



Electronic Record Services B.V.

# International e-Health developments

Brussels

Friday 15 October 2010



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# Gerard Freriks

**Past chair CEN/TC251 wgl**

**Vice-president EuroRec**

**ERS b.v.**





# INFORMATION DOCUMENTATION

## **1. 2LM Paradigm and Innovation**

## **2. ENI 3606 and Innovation**

## **3. Missing Semantic Interoperability Stack - INFOstructure**

## **4. ENI 3606 Consortium/Association**

## **5. European plans: Digital Agenda and FP7**

- | -

# **Two Level Modeling Paradigm and Innovation**

## Effect on Society

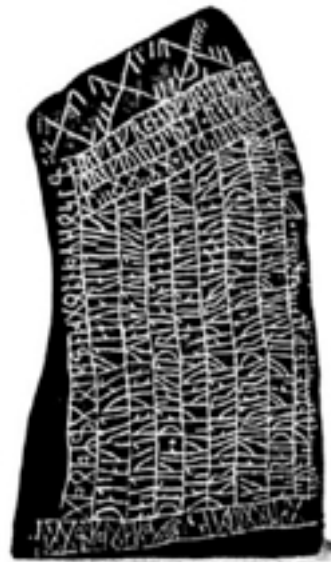
**Easy access** to data, information and knowledge

**Instantly connecting,** synchronising people and organisations

## New Products



## Old Products



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Innovation in general.

New products by them selves do not create innovation.

What is needed to create Innovation?

Answer: When they change society.

1- Old Product are replaced by new products.

The Parchment and Quail and INk by printed materials

Creating access to information via mass media.

It changed society and therefor was an Innovation.

2- The new telephone by Gr. Bell became an Innovation when it became a commodity product in stead of a one-off, unique , product for instantly contacting people.

And it needed a supporting infrastructure.

The Innovation: Instant Access to data and information by people so they can be synchronised.

# 2LM Paradigm - Innovation

## Effect on Society

**Easy speedy access** to data, information, knowledge and people plus organisations

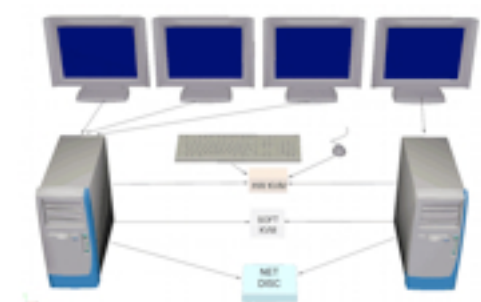
**Instantly speedily connecting, synchronising** people, organisations and **business processes**

## New Products



EHR-systems

## Old Products



EMR-systems

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Innovation in general.

New products by them selves do not create innovation.

What is needed to create Innovation?

Answer: When they change society.

1- The old computer was a one-off, unique product.

Only the commodity and the supporting infrastructure will Innovate,

because it changes the way people and organisations have speedy access to data and information.

2- When it comes to the EHR,

it is clear that present day Electronic Medical Record Systems are one-off products and not a commodity.

Each is highly unique, even per department they can be unique.

And there is NO supporting INFRASTRUCTURE.

Present day systems can NOT provide Innovation by

Instantly connecting people, organisations and business processes.

# 2LM Paradigm - Innovation

Effect on society	-	Innovation
Infrastructure	-	Infrastructure
R&D - New products	One-off	Commodity



# 2LM Paradigm - Innovation

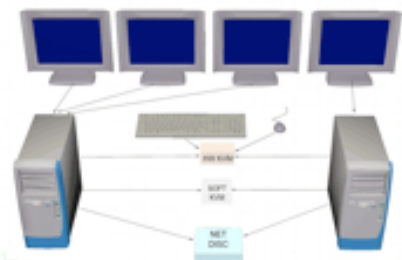


Digital  
Agenda

Infrastructure  
Infostructure

Legislation  
Standards

Effect on society	-	Innovation
Infrastructure	-	Infrastructure
R&D - New products	One-off	Commodity



