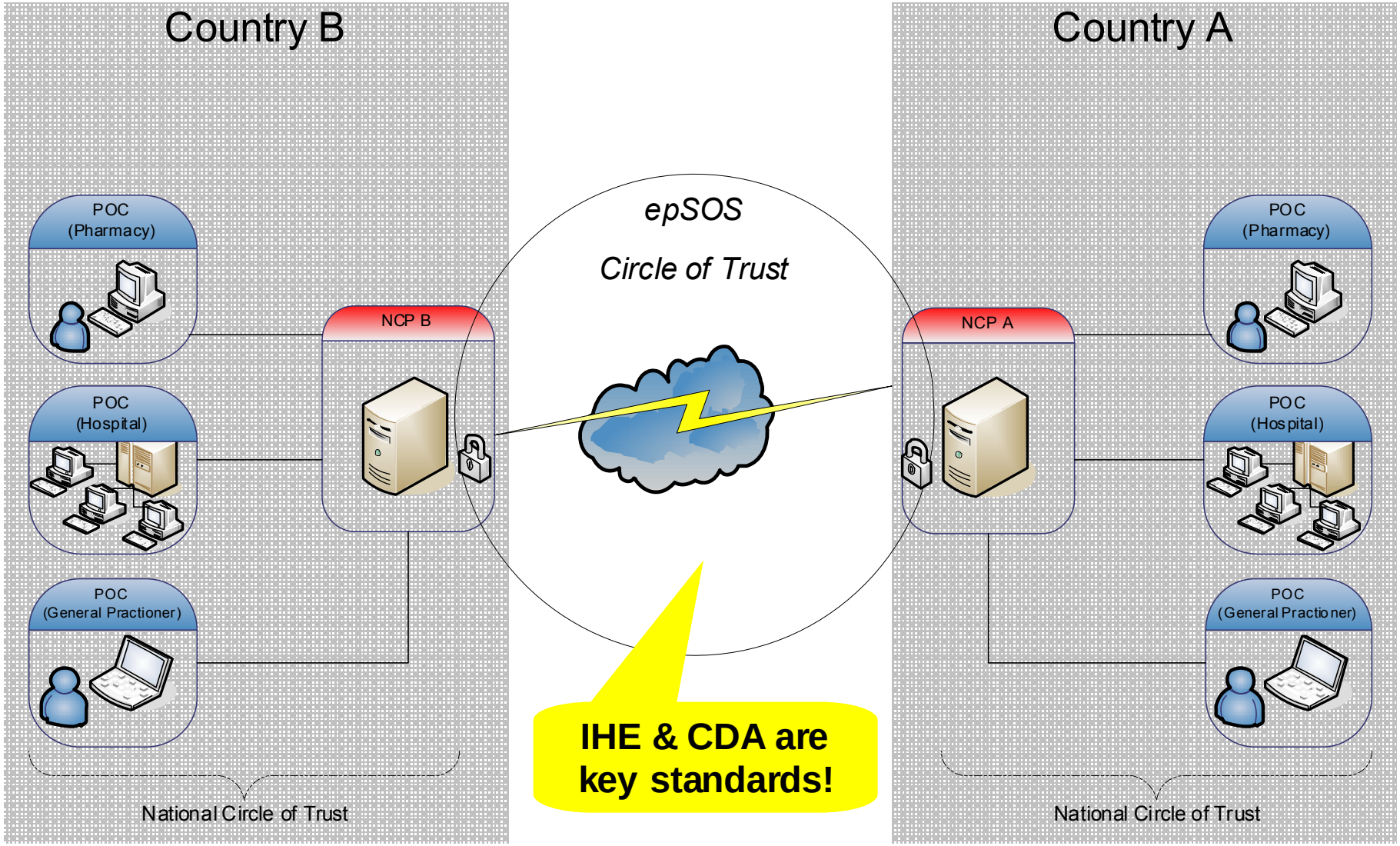
The HyperGenes IT Landscape



IHE Cross-Enterprise Document Sharing (XDS)

