

# Standards in healthcare

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Foliendesign: Christoph Aigner, Nadja Lederer

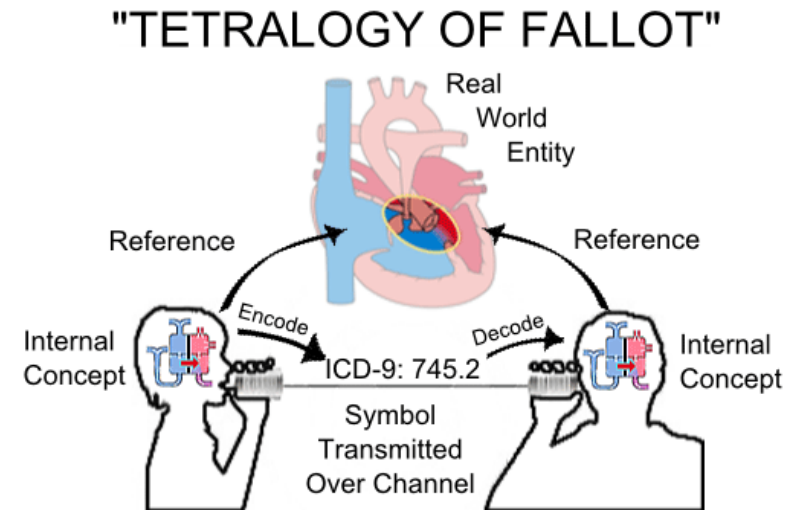


INSO - Industrial Software

Institut für Rechnergestützte Automation | Fakultät für Informatik | Technische Universität Wien

# Semantic interoperability

- We need standards to build large, complex and distributed healthcare infrastructures with many different stakeholders involved!
- Standards help to achieve semantic interoperability.
- Semantic interoperability is the ability to automatically interpret the information exchanged meaningfully and accurately in order to produce useful results as defined by the end users of both systems. [1]



[1] <http://www.en13606.org/>

Bild: <http://wareflo.com/2014/03/from-syntactic-semantic-to-pragmatic-interoperability-in-healthcare-submitted-to-himss14-blog-carnival/>

# Standards

- Health Level 7 (HL7)
  - V2
  - V3 RIM, CDA
  - FHIR
- CEN EN 13606
- openEHR
- IHE

Versions 2 and 3, RIM, CDA, FHIR

# HL7 – HEALTH LEVEL 7



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

Vision:  
Being lords of #awesomeness  
in the world of #standards

Focus TODAY:

- **provide a framework** and related standards
  - to **exchange, integrate and share** EHR information
  - on health services to **manage and evaluate** EHR information

## What it IS #allthereistoknow

- It has a **different formal name**

=> no worries - we are not gonna bother you with that

BUT

- “*most widely used protocol*” for **exchanging messages**  
between different health care providers and medical systems

## What it IS NOT #allthereistoknow

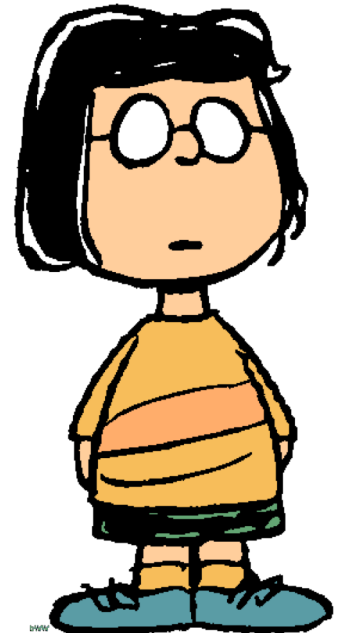
- was NOT developed systematically

*Charlie: What about **consistency**?*

*Marcie: **Crap... I mean, it's lacking.***

*Charlie: What about **flexibility**?*

*Marcie: **Way cool. Allows it big time.***



## What it IS NOT #allthereistoknow

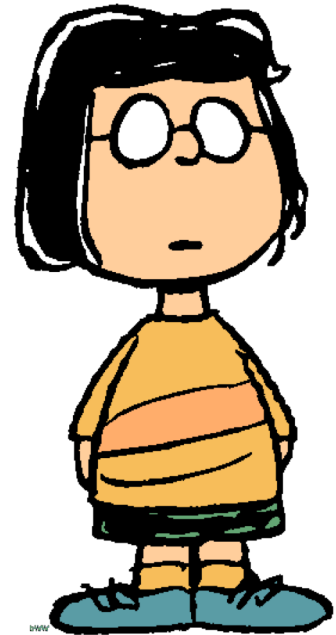
- ..and it is **NOT** based on any underlying reference model

*Charlie: Huh?!?*

*Marcie: That's an even crappier fact.*

*1.) Implementations will be inconsistent.*

*2.) Applications now need to rely on **ADDITIONAL AGREEMENTS** to ensure interoperability.*





Everything to the better with..

# HL7 VERSION 3 AND V3 RIM?

# HL7 – Version 3 and v3 RIM (i)

*Charlie: So - what's the catch with this v3 and v3 RIM thing again?!?*

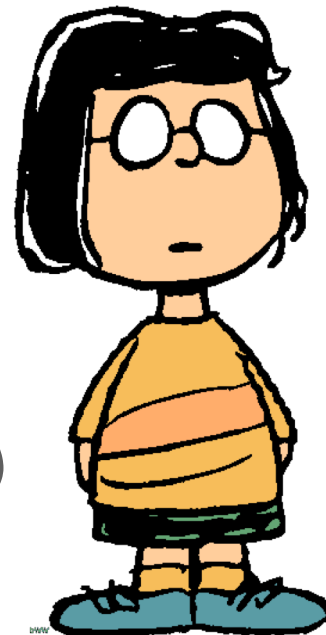
*Marcie:*

*1.) Awesome new features are awesome. #better*

*2.)  $3 > 2$*

*3.) So, people from v3 were smart enough to solve most problems of v2. #solutions*

- Key feature of v3 is the newly introduced **Reference Information Model (RIM)**
- it is NOT a full specification of an EHR system!



## HL7 – a more graphical comparison

# HL7 v2.x message

```
MSH | ^~\& | AcmeHIS | StJohn | ADT | StJohn | 20060307110111 || ADT^A04 | MSGID20060307110111 | P | 2.4  
EVN | A04  
PID | || 12001 | Jones^John | 19670824 | M | || 123 West St.^Denver^CO^80020^USA  
PV1 | O | OP^PAREG^ ||| 2342^Jones^Bob ||| OP ||||| 2 ||||||||| 20060307110111 |  
AL1 | 1 | | 3123^Penicillin | Produces hives~Rash~Loss of appetite
```

*name*

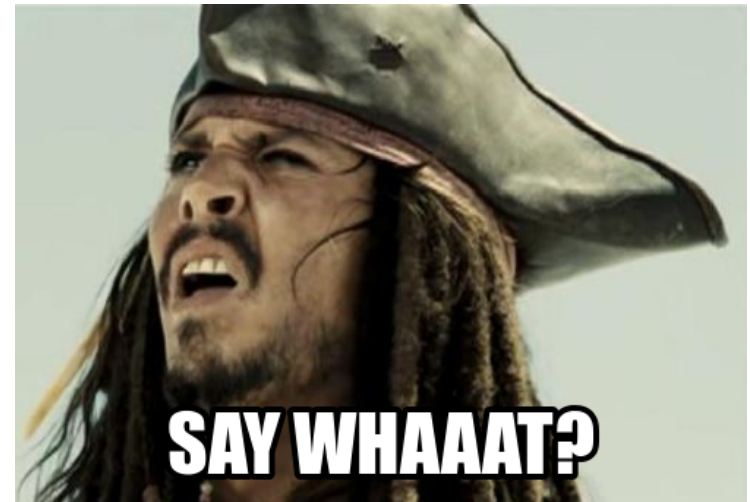
*date of birth*

- A more graphical comparison of version 2 versus **version 3**
- Which one do you like better?