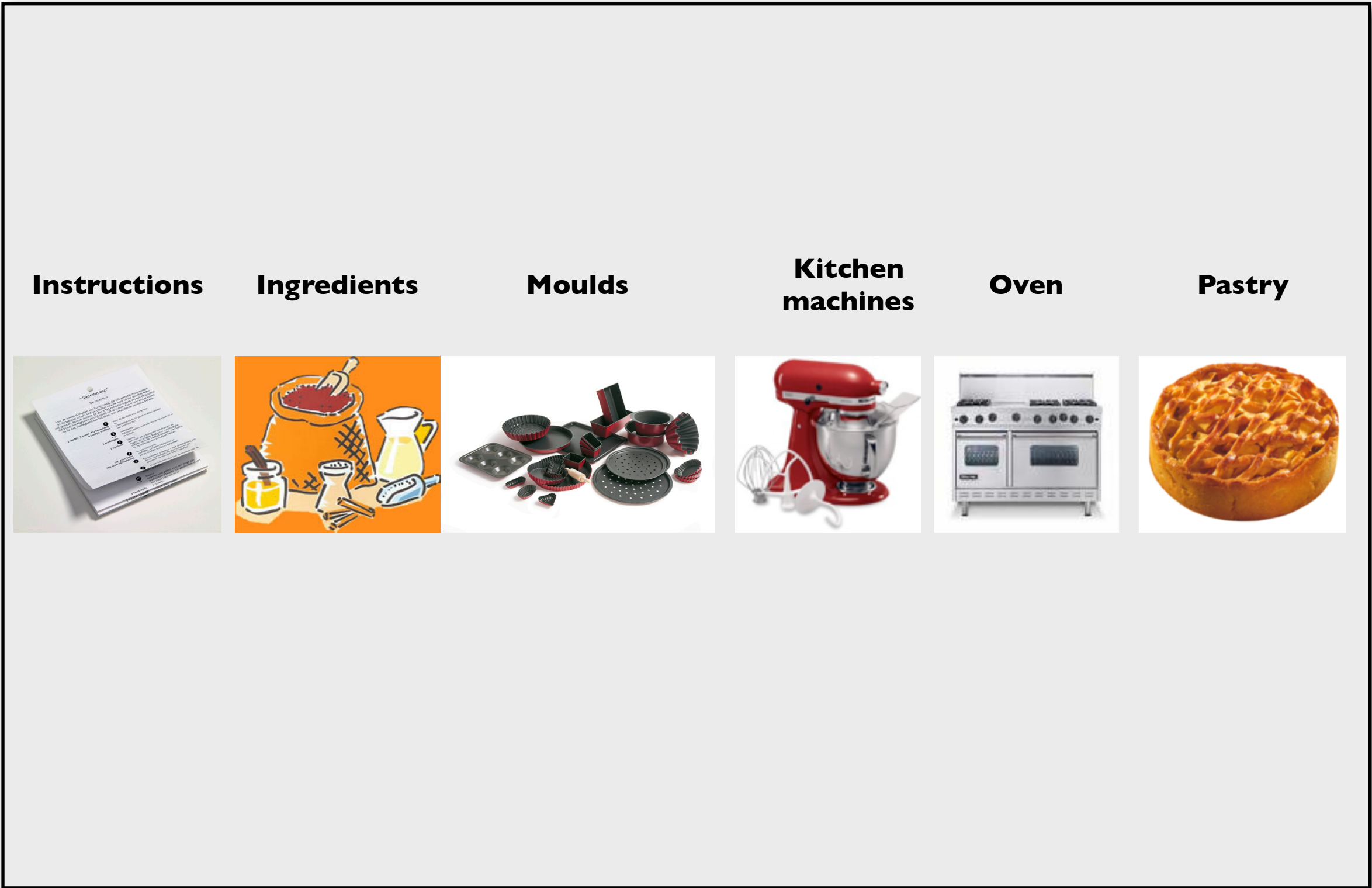
EMR

?  
EHR

Two Level Model  
Paradigm  
ENI 3606

-2-

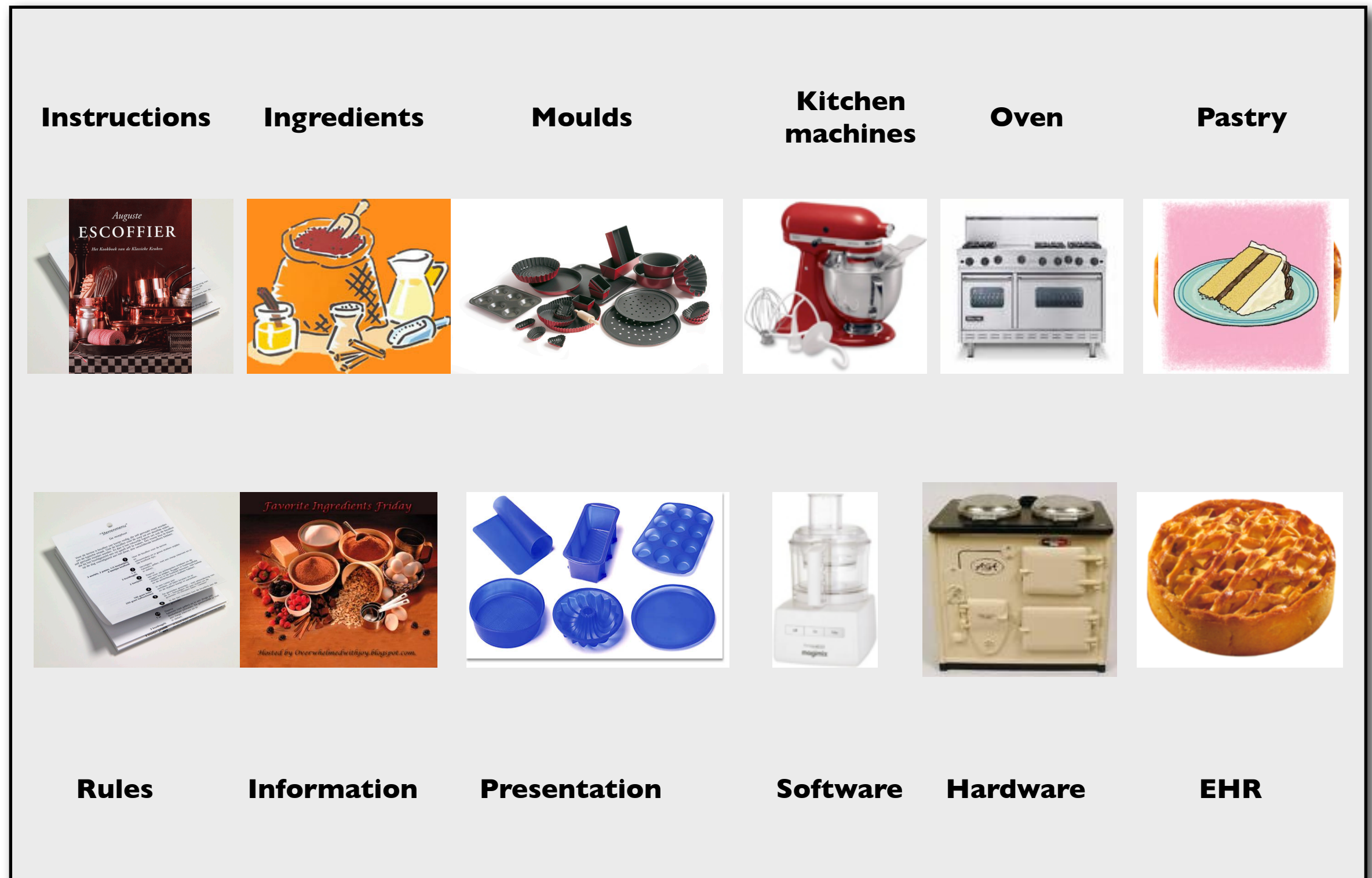
# **EN I 3606 Introduction (High level) and Innovation**



# Bakery/EHR expectations

# ERS

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Different Instructions and ingredients make an other type of pastry

The same Instructions used in a different setting produce the same pastry

Metaphor

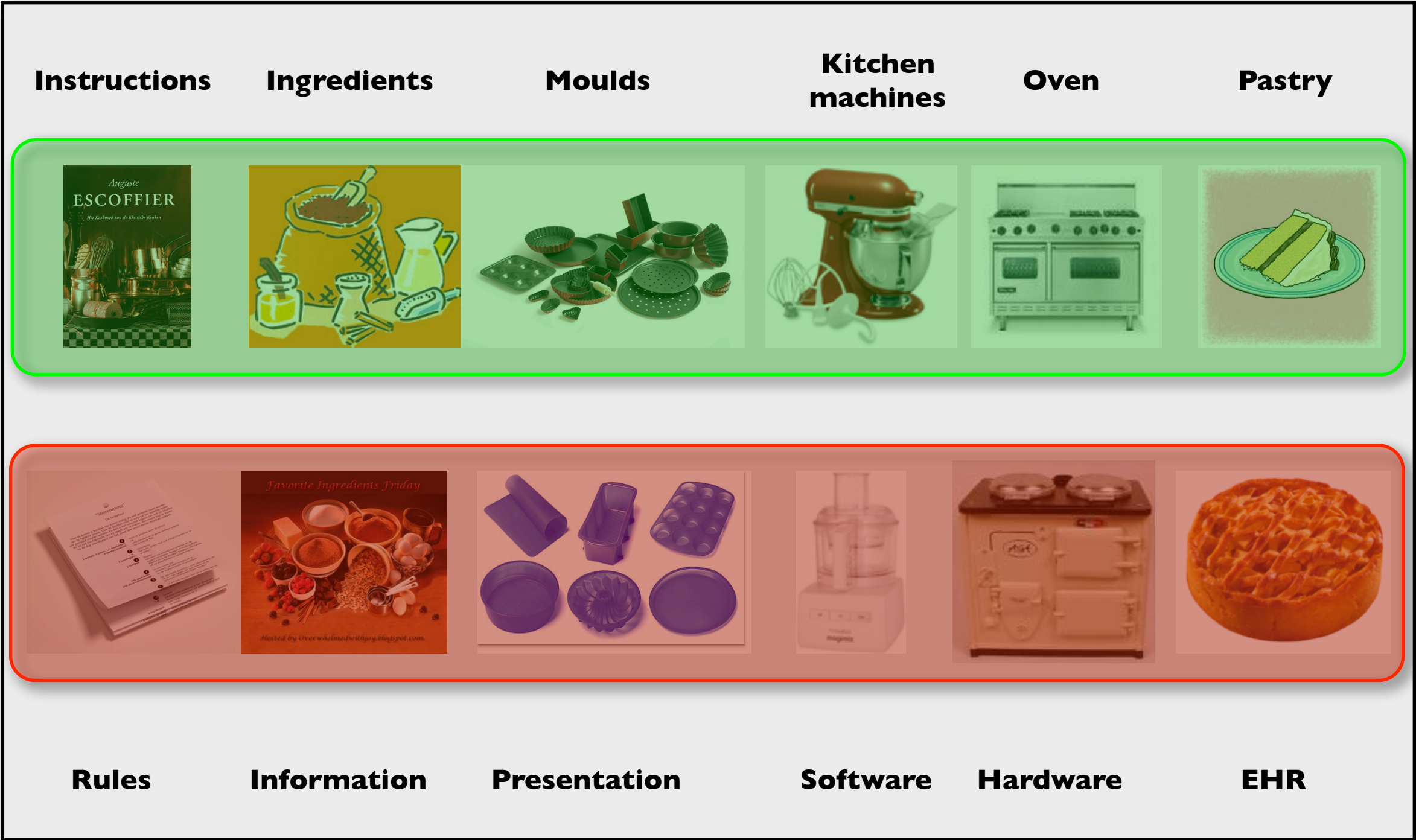
- Instructions = Business Rules
- Ingredients = Information
- Moulds = Presentation
- Kitchen machinery = Software
- Oven = Hardware