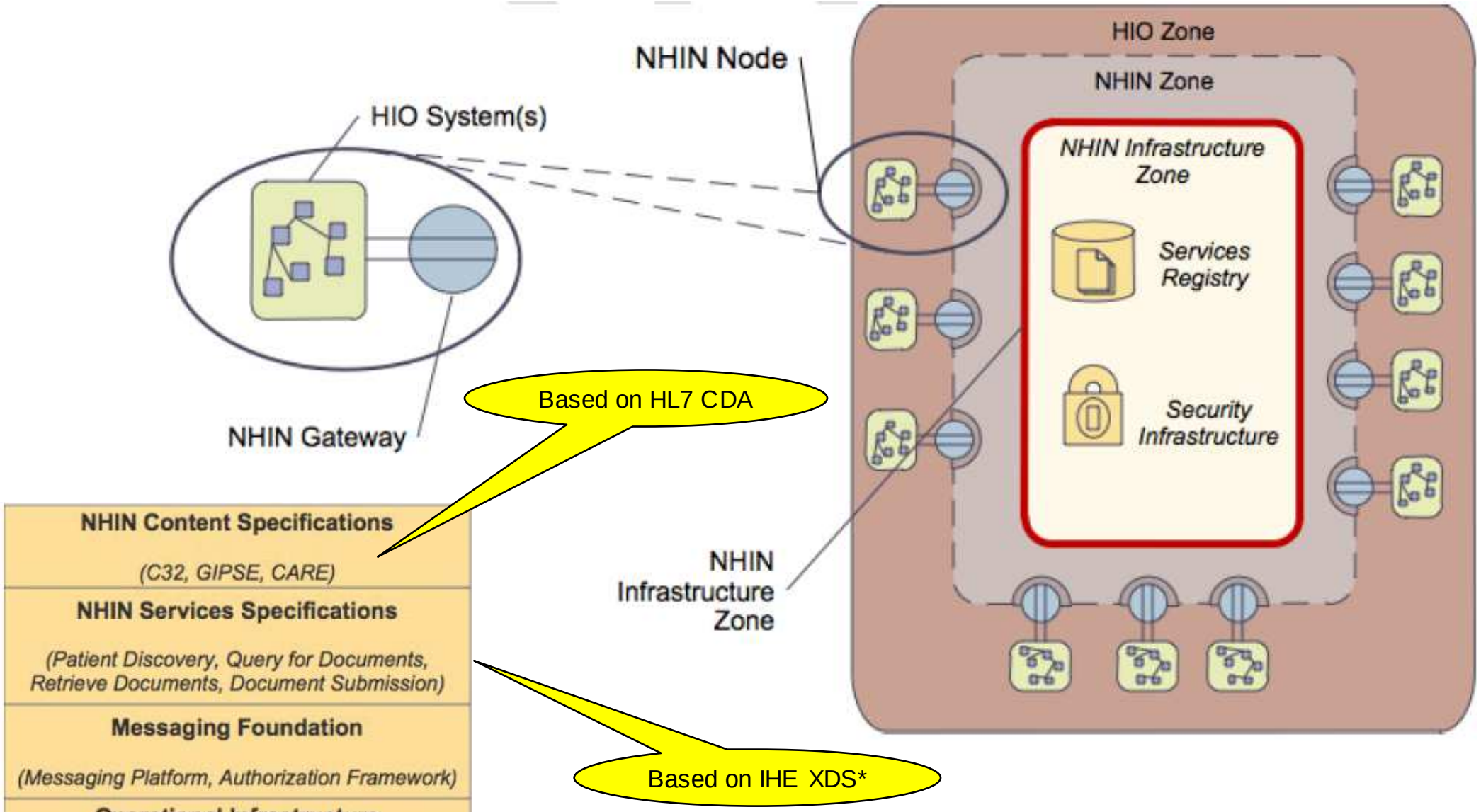


epSOS – European Patients Smart Open Services



Source: epSOS project documentation

USA National Health Information Network



Source: NHIN specifications

*IHE XDS = Integrating the Healthcare Enterprise – Cross Enterprise Document Sharing

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- **Interoperability Foundations**
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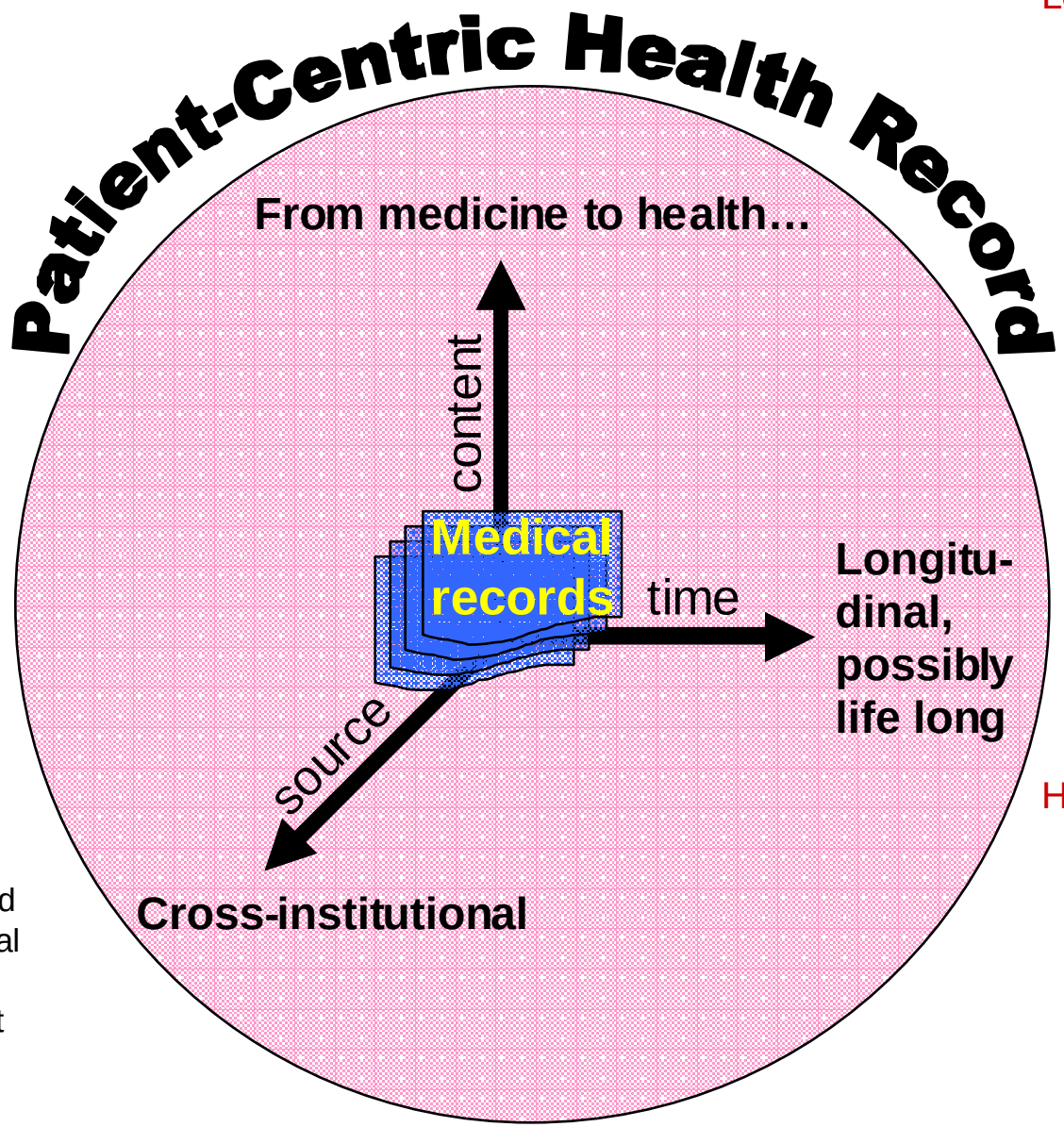
  - **CDA**
  - **Family History**
- **The EHR**
- **IHRB**

From Medical Records to EHR



Longitudinal (possibly lifetime) EHR

A single computerized entity that continuously aggregates and summarizes the medical and health records of individuals throughout their lifetime