# HL7 v3 message

```
<author>
  <assignedEntity>
    <id root = "2.16.840.1.113883.9876.210.3" extension = "5332443" />
    <telecom value = "tel: +1(317)630-7960" />
    <assigneePerson>
      <name>
        <given>Keiko</given>
        <family>Jones</family>
        <suffix>MD</suffix>
      </name>
    </assigneePerson>
  </assignedEntity>
</author>
<!-- Removed consumable -->
<patientSubject>
  <patient>
    <id root = "2.16.840.1.113883.9876.211" extension = "344253425" />
    <addr>
    <telecom value = "tel:213-555-4344" />
    <patientPerson>
      <id root = "2.16.840.1.113883.4.1" extension = "333224444" />
      <name>
        <given>George</given>
        <given>Simon</given>
        <family>Wigny</family>
      </name>
      <administrativeGender code = "M"
        codeSystem = "2.16.840.1.113883.5.1" />
      <birthTime value = "19740423" />
    </patientPerson>
  </patient>
</patientSubject>
```

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



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



- it defines all classes and their attributes

*Charlie: What if classes / attributes change over time?*

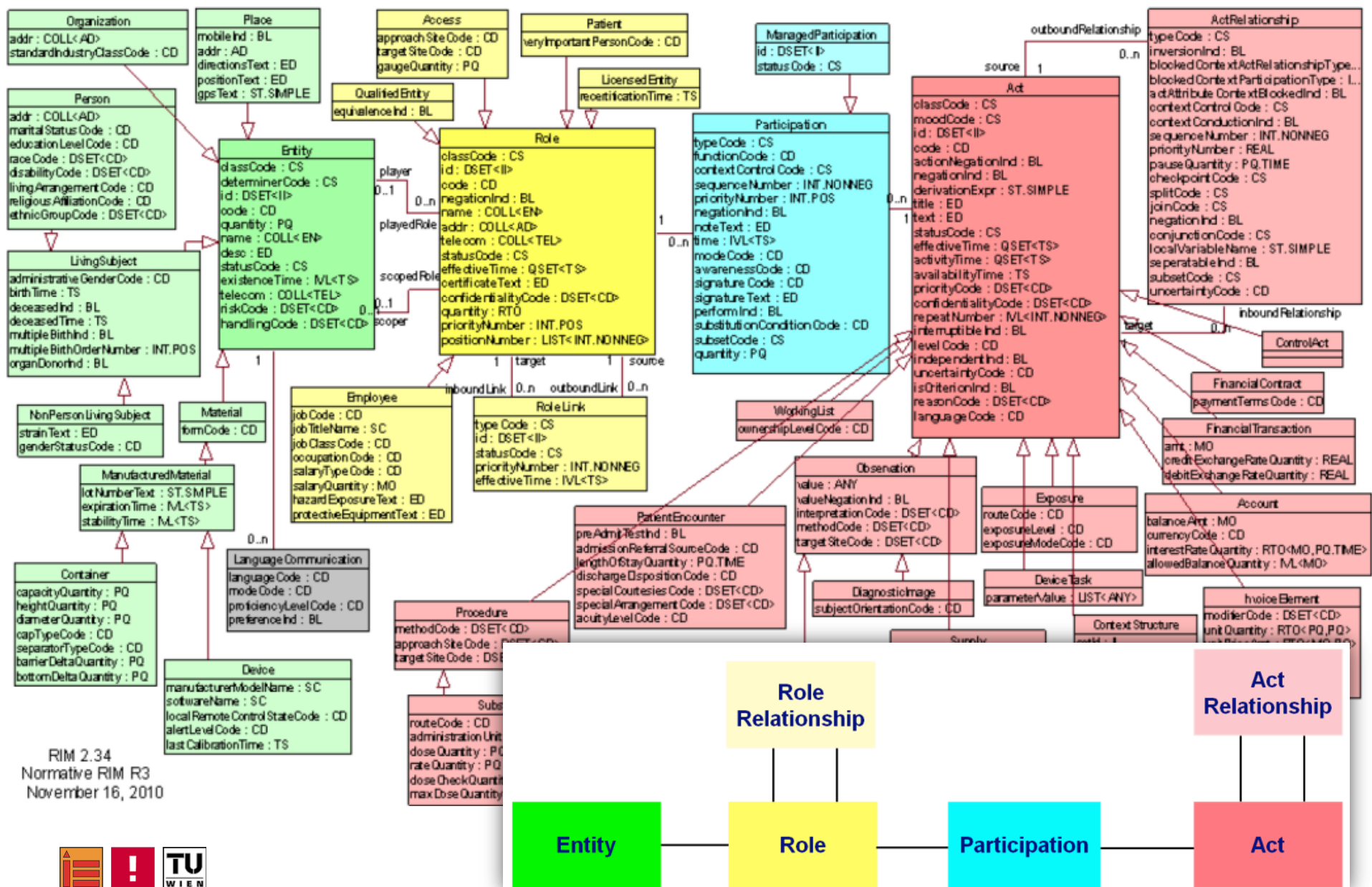
*Marcie: Hm... too bad.*

- and it is hard to extend the model itself

*Charlie: What if one wanted to maintain their applications?*

*Marcie: Hm... that's hard. My bad.*

## HL7 v3 RIM Core Classes (Extract)



# HL7 – Clinical Document Architecture (CDA) (i)

- CDA **provides** medical documents with **structure** and **semantics**

*Charlie: Well... who cares, I guess?!?*

*Marcie:*

*This is different compared to messaging standards we went through previously.*

- CDA defines **how documents are exchanged** by using classes from the RIM