# EHR's now

# ERS

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Each IT-vendor delivers a unique (proprietary) system with limited possibilities to adapt to local needs

Rules, Information, Moulds, Machines, and the Oven can not be exchanged.

Each IT-system has proprietary solutions that can not be exchanged

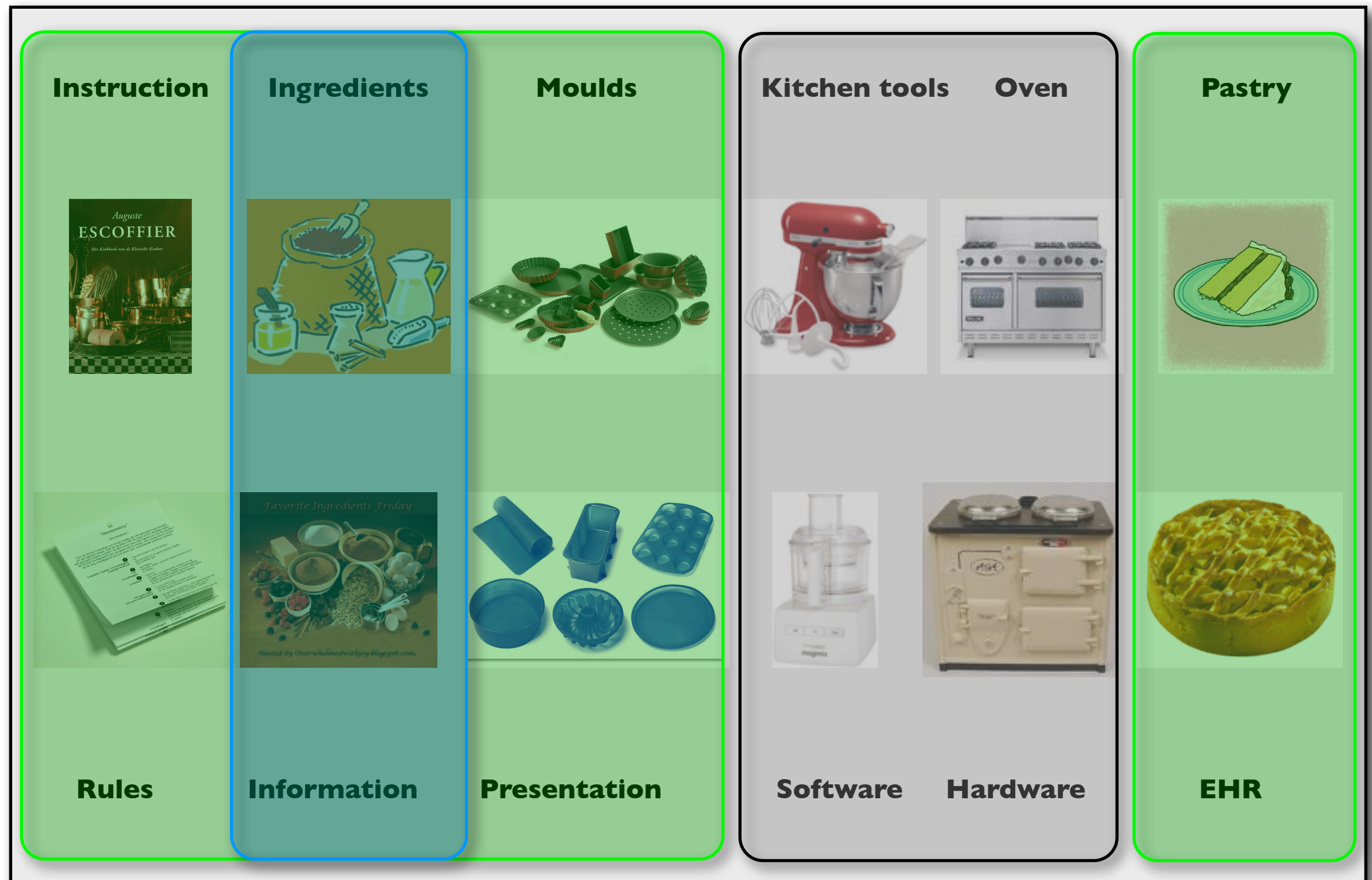


# EHR systems now





# EHR-systems we need



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The baker in his bakery is able to exchange all component.

What we need in healthcare is that healthcare providers and organisations can select the components freely.

No more proprietary solutions.

And an absolute separation between Healthcare and the IT-world.

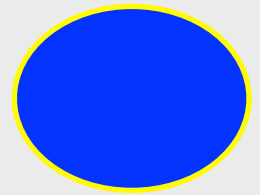
What ever healthcare defines in terms of Instructions (Rules), Ingredients (information), and Moulds (Presentation) the IT-world can deal with it without reprogramming and database conversions.

Any set of Rules, any set of Information, any presentation spec, can be executed by all IT-systems.