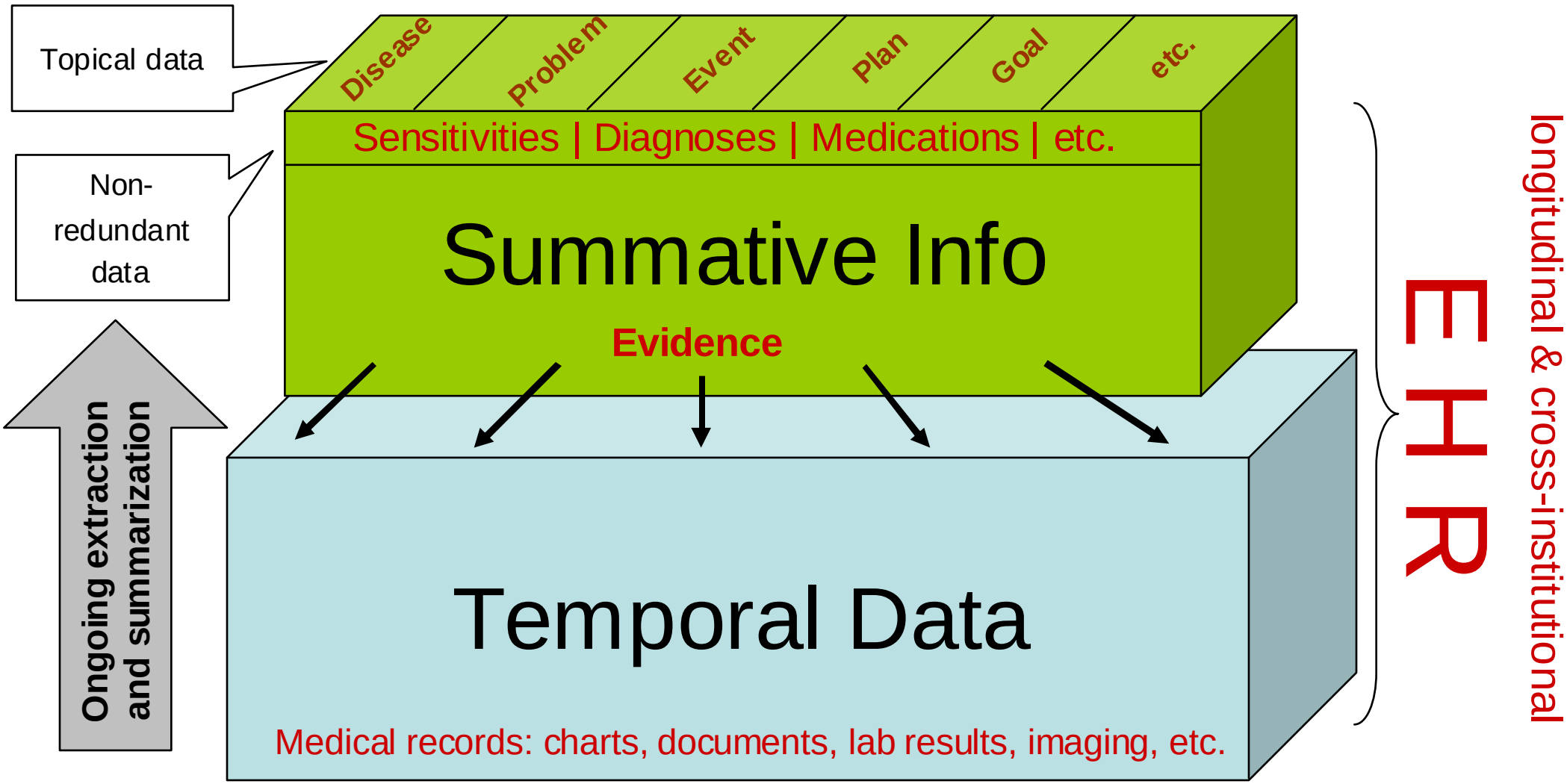
Medical record

Every authenticated recording of medical care (e.g., clinical documents, patient chart, lab results, medical imaging, personal genetics, etc.)

Health record

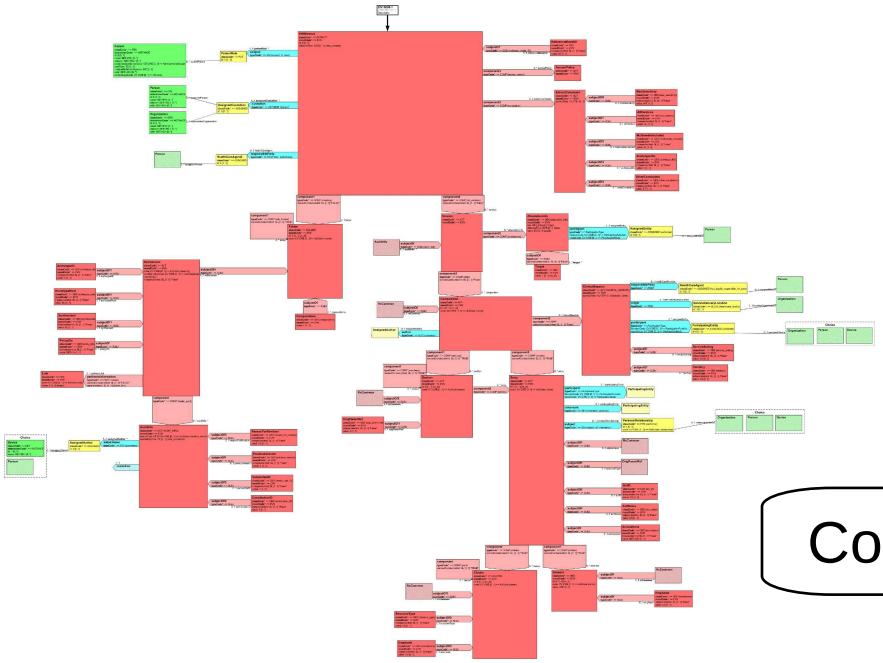
Any data items related to the individual's health (including data such as genetic, self-documentation, preferences, occupational, environmental, life style, nutrition, exercise, risk assessment data, physiologic and biochemical parameter tracking, etc.)