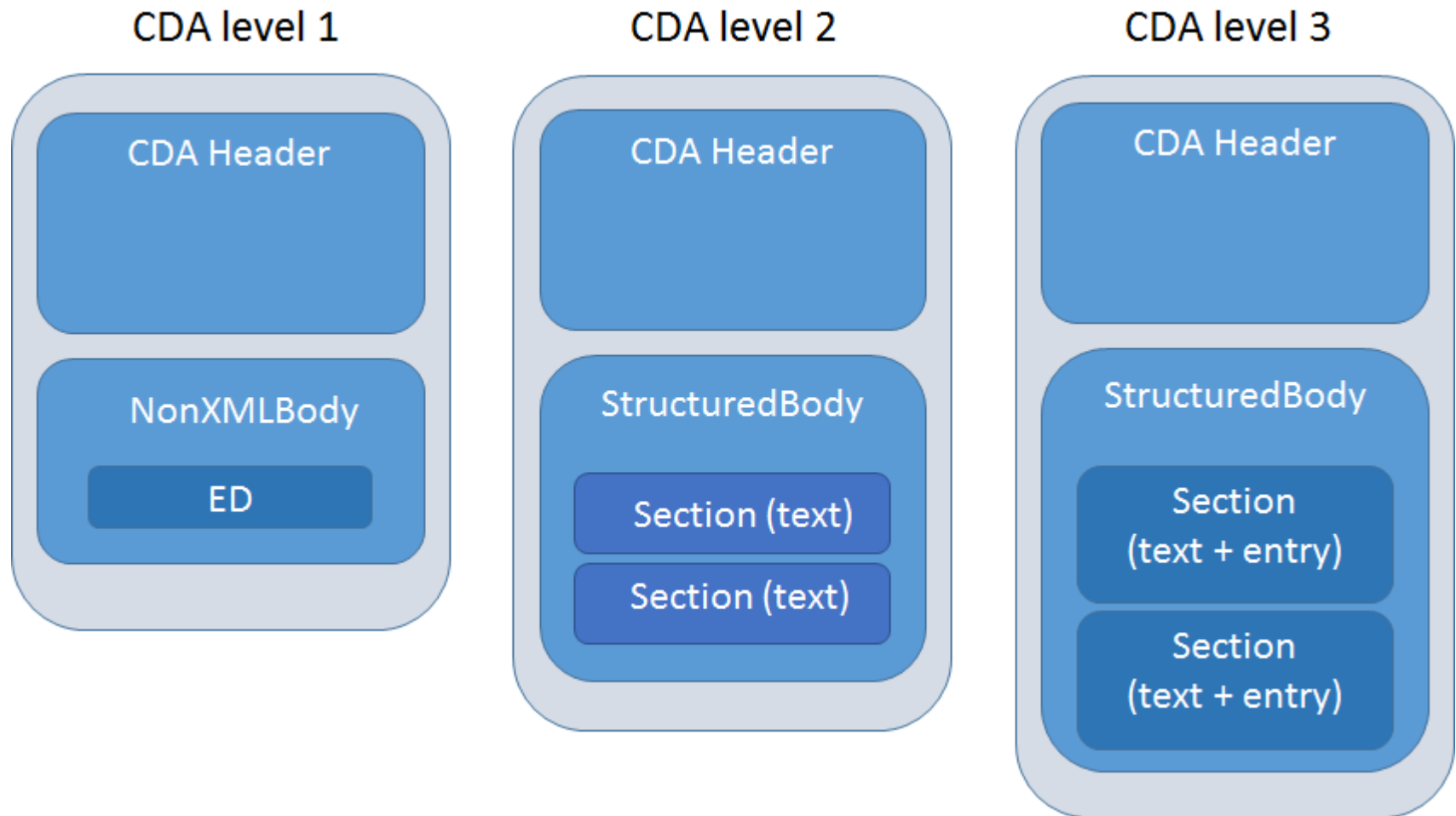
*Marcie:*

*That way, it ensures interoperability.*

*Charlie: Don't be such a smartass, Marc!*



# HL7 – Clinical Document Architecture (CDA) (iii)

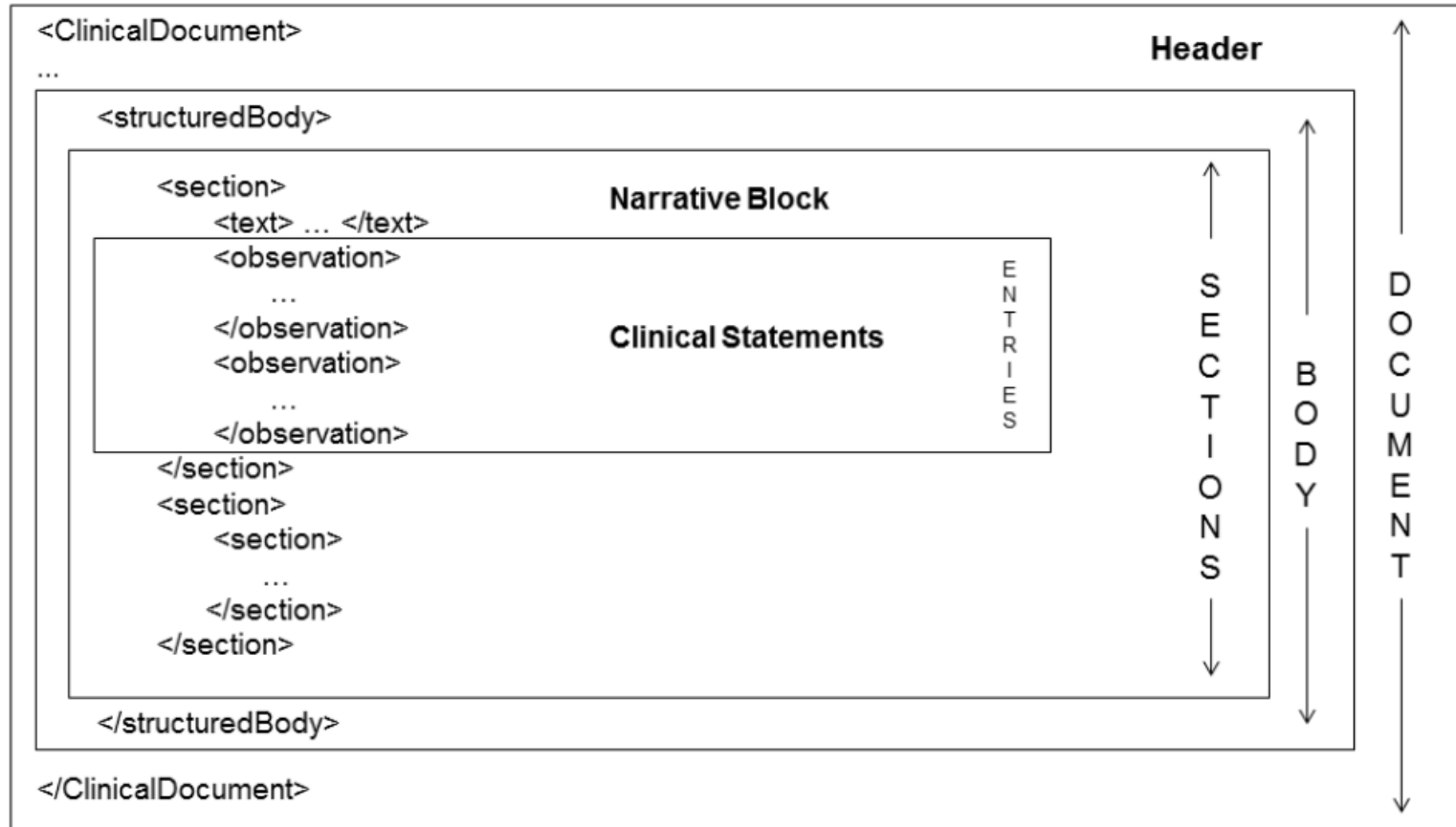


<http://iehr.eu/knowledge/what-is-hl7-cda/>



# HL7 – Clinical Document Architecture (CDA) (ii)

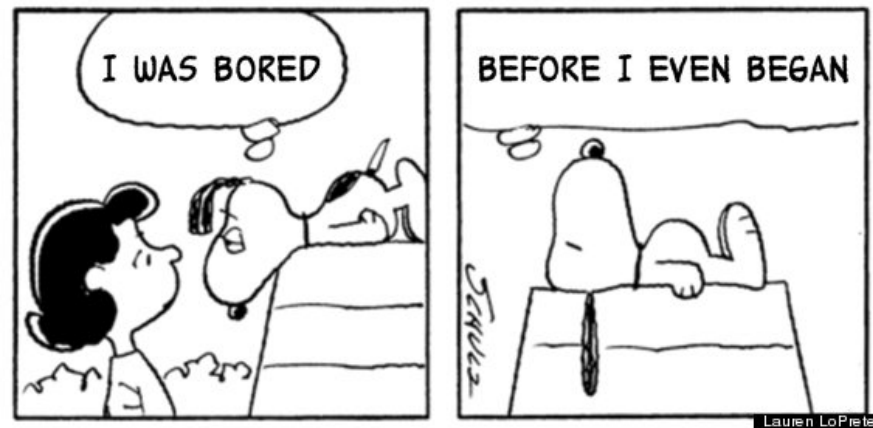
- CDA is based on **XML schemas**



ELGA: [Allgemeiner CDA-Implementierungsleitfaden \(Version 2.06.1\)](#)

# Interoperability is on FHIR

## HL7 FHIR



# The acronym

- **F**ast

Relative – No technology can make integration as fast as we'd like

- **H**ealthcare

- **I**nteroperability

That's why we're here

- **R**esources

Building blocks - more on these to follow

# Facts about HL7 FHIR

- a next-generation standards framework
- combines best features of HL7 Volume 2, 3, CDA
- leverages latest **web standards**
- aims to make implementation easier
- can address **mobile-** and **cloud-based** solutions
- supports exchange via **JSON / XML**
- in FHIR everything is a **resource**

# Implementer Focus

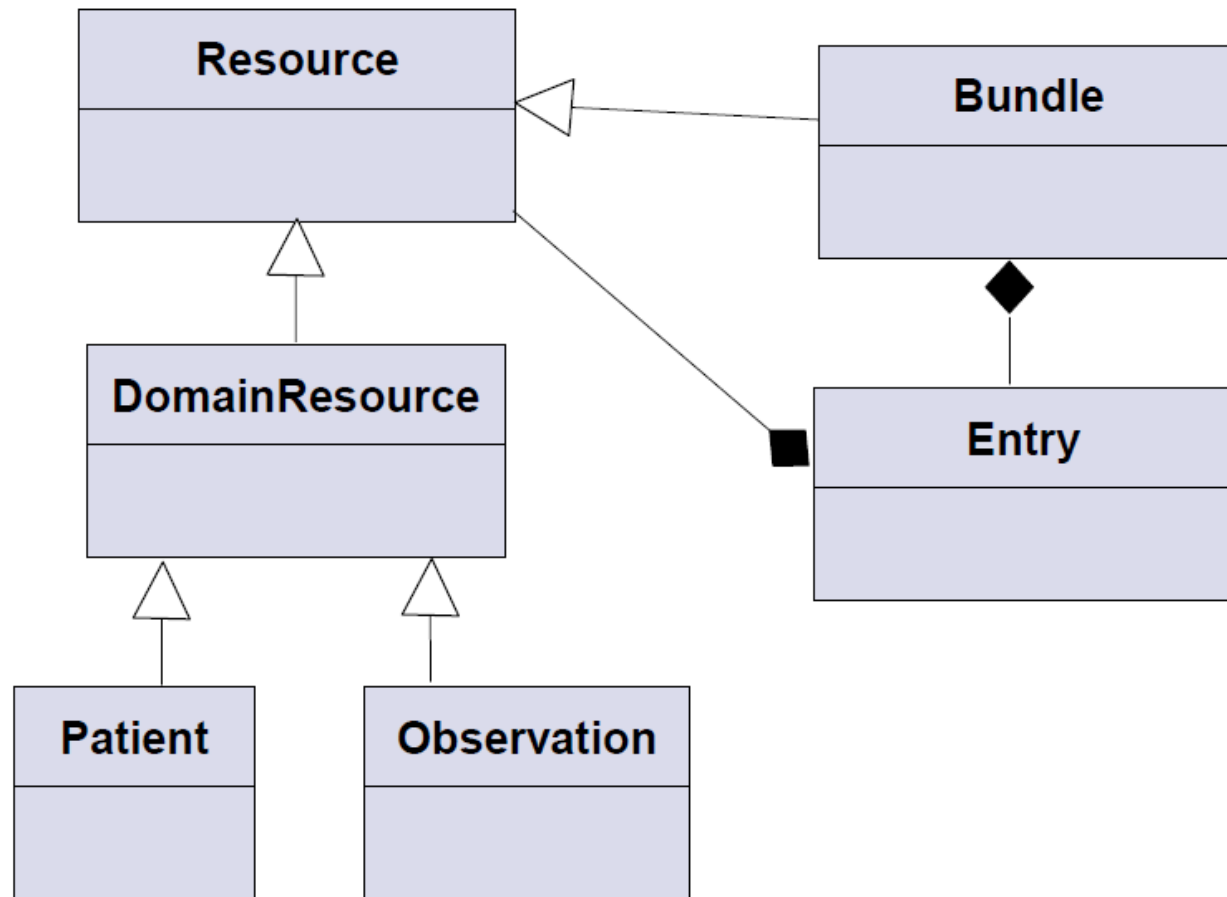
- Specification is written for one target audience: implementers
- Multiple reference implementations
- Publicly available test servers
- Starter APIs published with spec
- Delphi, C#, Java –more to come
- Connectathons to verify specification approaches
- Lots of examples

```
56  )
57  public class Patient extends BaseResource implements
58      @SearchParamDefinition(
59          name = "identifier",
60          path = "Patient.identifier",
61          description = "A patient identifier",
62          type = "token"
63      )
64      public static final String SP_IDENTIFIER
```