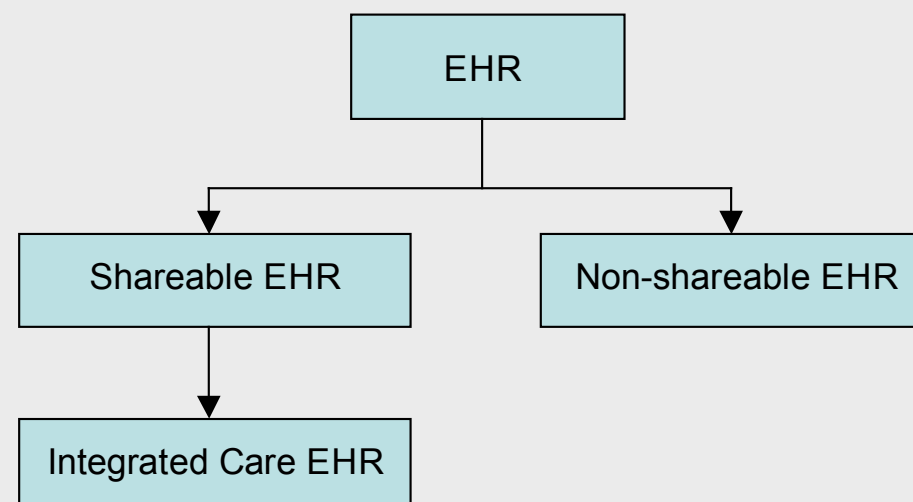
# Integrated Care Electronic Health Record

## Definition

(ISO/tc215 20514: EHR - Definition, Scope and Context)



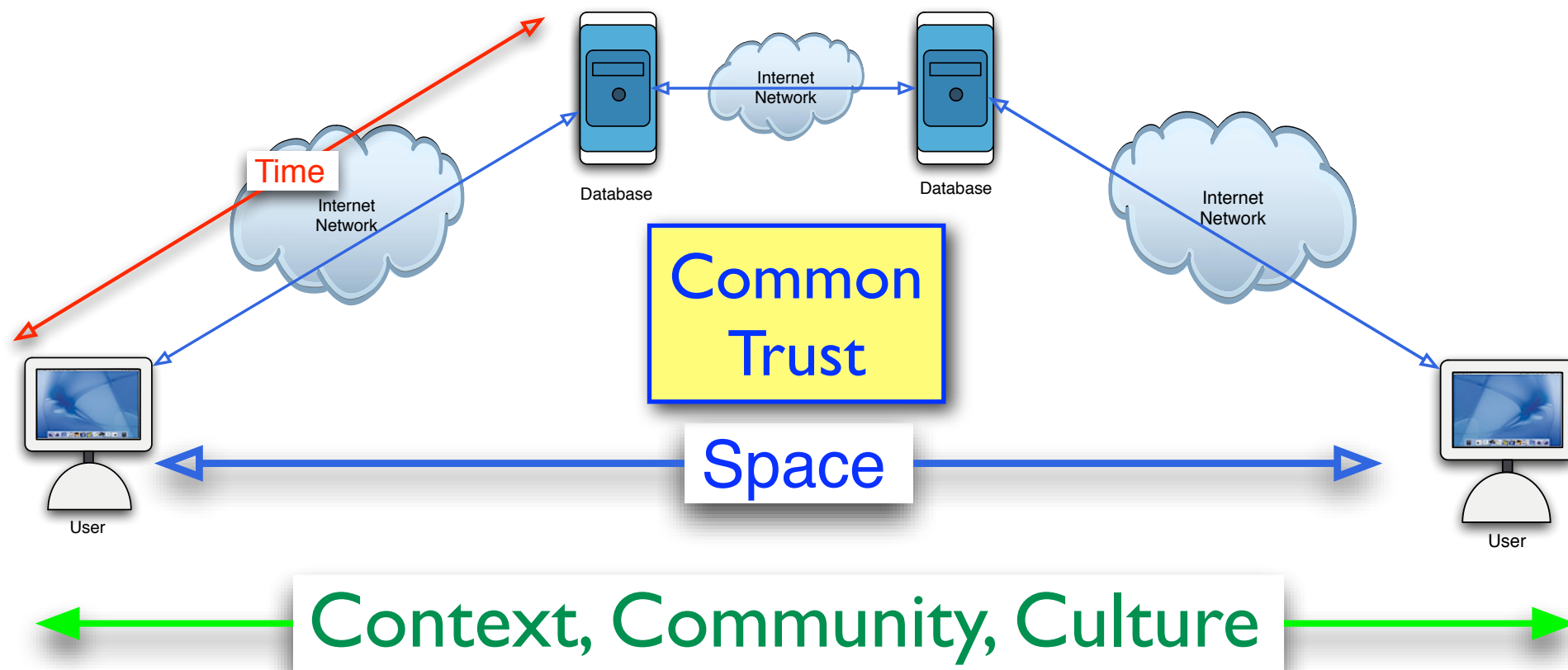
The IC-EHR has a standardised **information model**, which is **independent** of EHR systems. Its primary purpose is the support of continuing, efficient and quality integrated healthcare and it contains **information** which is **retrospective, concurrent and prospective**.