EHR – Layers of Temporal and Summative Data



CEN / ISO EHR 13606 Standard

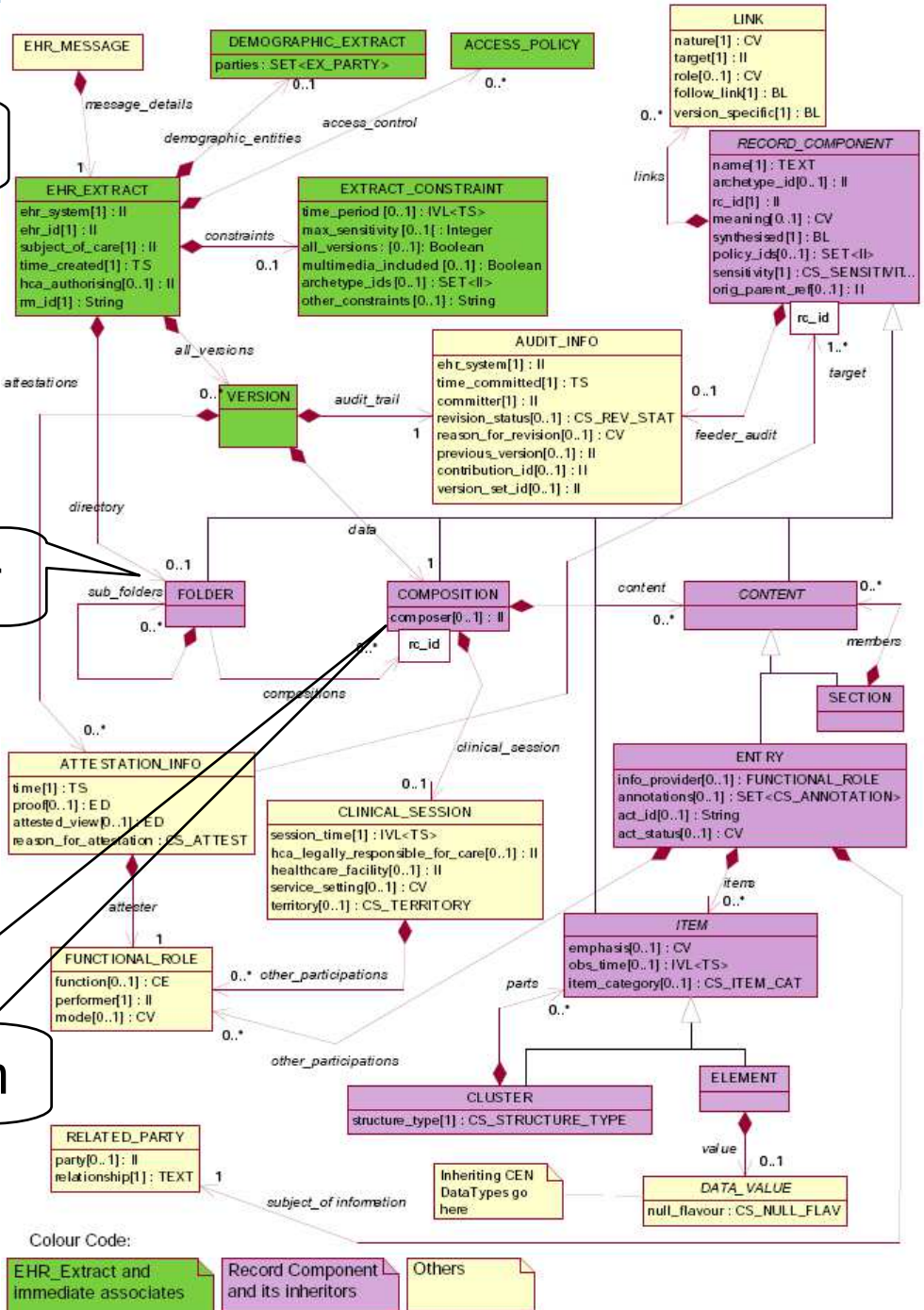
A collaboration* of CEN and HL7 experts to express the EHR model using the HL7 Reference Information Model (RIM)