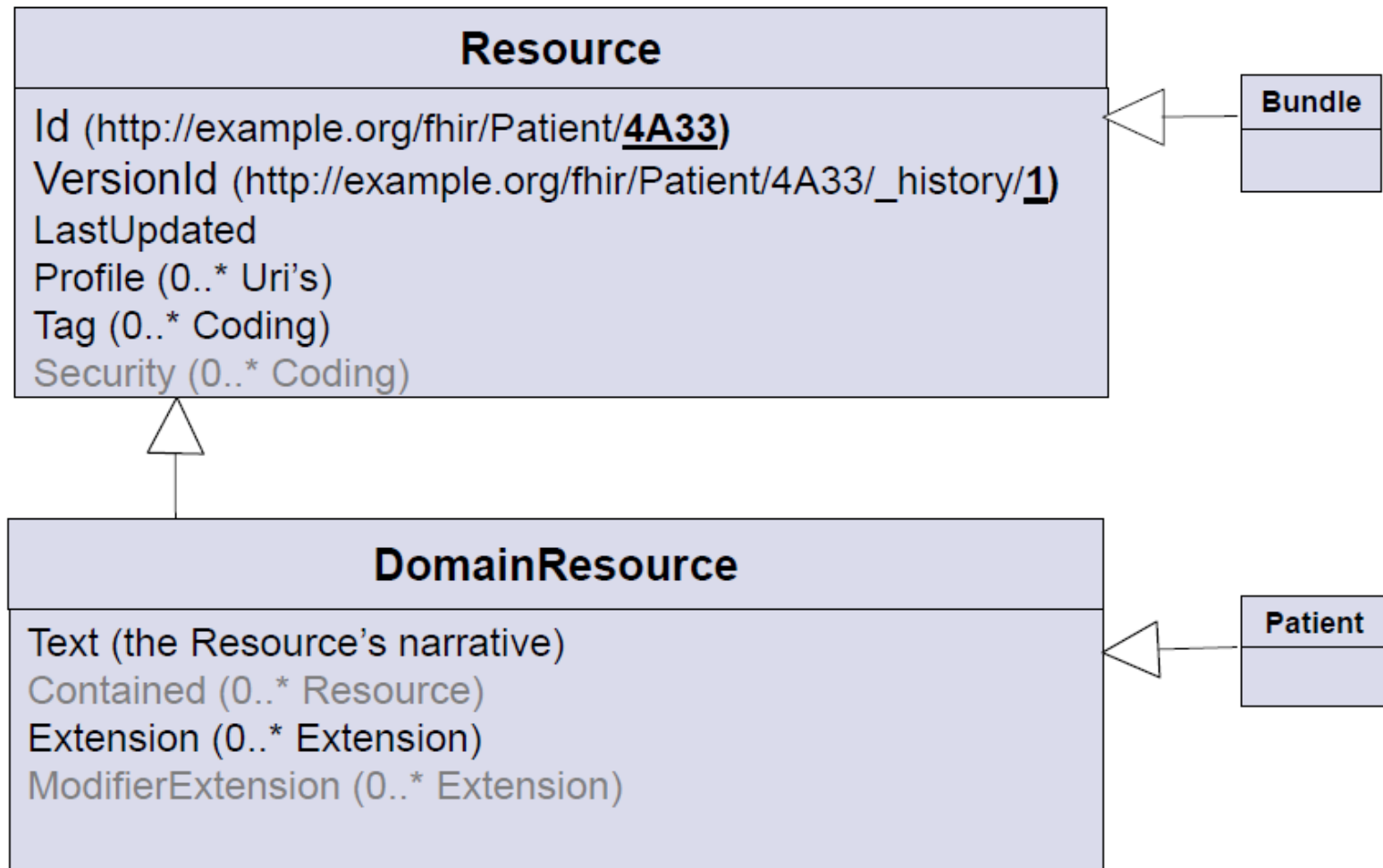
- **“Resources” are:**
  - Small logically discrete units of exchange
  - Defined behaviour and meaning
  - Known identity / location
  - Smallest unit of transaction
  - “of interest” to healthcare
- **Examples**
  - Administrative: Patient, Location, Encounter, Organization
  - Clinical Concepts: Medication, CarePlan, Observation
  - Infrastructure: Document, Message, Profile, Conformance

# Class hierarchy





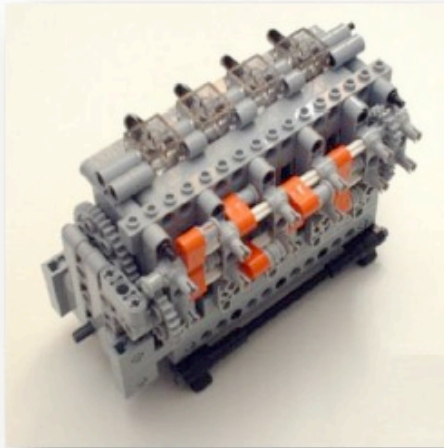
# Basic elements



# Example

```
<Patient xmlns="http://hl7.org/fhir">
  <id value="example"/>
  <meta>
    <versionId value="1" />
    <lastUpdated value="2013-03-17T16:18:45.001" />
    <profile value="http://example.org/fhir/StructureDefinition/patient-nl" />
    <profile value="http://example.org/fhir/StructureDefinition/out-patient-nl" />
    <security>
      <system value="http://hl7.org/fhir/v3/ActCode"/>
      <code value="CEL"/>
      <display value="Celebrity"/>
    </security>
    <tag>
      <system value="http://example.org/fhir/vs/ProductionState"/>
      <code value="TEST" />
      <display value="Testdata - do not use" />
    </tag>
  </meta>
  <text>
    <status value="generated"/>
    <div xmlns="http://www.w3.org/1999/xhtml"><!-- snip --></div>
  </text>
  <extension url="http://hl7.org/fhir/StructureDefinition/patient-birthTime">
    <valueTime value="14:35:45"/>
  </extension>
  <!-- MRN assigned by ACME healthcare on 6-May 2001 -->
  <identifier>
    <use value="usual"/>
    <label value="MRN"/>
    <system value="urn:oid:1.2.36.146.595.217.0.1"/>
  </identifier>
</Patient>
```

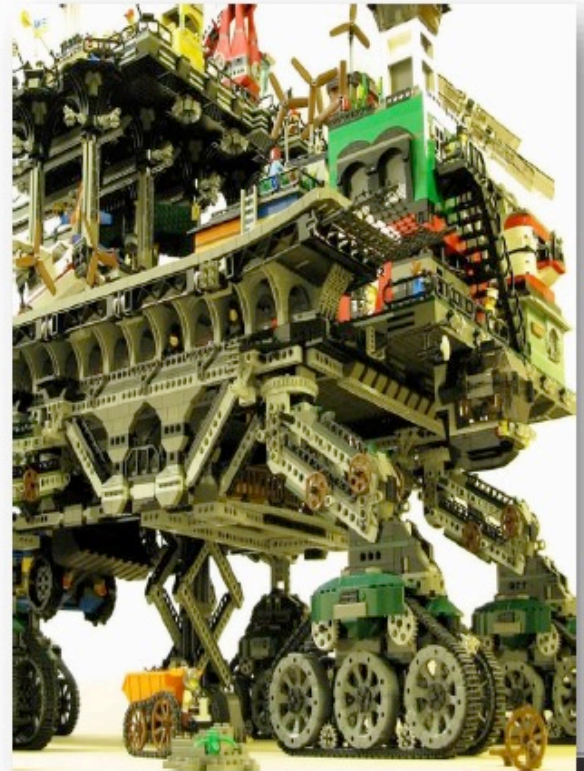
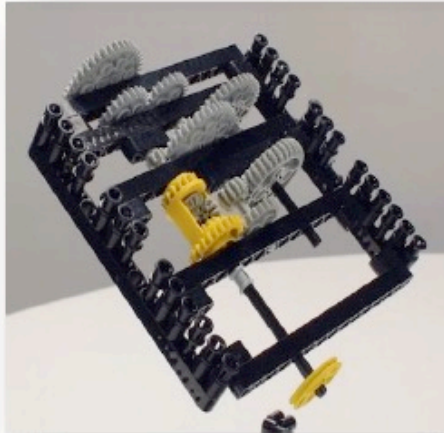
# Extensibility



+



=



- Simple choice –design for absolutely everything or allow extensions
- Everyone needs extensions, everyone hates them
- Define, publish, find extensions
- Repository
- Documented just like resources
- Can be fetched & interpreted by clients

# Extensions

- You can extend:
  - Resources
  - Elements of Resources
  - FHIR Datatypes



- Example:

```
1 <Patient xmlns="http://hl7.org/fhir">
2   <!-- stuff -->
3   <extension url="http://www.tuwien.ac.at/extension#Matrikelnummer">
4     <valueString value="1234567" />
5   </extension>
6   <!-- more stuff -->
7 </Patient>
8
```

# REST service interface

- “REpresentational State Transfer”
- Represent your data as “resources”
- Make “Resources” URI addressable
- Use HTTP to do CRUD operations
- Resources may be exchanged using different representations

endpoint  
`http://server.org/fhir/`

resource type  
`Patient/1/_history/4`

identifier  
version id

The diagram illustrates the components of a REST URI. The first part, `http://server.org/fhir/`, is bracketed and labeled 'endpoint'. The second part, `Patient/1/_history/4`, is also bracketed and labeled 'resource type'. Within this resource type, `1` is bracketed and labeled 'identifier', and `4` is bracketed and labeled 'version id'.