# ENI 3606

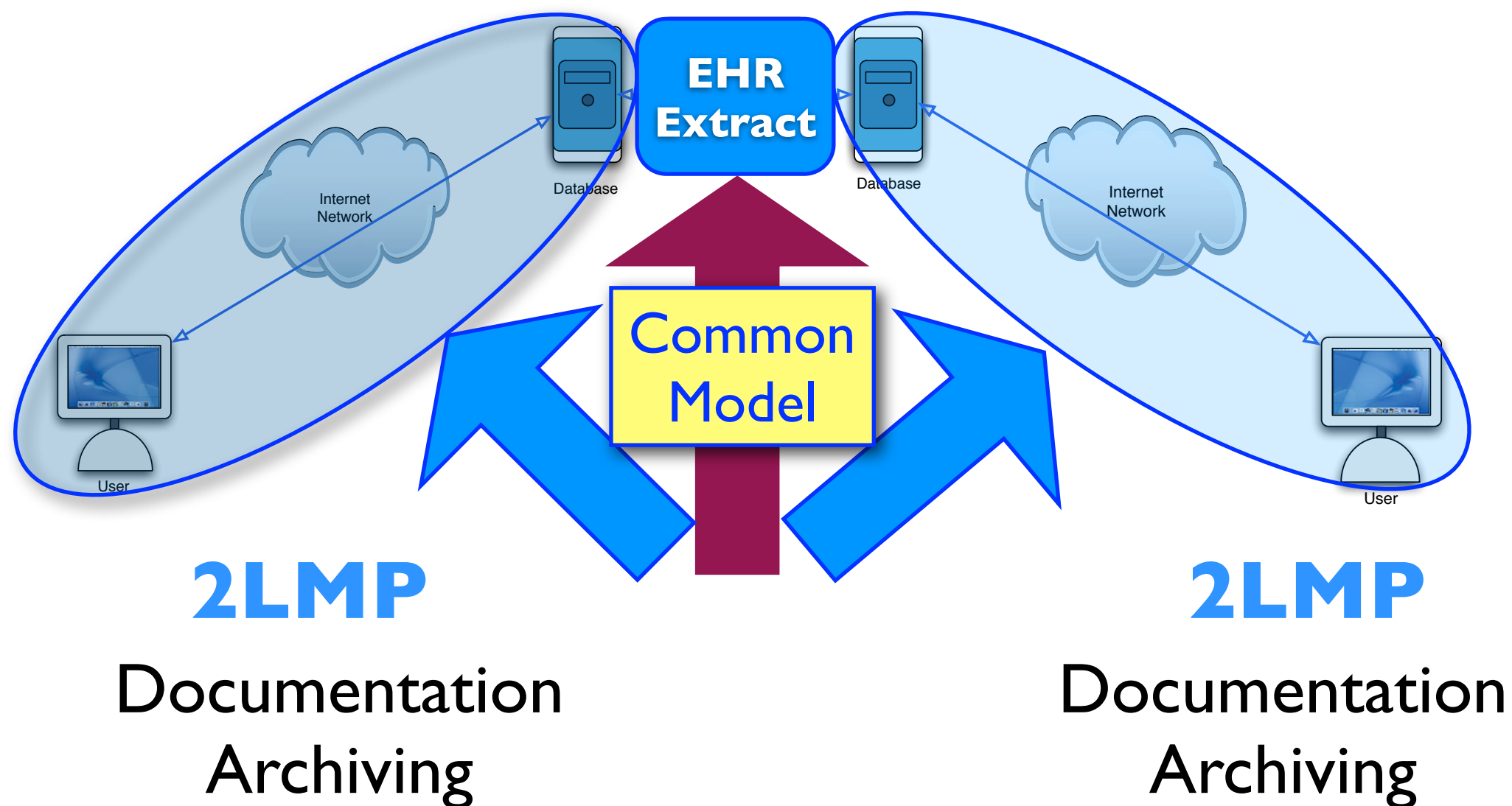
## Basics



# ENI3606

## Basics

**Many, many unique identifiers**



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Creating the EHR (eHealth) Infrastructure there two points of departure.

1-

For many years CEN/tc251 (like HL7) has started in the middle.

Message standards we produced to update proprietary databases.

2-

This century CEN/ISO started to think about standards at the EHR-system.

It standardised how Data or Information is stored, retrieved, archived AND exchanged.

It must be clear that therefor Message standards and EHR-standard have one thing in common.

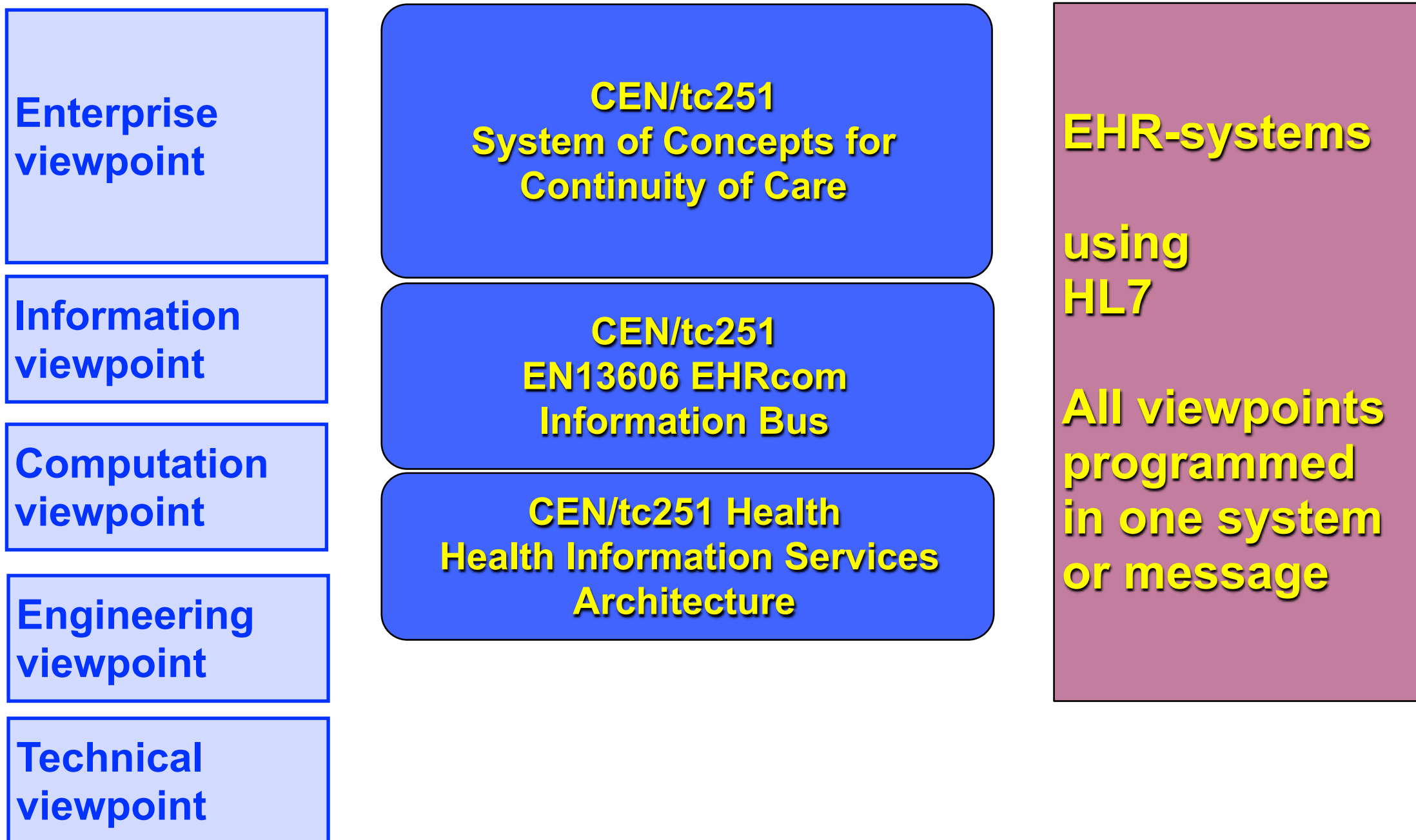
But for many other aspects they have NOTHING in common.

There is only a partial overlap.

All this reflects different point of departure in CEN: Multiple languages.

# EN I 3606

## Basics



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Depicted here is that in the case of messages

- work processes are standardised,
- translated in an Information Model
- the exchange between databases is choreographed
- and implemented in IT-systems, by programming and
- that have to rolled out.

State-of-the-Art EHR-systems that are based on EN13606 behave differently.  
They only define what has to be Documented, Exchanged, Archived and Re-Used.

They do NOT standardise Workflow or the way information is exchanged.  
They define define Engineering and Technology choices.

They ceate EHR-systems that facilitate healthcare maximally.