EHR Extract

Folder

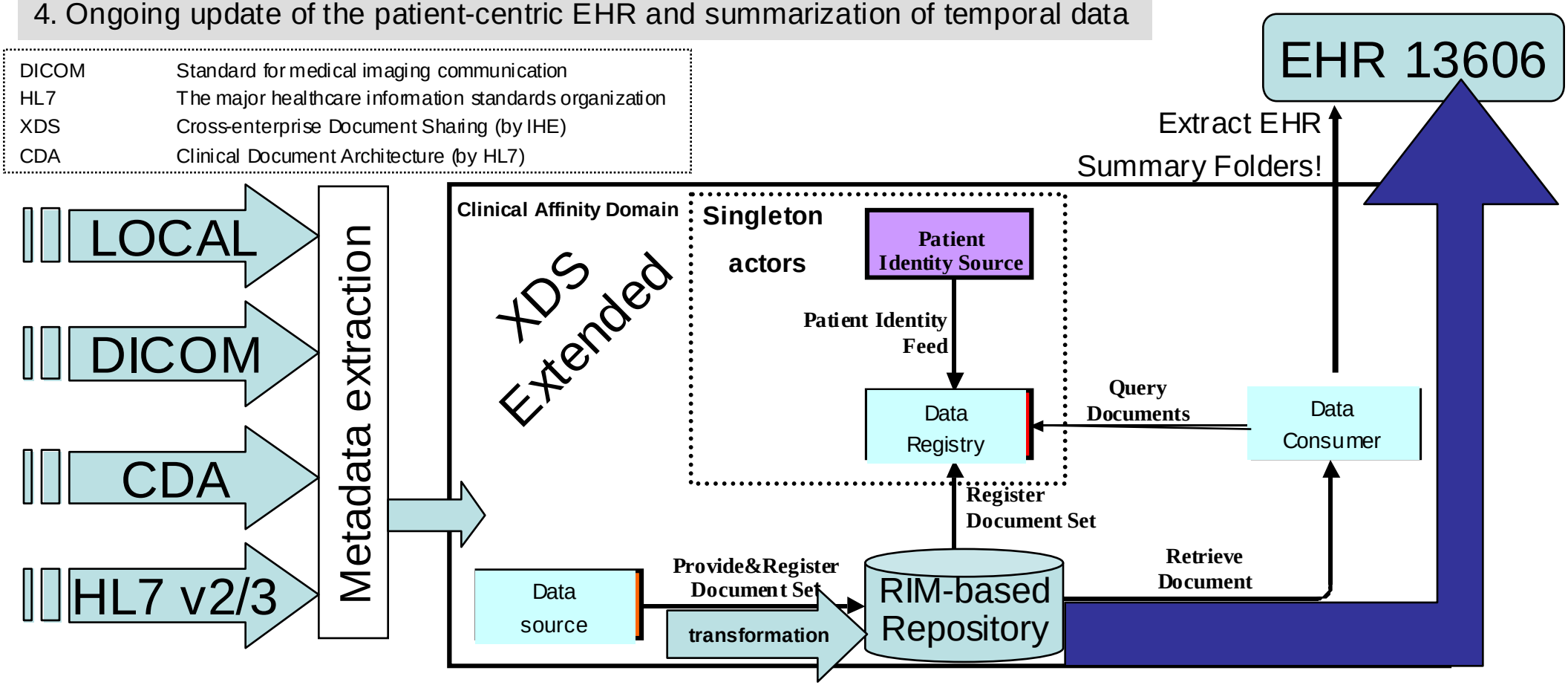
Composition



Rise of the EHR…

1. Extend IHE XDS* to handle any source data while transforming to RIM-based representation
2. Persist incoming data in a RIM-based repository that also plays an XDS Repository
3. Represent the CEN EHR 13606 spec over the RIM
4. Ongoing update of the patient-centric EHR and summarization of temporal data

DICOM	Standard for medical imaging communication
HL7	The major healthcare information standards organization
XDS	Cross-enterprise Document Sharing (by IHE)
CDA	Clinical Document Architecture (by HL7)



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How could Lifetime EHR be Sustained and Preserved?

- From the PCAST report:
  "*The approach that we describe requires that there be a common infrastructure for locating and assembling individual elements of a patient's records, via secure "data element access services" (DEAS). Importantly, this approach does not require any national database of healthcare records; the records themselves can remain in their original locations. Distinct DEAS could be operated by care delivery networks, by states or voluntary grouping of states, with possibly a national DEAS for use by Medicare providers. All DEAS would be interoperable and intercommunicating, so that a single authorized query could locate a patient's records, across multiple DEAS.*"

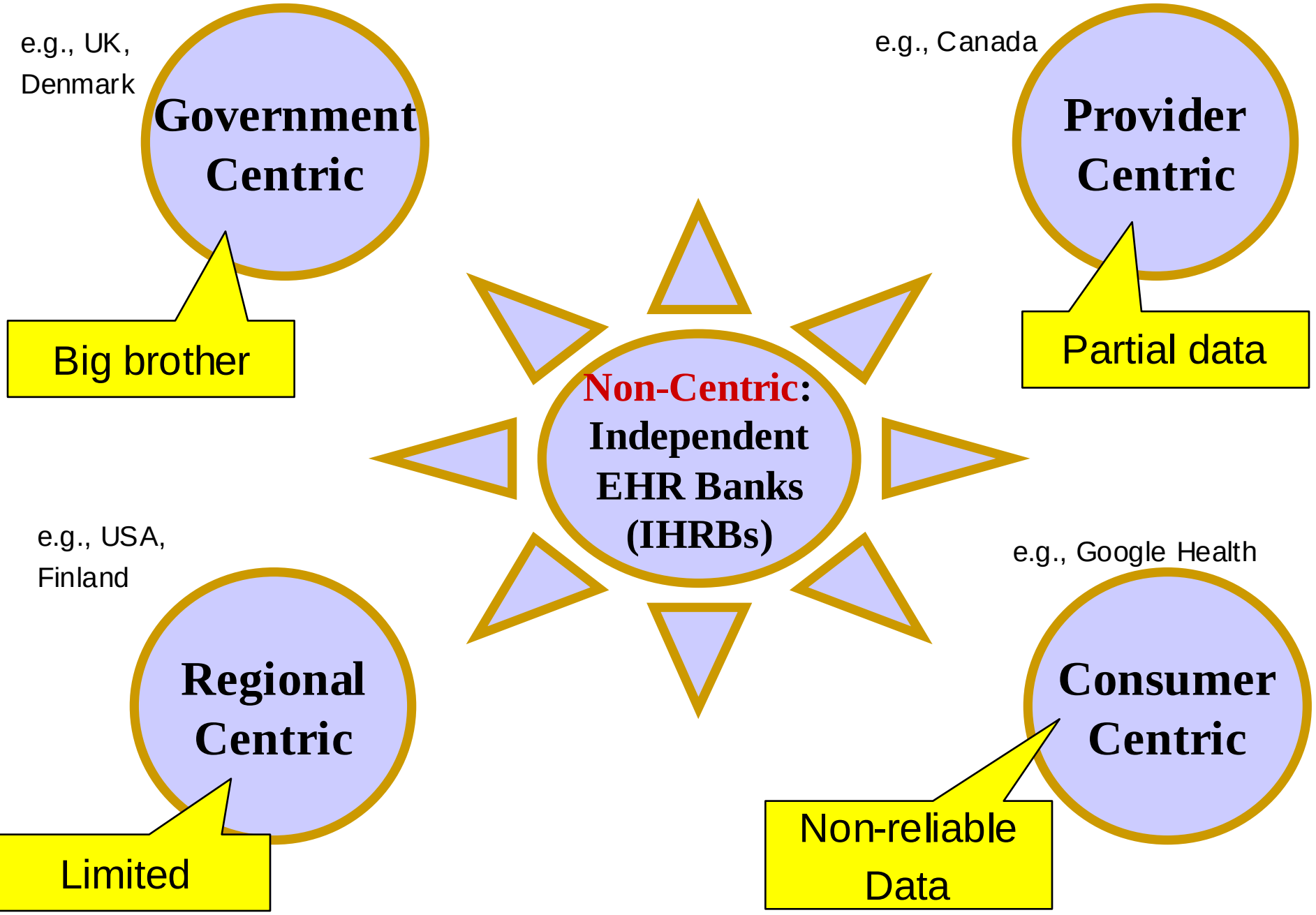
Is it really an axiom?!