# REST „representation“

```
GET /fhir/Patient/1?_format=json HTTP/1.1
```

```
HTTP/1.1 200 OK
```

```
Content-Type: application/json+fhir;charset=utf-8
```

```
Content-Length: 787
```

---

```
GET /fhir/Patient/1 HTTP/1.1
```

```
Accept: application/json+fhir
```

```
HTTP/1.1 200 OK
```

```
Content-Type: application/json+fhir;charset=utf-8
```

```
Content-Length: 787
```

<https://simplifier.net/>



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**

- defines a separation between **information** and **knowledge**:
  - ***Information***: actual info about a certain case
    - stored in basic entities built and structured through the Reference Model (RM)

e.g. “Gina Smith (2y) has an atrial septal defect, 1cm x 3.5 cm”

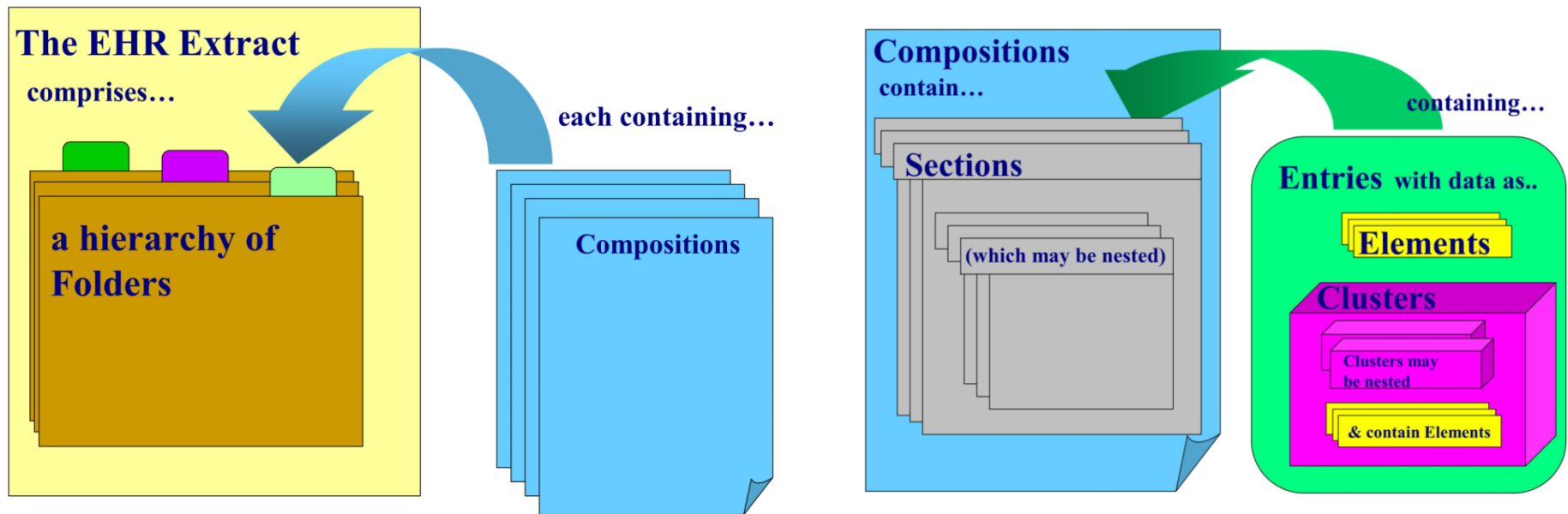
(more on Dual Model Architecture at the openEHR standard)

- defines a separation between **information** and **knowledge**:
  - **Knowledge**: formal representation of clinical concept (like glucose measurement, family history)
    - Based on so-called archetypes
    - Archetypes are built by structured and constrained combinations of RM entities – using the Archetype Model (AM)
    - Archetypes give semantic meaning to the RM

e.g. “the atrial septum divides the right and left chambers of the human heart”

# 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

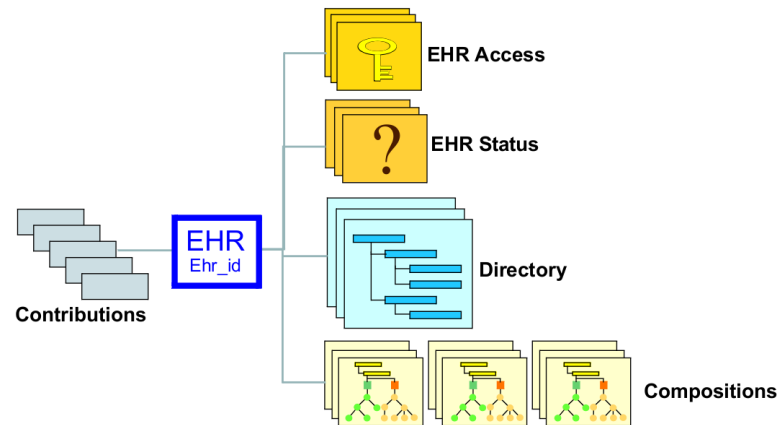
**OPENEHR**

# openEHR: Requirements

- record **clinical information**
- **archetype- and template-enabling** of all clinical systems  
=> two model approach
- support **integration** of **terminology systems**
- let system be able to **communicate via messaging systems** like **HL7v2** or **EDIFACT** => interoperability!
- **Easy integration** with existing Hospital Information Systems  
=> open and defined interfaces
- provide an **Application Programming Interface (API)**
- Allow **distributed versioning** of EHR data

# openEHR: the EHR Design (i)

- **EHR class** is the center piece (has a unique EHR\_ID)
- **Compositions** store the actual information of EHR

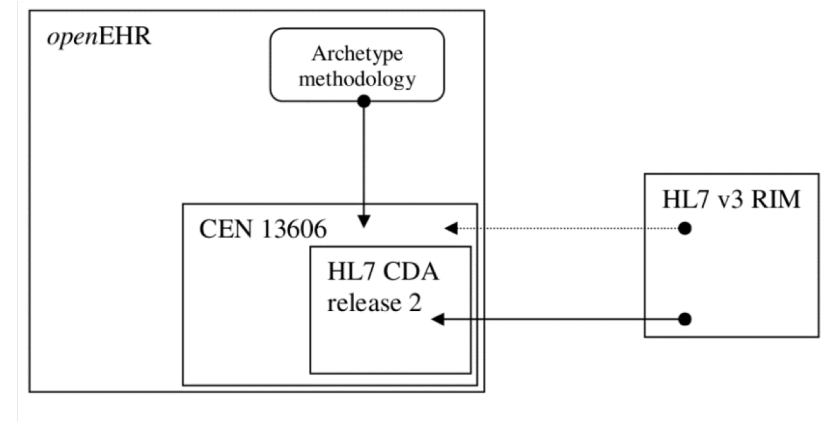


- **EHR access** and **status** store / enable **security**, **versioning** and **workflow information**
- **Directory** includes **hierarchical arrangement** of information
- **Contributions** hold all the changes of the EHR