# ENI 3606 Basics

## Paradigm: Two-Level-Model

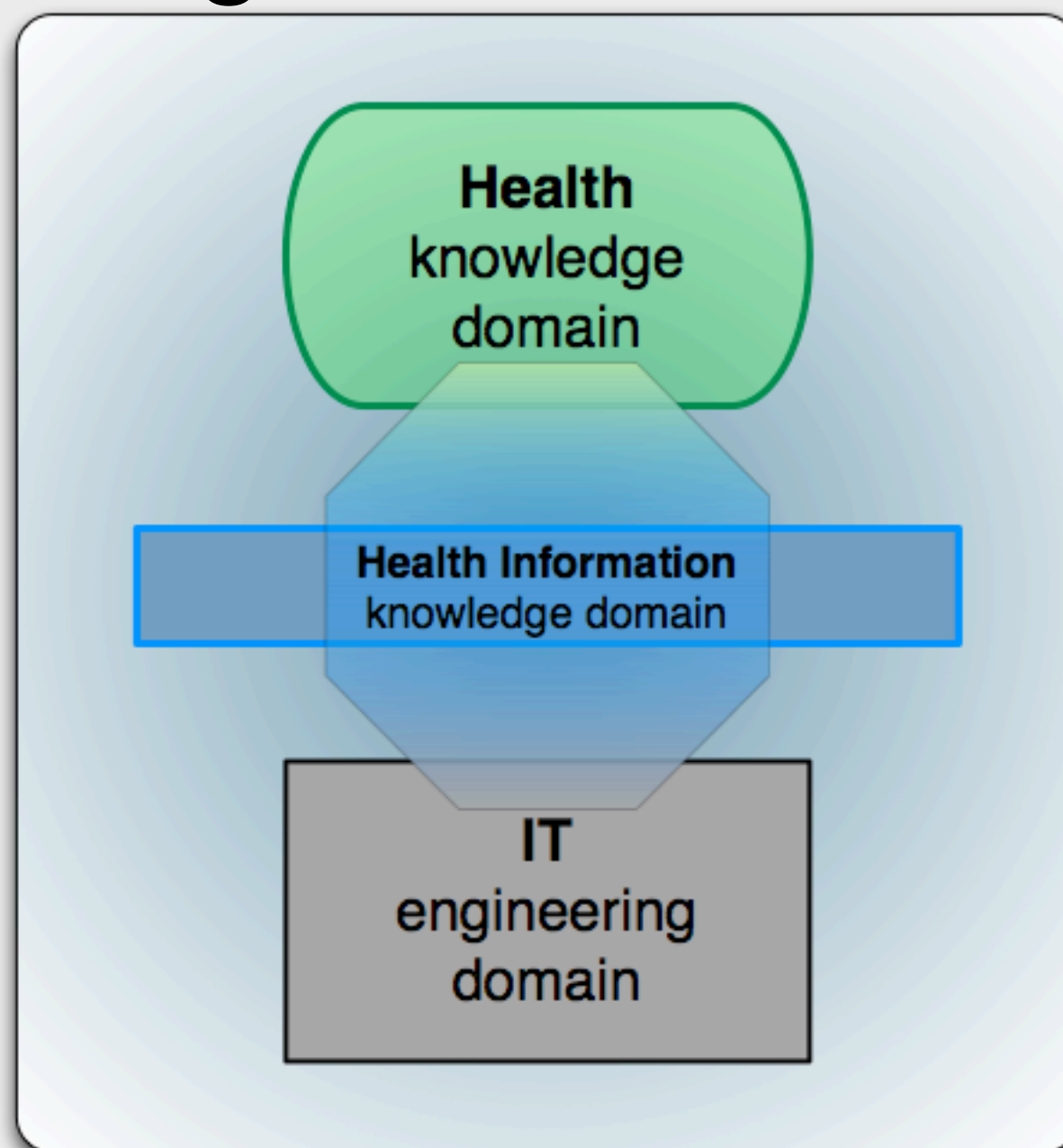
*Coding systems*  
**Archetypes**  
*Templates*  
*Rules*