Patient-centric EHR Challenges

- Longitudinal EHRs should not be virtual / federated
  - Rationale*: sources might not be available or be semantically different; true summarization cannot be done “on the fly”
- Given the need for aggregated EHR, the challenge is –
  EHR sustainability!
- Main assertion*:
  None of the existing players in the healthcare arena can, or should, sustain lifetime EHRs
  - Rationale:
    - Involves intensive IT computing tasks (archiving / preservation in particular) which are not the main focus nor expertise of existing players
    - If an existing player sustains EHRs, it might lead to ethical conflicts

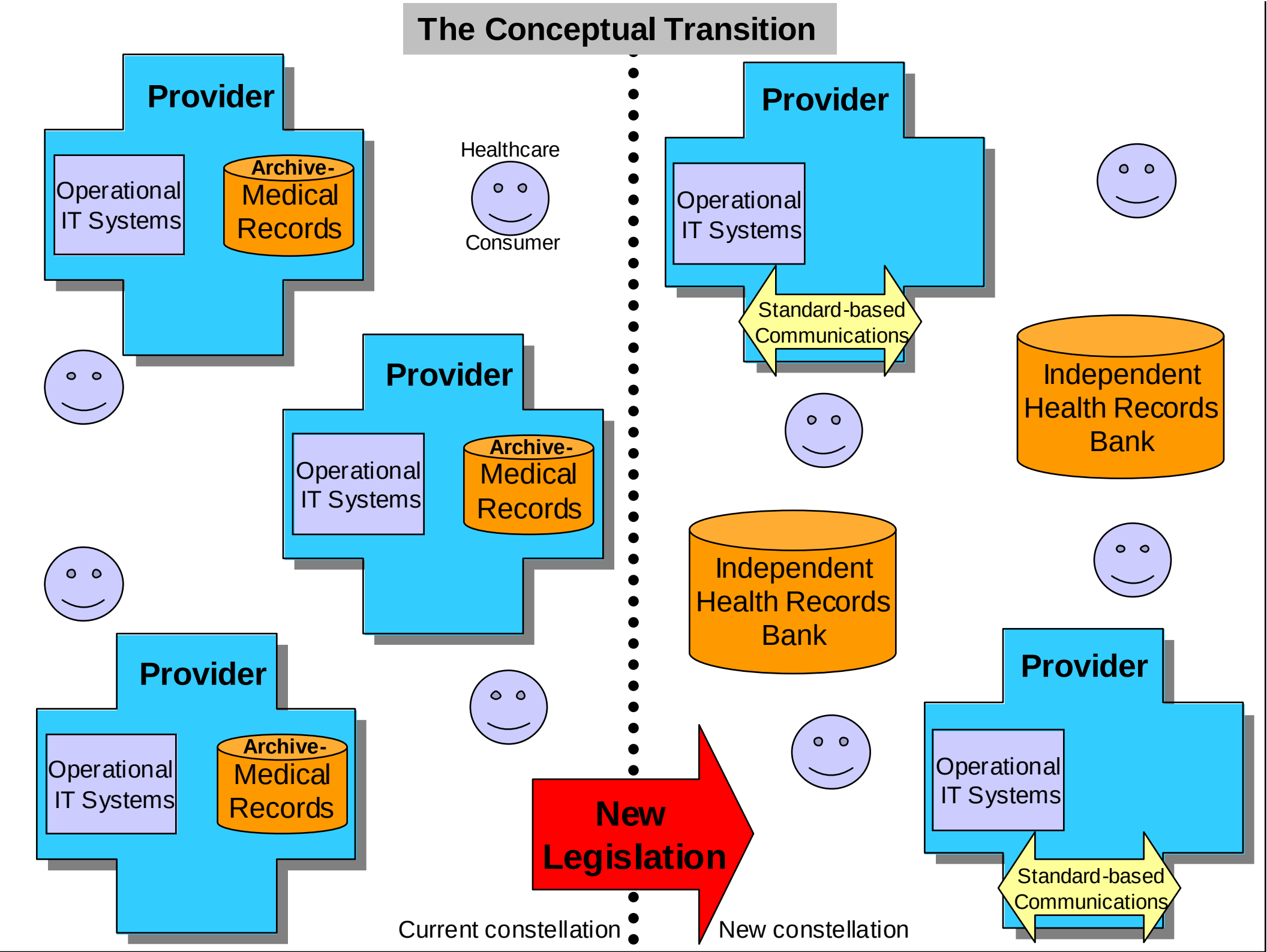
* These assertions and the IHRB vision are not necessarily the view of the IBM corporate; they are research hypotheses.