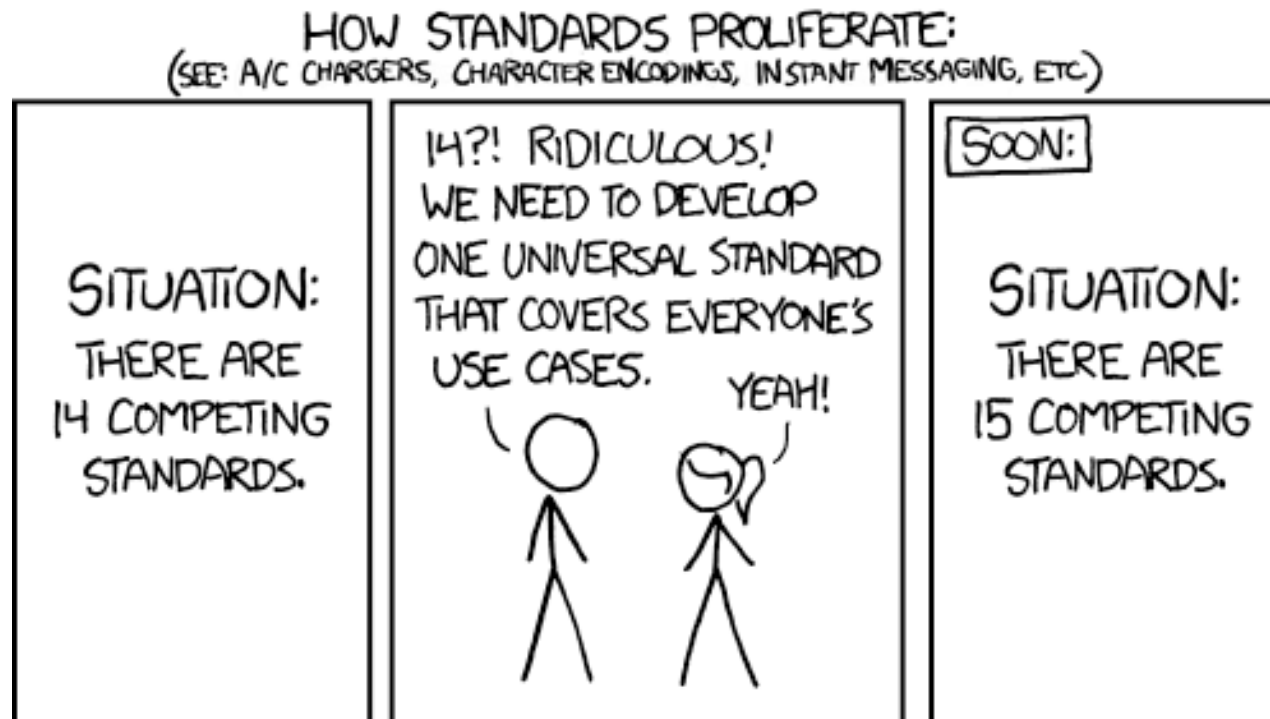
# Relationships of the discussed standards

- openEHR is the most influencing standard
- with the introduced archetype methodology, **CEN** and **openEHR** build upon a **flexible two-level approach**



- CEN EN-13606 is a **complete subset** of the openEHR standard
- 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**
- HL7 FHIR => emerging standard

# In the meantime...true story!



# Standards

- Are these standards sufficient to build complex healthcare infrastructures?
- Standards often describe an information architecture somewhat more general and abstract than that required by engineers designing and implementing systems.
- Sometimes issues are left open to interpretation or a range of choices are provided to the implementer.
- It therefore may require a major effort to achieve substantial integration of multiple systems - even when all the systems involved comply with established standards.
- So, how can we solve this problem?

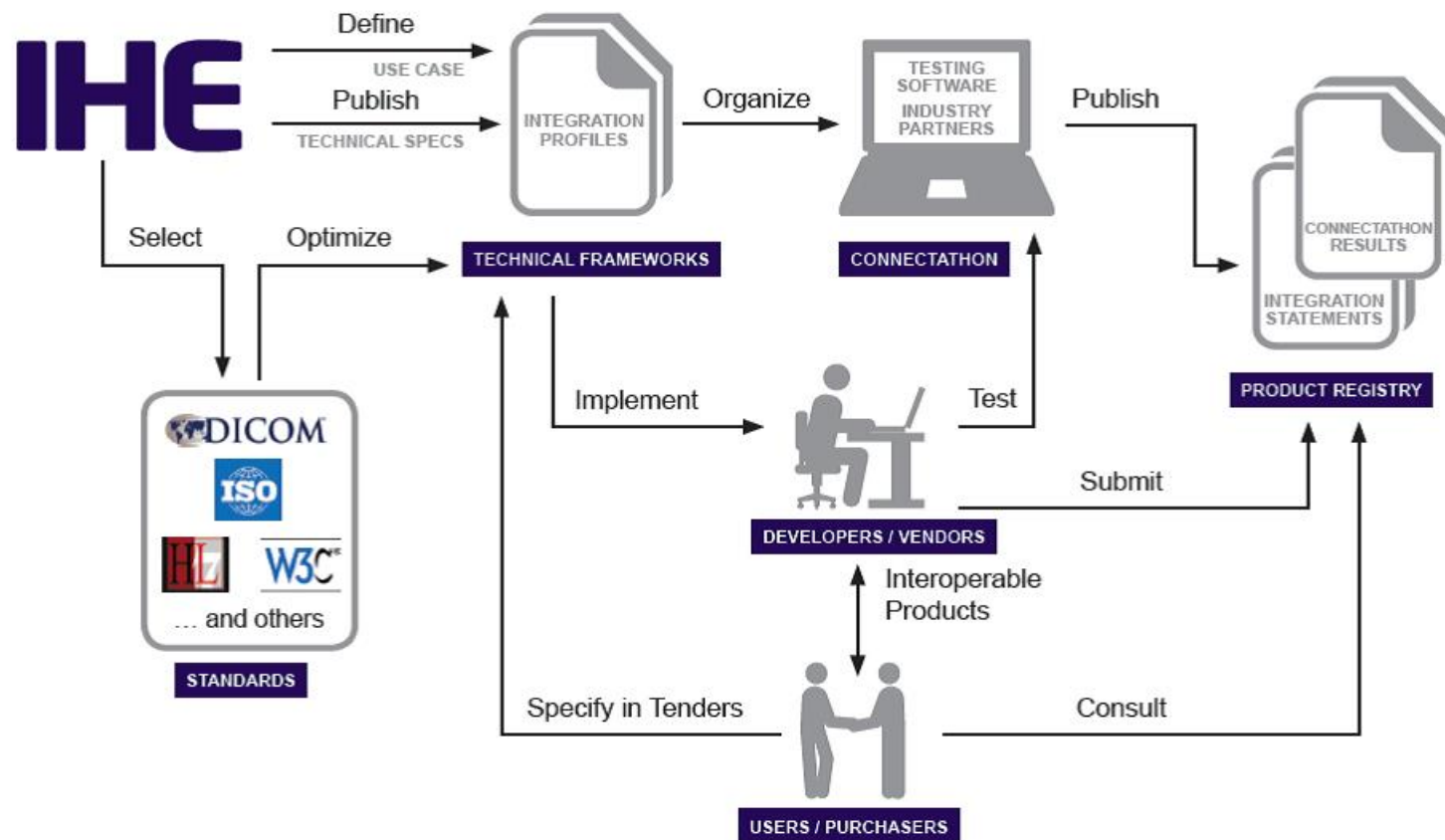
[https://www.researchgate.net/publication/10871295\\_IHE\\_A\\_model\\_for\\_driving\\_adoption\\_of\\_standards](https://www.researchgate.net/publication/10871295_IHE_A_model_for_driving_adoption_of_standards)

# Integrating the Healthcare Enterprise



- Non-profit organization based in the USA
- Established in 1998 by a consortium of radiologists and IT experts.
- Austrian branch: „Verein zur Förderung der Integration der IT- und Medizintechnik im österreichischen Gesundheitswesen“
- Initial focus: Interoperability between equipment in clinical departments with hospital information systems.
- Starting point: Radiology
- Moved on to cardiology, clinical laboratories, etc.
- Connectathons to test and verify interoperability and conformance.