**Tools**

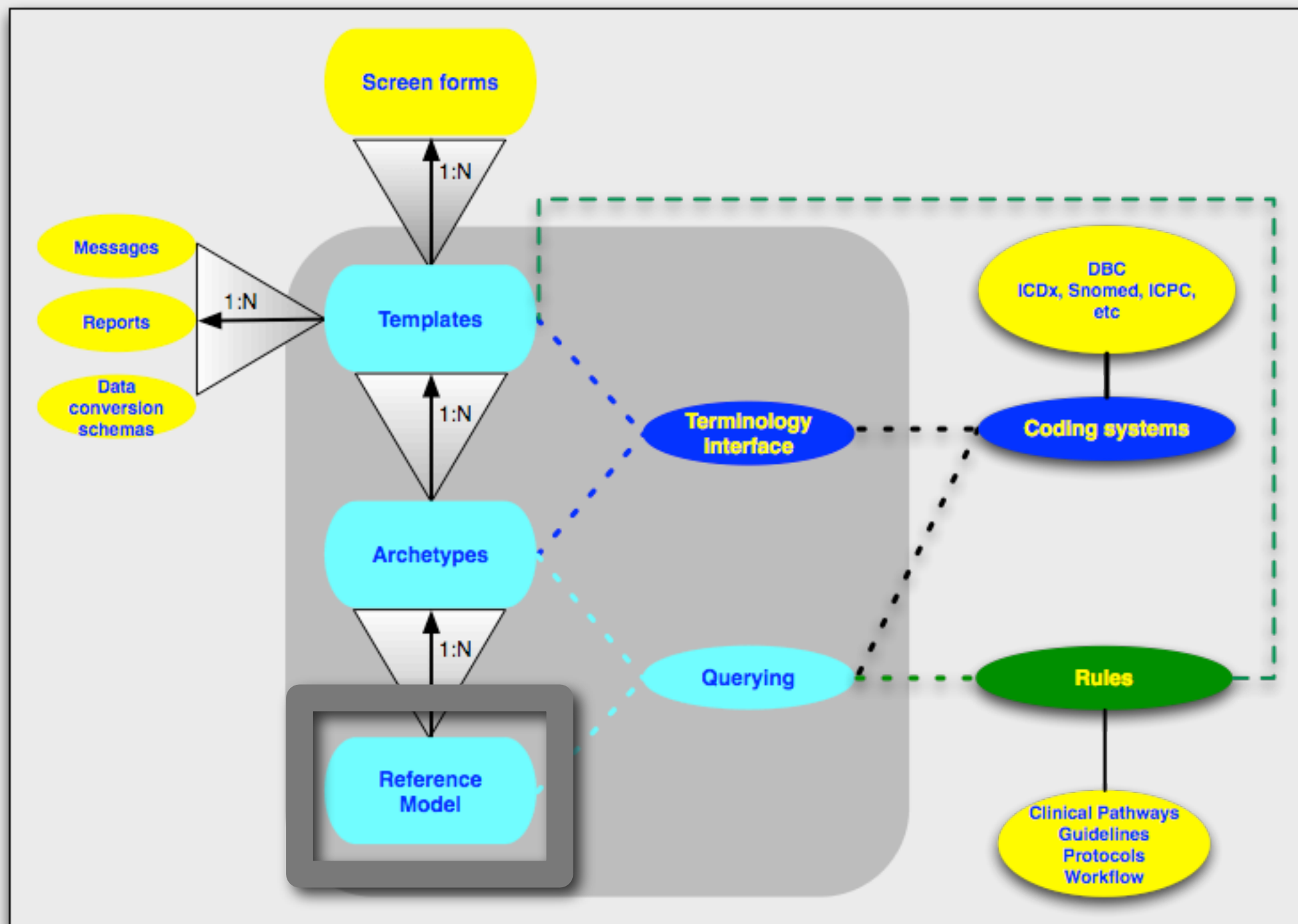
*Software*  
*Tools*  
*Services*

ENI 3606-2

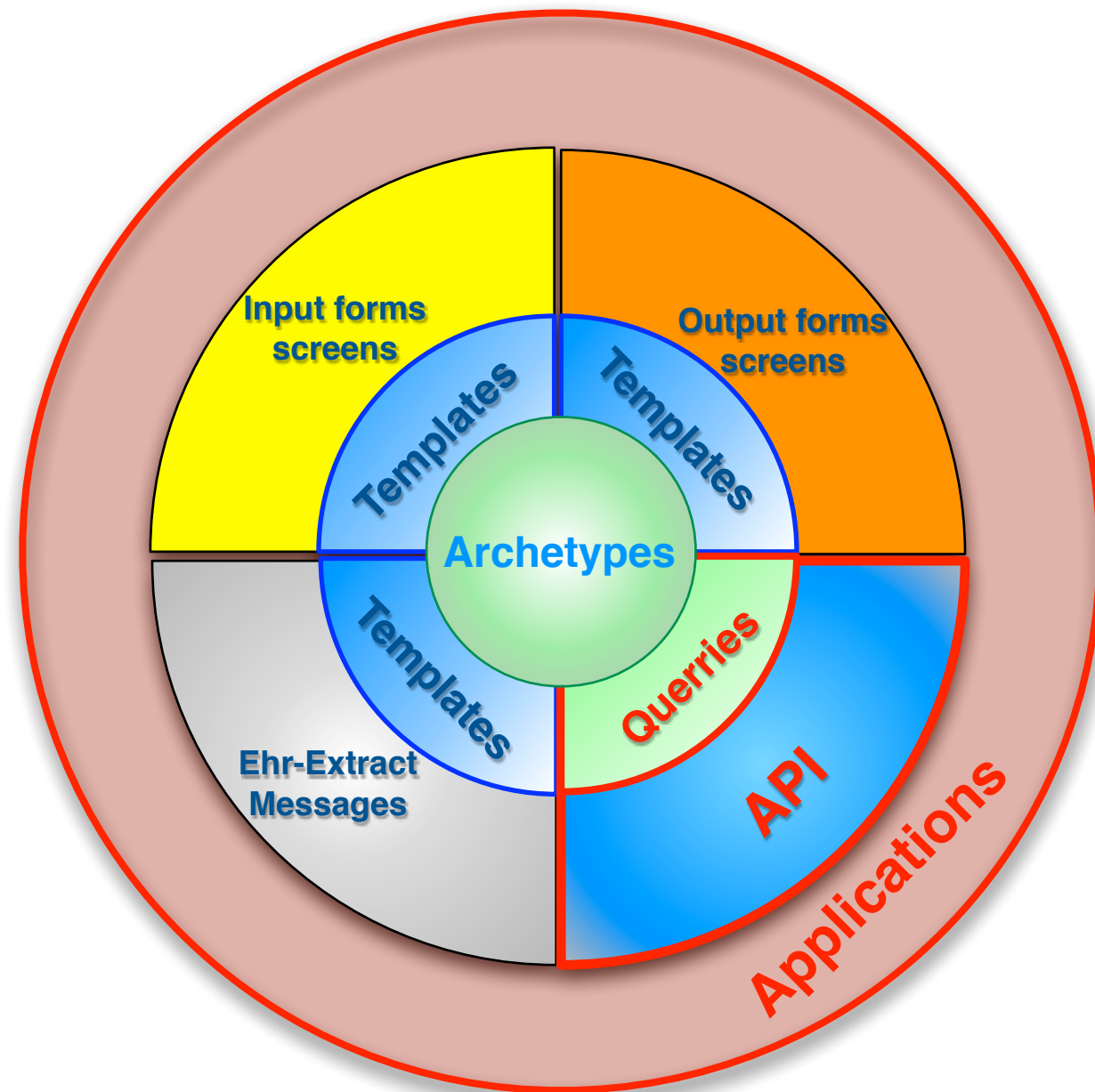
ENI 3606-1



# Archetypes/Templates



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#### Applications Services

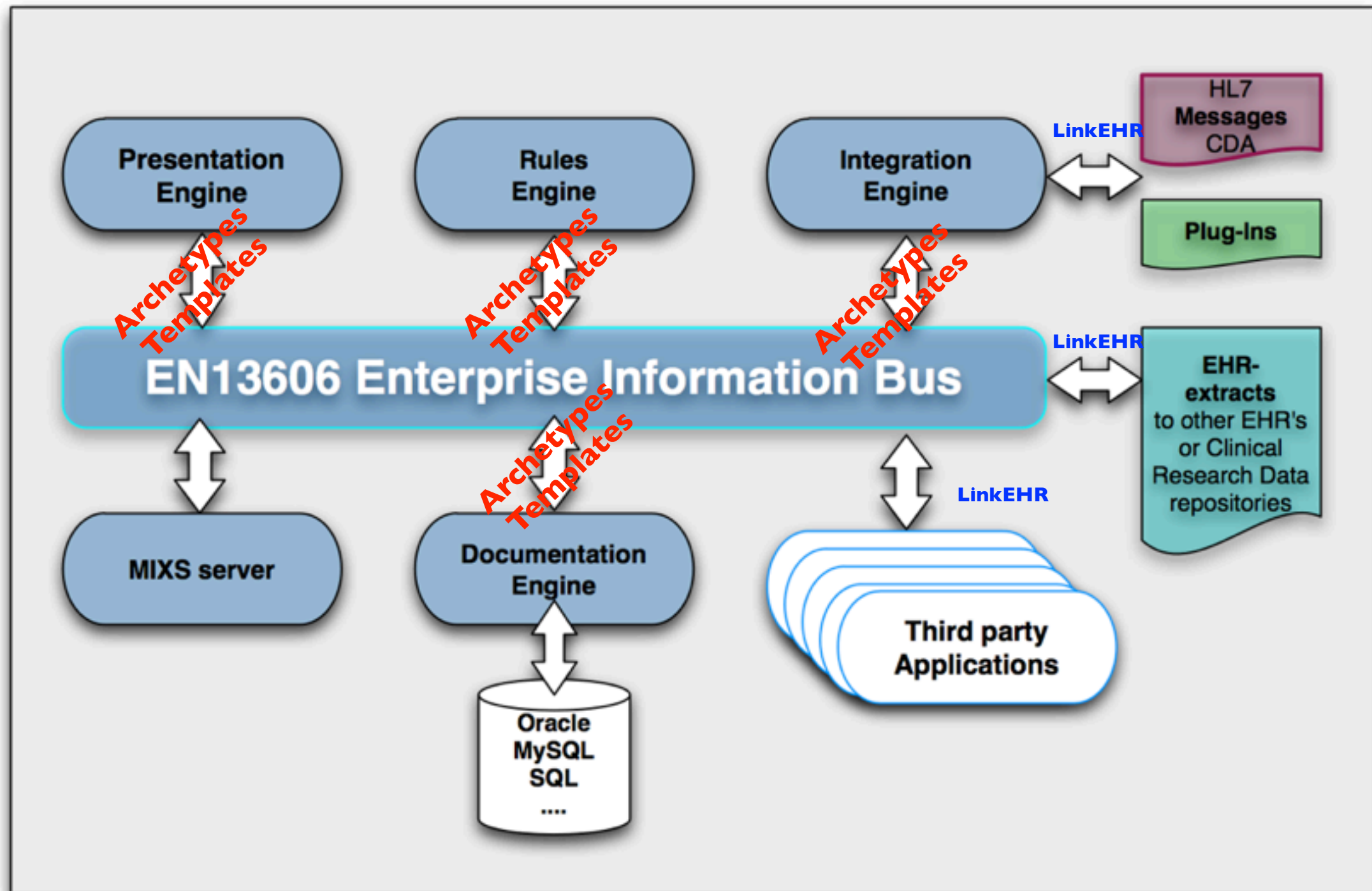
PAS  
MPI  
Pacs  
RIS  
e-Prescription  
Clinical Paths  
Work flow  
Case management  
Data Mining  
Reporting  
Billing  
...