EHR Sustainability Constellations



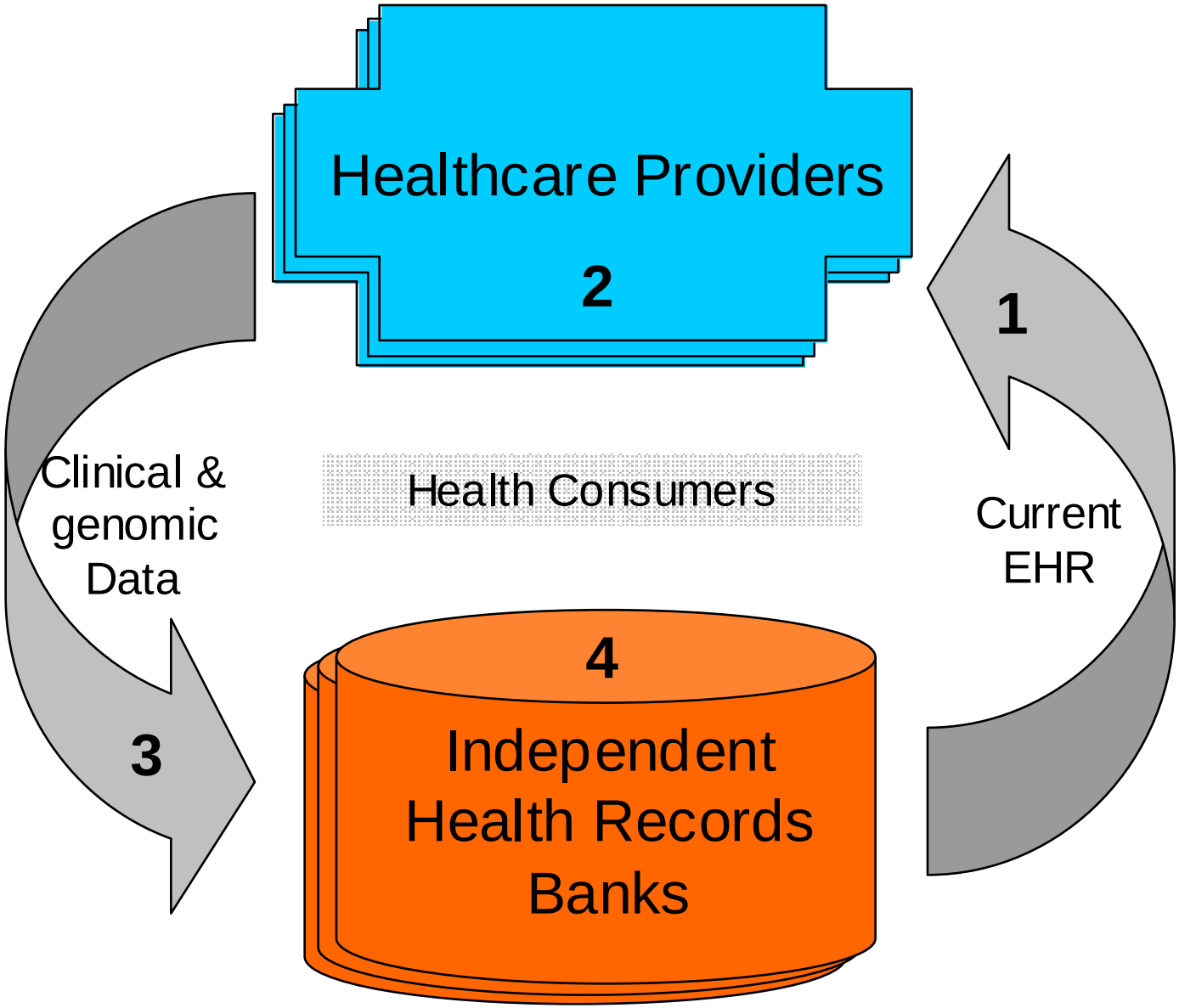
Main principles of the IHRB legislation

- The medico-legal copy of a medical record resides solely in an IHRB
- An IHRB must be independent of healthcare providers, health insurers, government agencies, or any entity that may present a conflict of interests
  - An IHRB must function as an objective entity, serving all stakeholders
  - An IHRB is the custodian of its customers' EHRs, thus avoiding the need for the sensitive definition of EHR ownership
- Allow for multiple independent IHRBs, regulated by national (or international) regulators
- A consumer's EHR is identified by its IHRB account number, so there is no need for unique IDs at any level (regional, national or international)
- Authorized access to all parties; only ethical committees can limit patient access
- A consumer can move from one IHRB to another
- Holding multiple accounts is not recommended, however
  - any attested medical record must reside in only one IHRB account


The Conceptual Transition
Provider
Operational IT Systems
Archive-
Medical Records
Healthcare
Consumer
Provider
Operational IT Systems
Standard-based Communications
Independent Health Records Bank
Provider
Operational IT Systems
Archive-
Medical Records
Independent Health Records Bank
Provider
Operational IT Systems
Archive-
Medical Records
New Legislation
Provider
Operational IT Systems
Standard-based Communications
Current constellation
New constellation

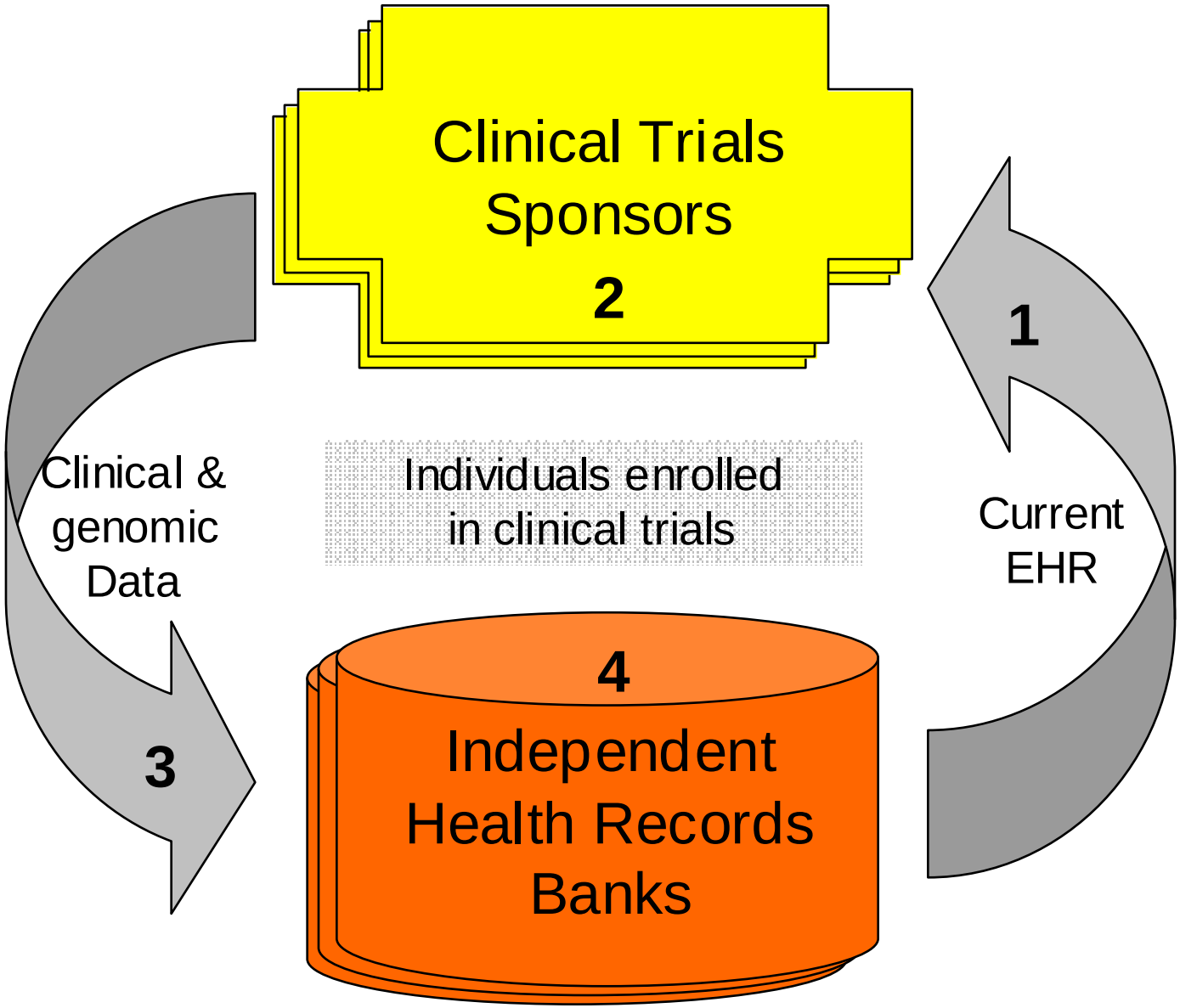
The EHR Main "Production Cycle"