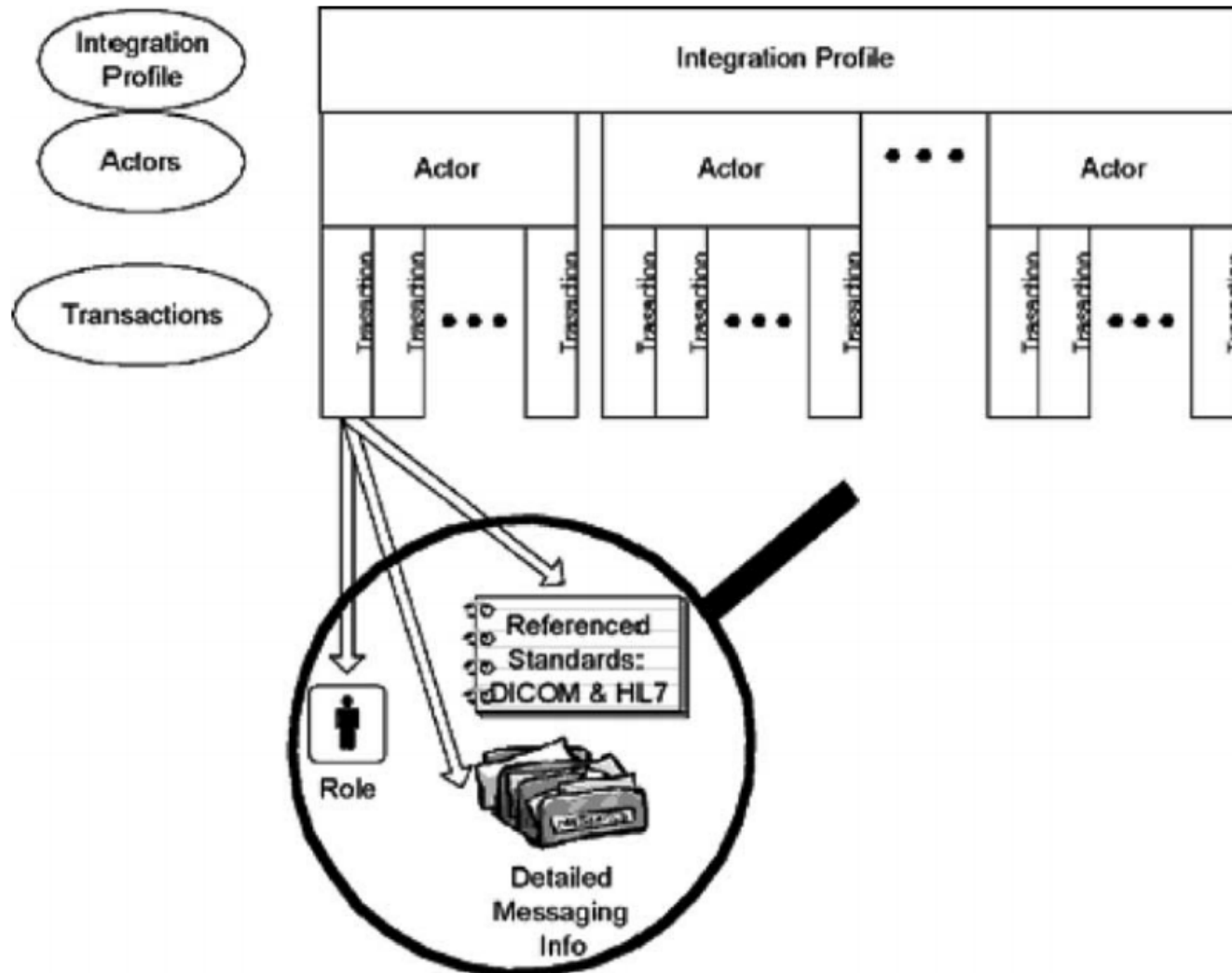
# IHE process



[https://www.ihe.net/IHE\\_Process/](https://www.ihe.net/IHE_Process/)

- Anatomic Pathology
- Cardiology
- Dental
- Endoscopy
- Eye Care
- IT Infrastructure
- Laboratory
- Pathology and Laboratory Medicine
- Patient Care Coordination
- Patient Care Device
- Pharmacy
- Quality, Research and Public Health
- Radiation Oncology
- Radiology

# IHE Technical Frameworks



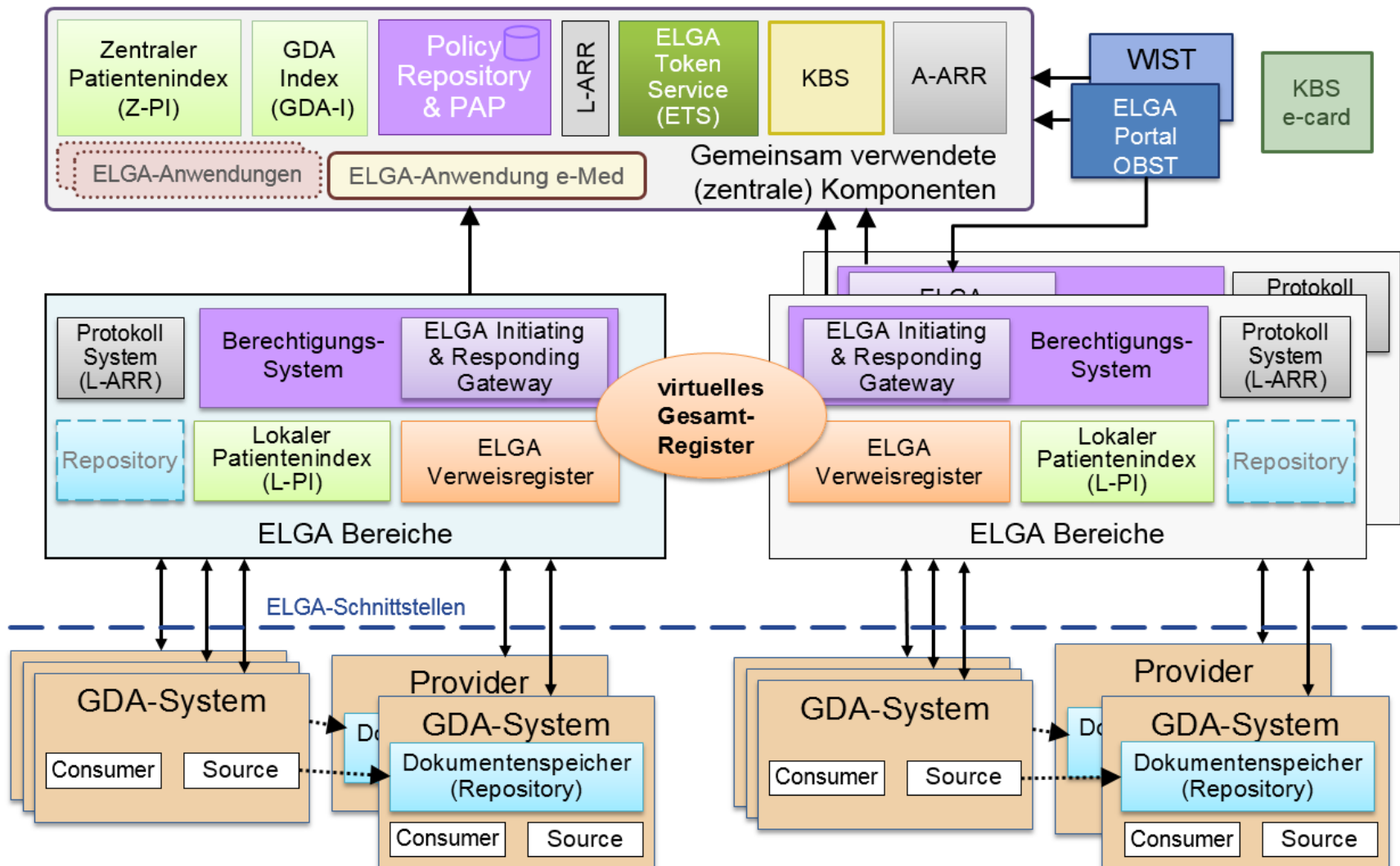
[https://www.researchgate.net/publication/10871295\\_IHE\\_A\\_model\\_for\\_driving\\_adoption\\_of\\_standards](https://www.researchgate.net/publication/10871295_IHE_A_model_for_driving_adoption_of_standards)

# IHE profiles used by ELGA

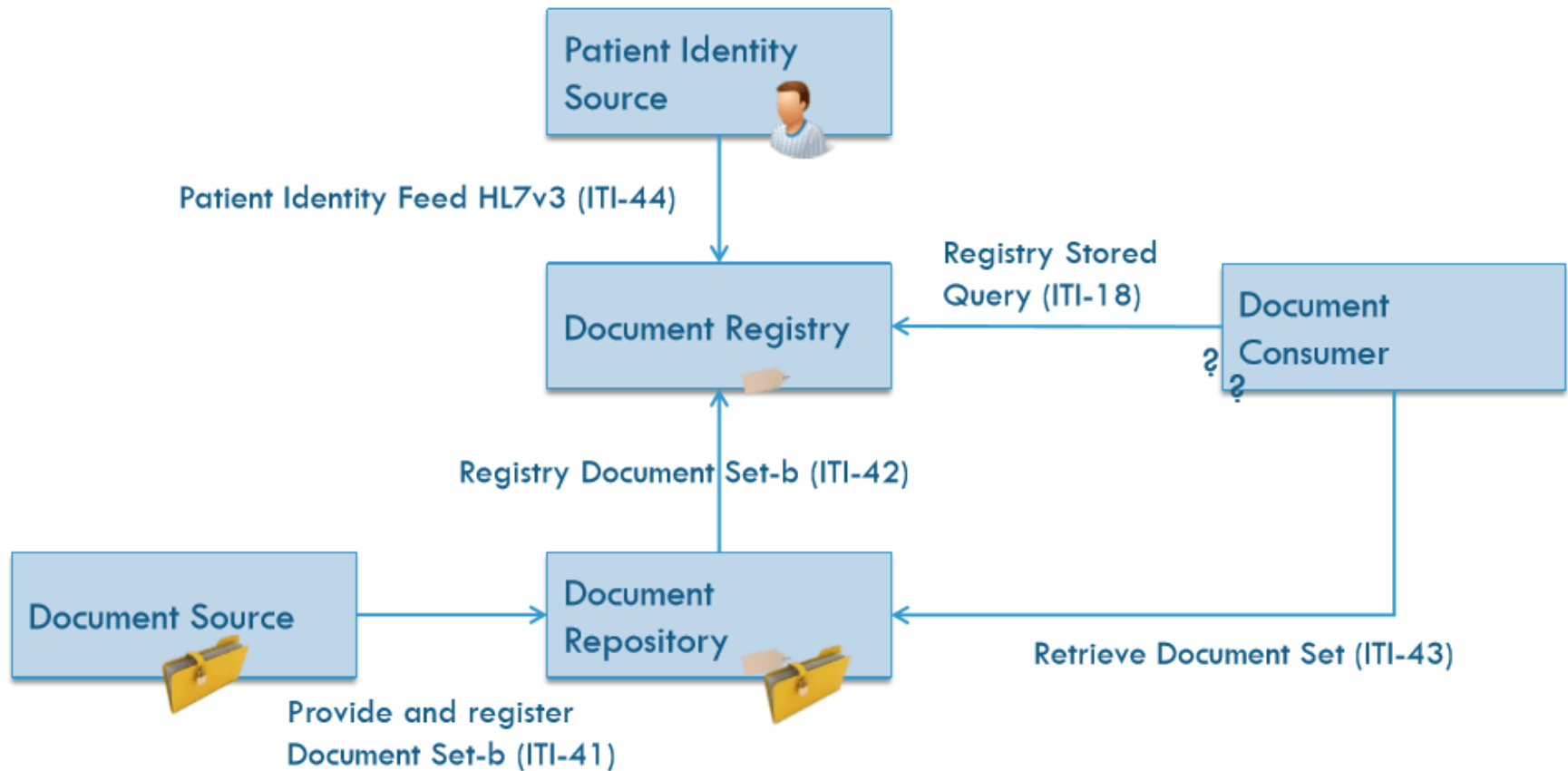
- Befundkommunikation: XDS/XCA (ITI-18, ITI-38, ITI-39, ITI-41, ITI-42, ITI-43, ITI-57, ITI-62)
- eMedikation: Pharmacy Profile CMPD, DIS, PRE, PADV, PML (PHARM-1)
- Patientenidentifikation: PDQ/PIXv3 (ITI-44, ITI-45, ITI-46, ITI-47)
- Protokollierung aller Transaktionen: ATNA (ITI-19, ITI-20)