1. Healthcare Provider receives the current EHR from the patient's IHRB
2. Provides care to the patient
3. Sends medical records back to the patient's IHRB
4. EHR is updated



The EHR "Production Cycle" with Pharma

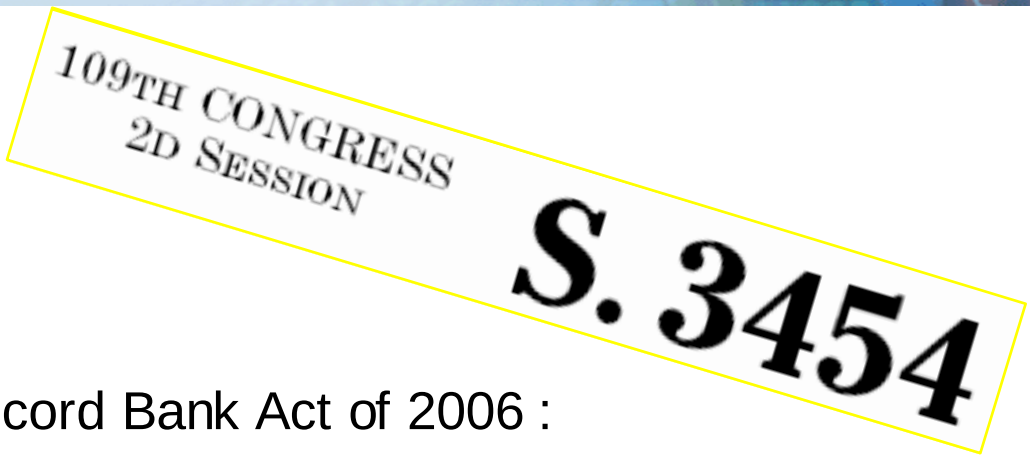
1. Clinical Trials Sponsor receives the current EHR from the patient's IHRB
2. Select, enroll & engage patient in a clinical trial
3. Sends trial records back to the patient's IHRB account
4. EHR is updated



IHRB Main Benefits

- Healthcare providers cut costs of long-term archiving for medical records
- Healthcare providers have a complete medical history of any patient requesting care
- Healthcare providers have EHR summative information that facilitates the intake of new patients
- The EHR might also include moderated self documentation and other sources of health data
- Multiple competing IHRBs will provide better services to all parties
- No need for unique IDs that might harm individual privacy
- Privacy is better protected as it is in the core of the IHRB activity; mitigates the unavoidable tension of privacy versus availability
- Based on proper patient consent, truly anonymized data could be made available to public health agencies, clinical research institutes, and the pharma

IHRB Bills were introduced in the US!



Brownback (R-KS): Independent Health Record Bank Act of 2006 :

- IHRB goals are to save money and lives in the health care system
- Only non-profit entities are permitted to establish IHRBs
- IHRBs function as cooperative entities that operate for the benefit and interests of the membership of the bank as a whole
- Revenue:
  - IHRB's may generate revenue by
    - charging health care entities account holders account fees for use of the bank
    - the sale of non-identifiable and partially identifiable health information contained in the bank for research purposes
  - Revenue will be shared with account holders and may be shared with providers and payers as an incentive to contribute data
  - Revenue generated by an IHRB and received by an account holder, healthcare entity or health care payer will not be considered taxable income

Find Out More on IHRB

- More details can be found in my papers published in the Journal "Methods of Information in Medicine"
- Comments: shabo@il.ibm.com

IHRB History:

1998: Amnon Shabo raises the idea and founds the **Bankomed** initiative, set out to establish a first experimental IHRB

1999: IHRB is the core of the **Bankomed** business plan, submitted to major venture capitalists in Israel

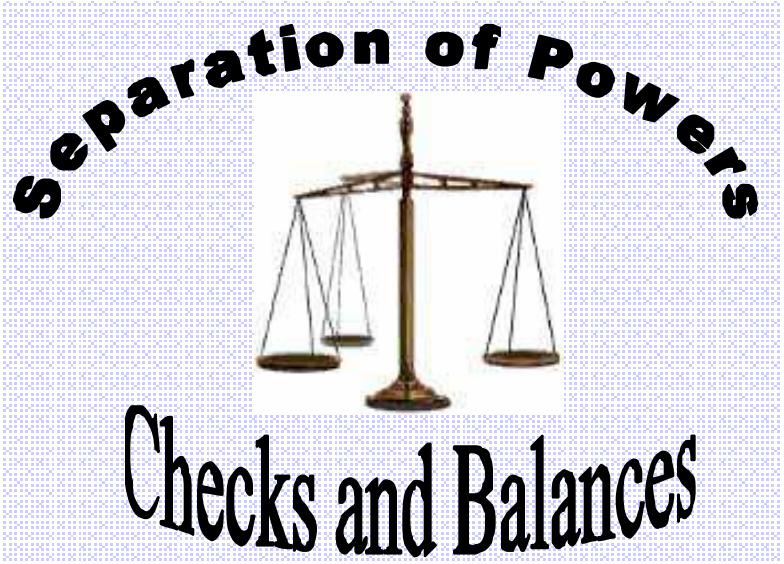
2001: IHRB is first presented by Amnon Shabo in the TEHRE 2001 conference, November 2001, London (as IBM Research paper)

2003: IHRB is the core of the **mEHR** proposal made to the EC FP6 by 19 European partners (including IBM Research Lab in Haifa)

2004: HRB (Health Records Banks) is a core part of **IBM Research** Strategy in Healthcare

2005: IHRB is published in IP.com

2006: IHRB Bills were introduced in the US



The End

- Thanks for your attention!
- Questions?
- Comments: shabo@il.ibm.com

Unlocking the Power of Health Information.