# ELGA architecture



# XDS.b workflow





- Private sector initiative to advance industry adoption of modern, open interoperability standards.
- Purpose is to rapidly develop a first-generation FHIR-based API and core-data-services specification
- Well known project sponsors like Accenture, Cerner, etc.

# Argonaut Mission Statement

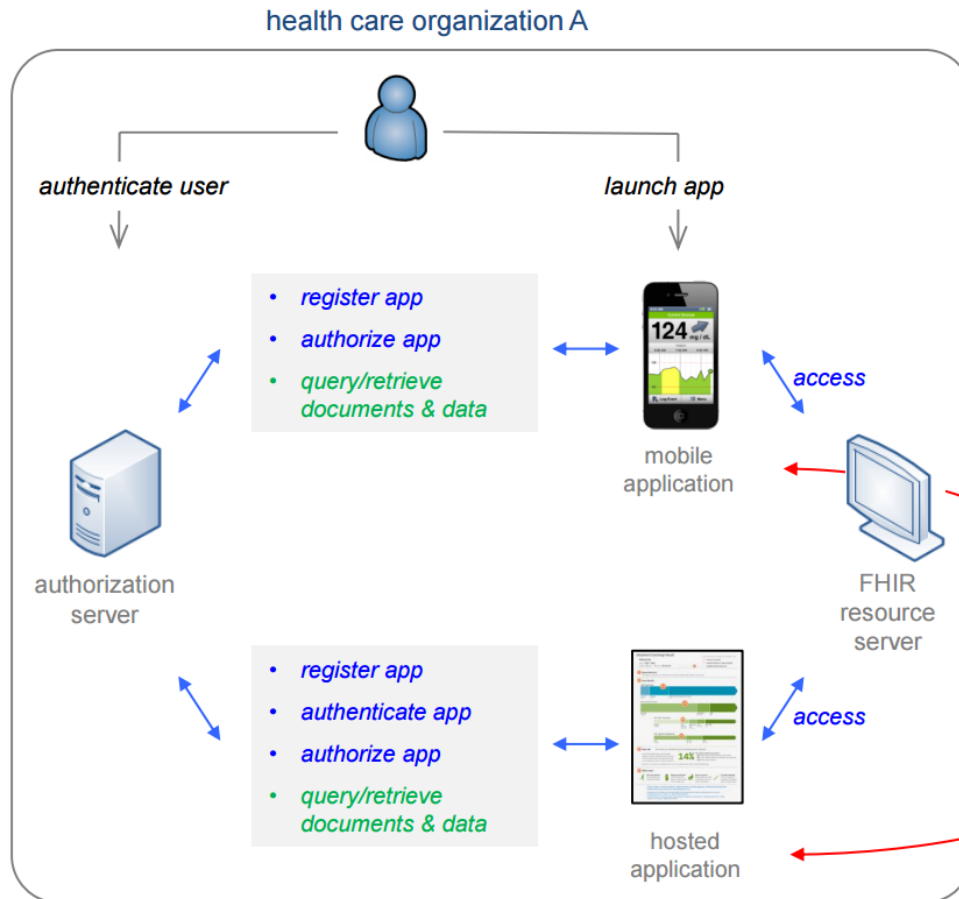
- Current standards like HL7 CDA and IHE are:
  - too broad and inefficient
  - highly complex
  - not based on modern internet standards
  - not scalable
- FHIR-based APIs are:
  - flexible to document-level and data-level exchange
  - based on modern internet conventions

# Argonaut Project results

- FHIR RESTful API Implementation Guides
- OAuth/OIDC Implementation Guides
  - Authorization of enterprise-approved applications
  - Single sign-on to enterprise-approved applications

# Argonaut Project results cont'd

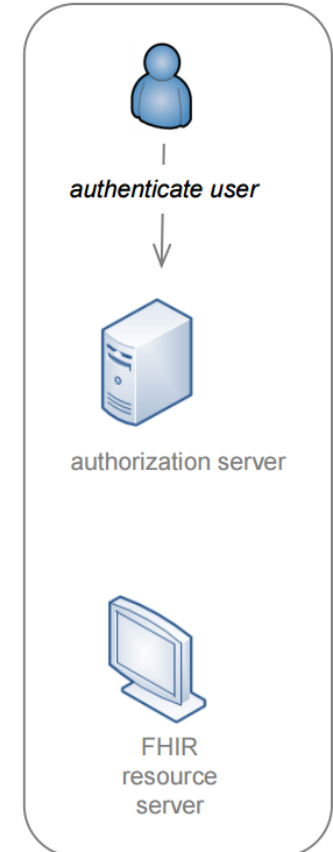
## Phase 1: "within" enterprise



## Phase 2: cross-enterprise

- *authenticate enterprise*
- *authenticate federated user identity across enterprises*
- *authorize app for access scope*
- *query/retrieve documents & data*

### health care organization B



*current Argonaut security scope*  
*future Argonaut security scope*  
*current Argonaut FHIR scope*

[http://argonautwiki.hl7.org/images/4/4e/Argonaut\\_Implementation\\_Program\\_Phase\\_2\\_-\\_23\\_Jul\\_2015-v2.pdf](http://argonautwiki.hl7.org/images/4/4e/Argonaut_Implementation_Program_Phase_2_-_23_Jul_2015-v2.pdf)

- SMART – An App Platform for Healthcare
- Argonaut security workgroup is working with the SMART Health IT team.
- Demonstration: SMART App Gallery (<https://gallery.smarthealthit.org/>)

# Summary

- Know about HL7v2, HL7v3, CDA, FHIR, CEN-EN13606, openEHR.
- Know what a **CDA-document** looks like.
- Know how a **FHIR Resource** looks like.
- **openEHR**: know about the **EHR design**.
- Know the **IHE technical framework**.
- Know how the **IHE process works**.
- Know about the **Argonaut Project**.
- **IT standards in healthcare** may not be the most exciting thing in the world, but they **are important to achieve interoperability**
- **IT standards** alone are not **sufficient** to build complex **healthcare infrastructures**.



That's it.

**THANK YOU**

# Sources and References

- HL7 and related:
  - <https://www.hl7.at/> (12/2017)
  - <http://www.healthstandards.com/>, <http://hl7book.net>
  - <http://www.hl7.org/fhir>
  - <https://www.elga.gv.at/>
- CEN EN-13606
  - <http://www.cen.eu>, <http://www.en13606.org/> (12/2017)
- openEHR
  - <http://www.openehr.org> (12/2017)
- IHE
  - <http://www.ihe.net/> (12/2017)
  - <http://ihe-austria.at/> (12/2017)
- Argonaut Project [http://argonautwiki.hl7.org/index.php?title=Main\\_Page](http://argonautwiki.hl7.org/index.php?title=Main_Page) (12/2017)
- SMART on FHIR <http://smarthealthit.org/smart-on-fhir/> (12/2017)