# ENI3606

## Basics

### IC-EHR Architecture



# Message based paradigm

## versus

# Archetype based paradigm

	Message based EHR-systems	Archetype based EHR-systems
Production of message	1-3 years	Minutes
IHE process Programming	1-2 years 1-2 years	nil nil
Roll Out	1 year	nil
<b>Total</b>	<b>YEARS</b>	<b>Minutes/Days</b>

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Why use the EN13606 in present day one-off IT-systems?

When the EN13606 is used for the exchange function only. There are already striking differences that will influence the discussions on eHealth Infrastructure and the EHR-architecture.

The time it takes to produce and implement new Message specifications or make changes to the database in RED

And the same in State-of-the-Art EHR-systems based on the Information Bus (EN13606)

The differences are exciting and staggering.



# HL7

## Virginia Lorenzi (2009)

### How long did/does it take?

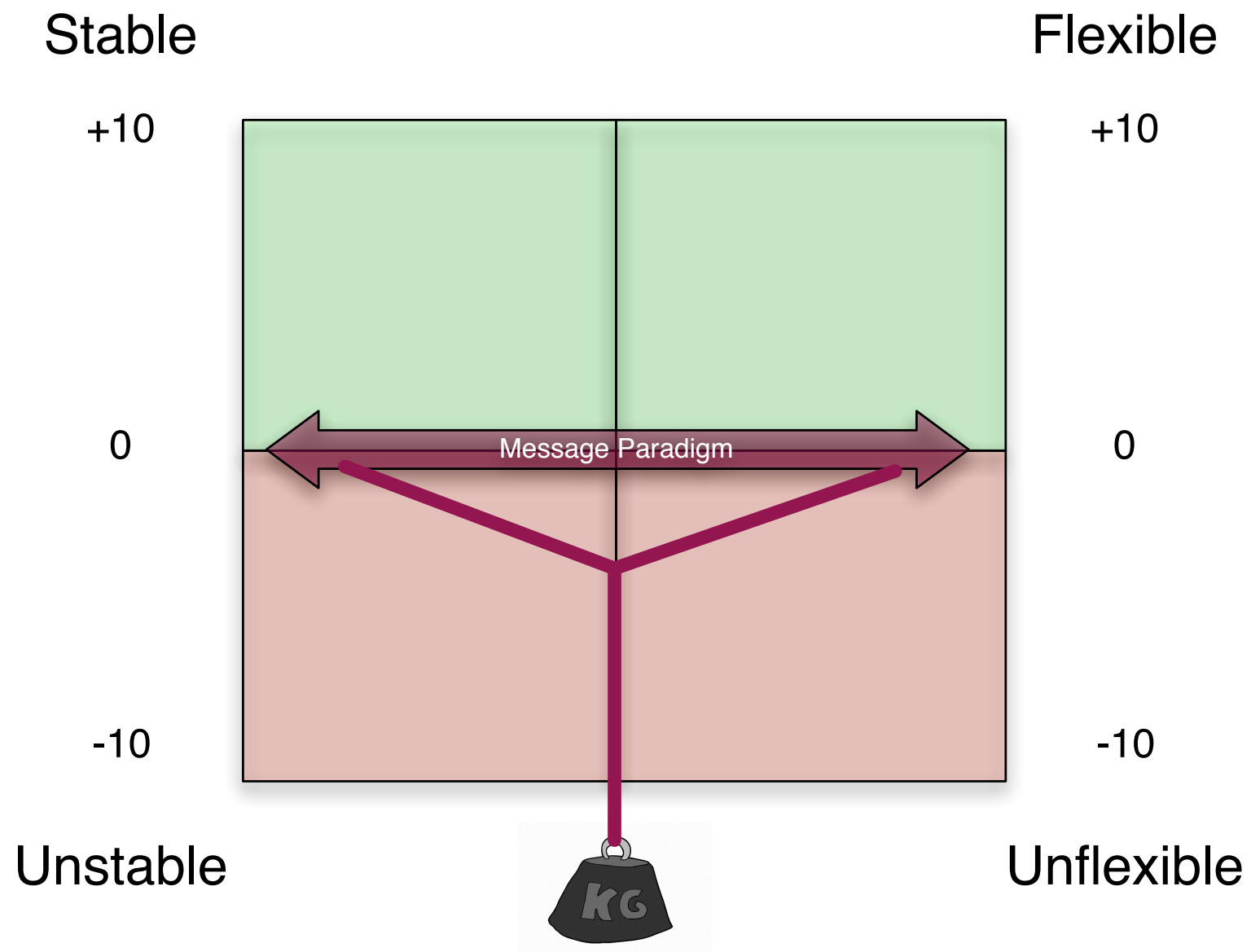
- Interface Engine preparation
  - about 18 man-months
- Proprietary to/from HL7
  - 3 to 7 man-months.
- HL7 to HL7
  - 1 to 3 man-months
- Estimates include
  - time for design, development, testing, production planning, and production move.
  - time for communication.

Exchange HL7		DCM	EN13606 Exchange			EN13606 EHR-system
<b>Message</b> to exchange between proprietary databases  <b>NOT conformant to ISO18308</b>	<b>Scope</b>		<b>EHR Extract</b> Reference Model describing documentation of: Structure of a document, archiving, digital signatures patient mandate, semantic links <b>Conformant to ISO18308</b>	<b>Scope</b>	<b>Reference Model En13606-1</b>	EHR-System Reference Model describing documentation of: Structure of a document, archiving, digital signatures patient mandate, semantic links <b>Conformant tom ISO 18308</b>
			Model describing how to make constraints on EN13606-1		<b>EN13606-2</b>	Model describing how to make constraints on EN13606-1
Not specified			Patient Mandate for complete record or any part of it		<b>EN13606-4</b>	Patient Mandate
		<b>DCM</b>	Describing what gets documented about: Information components/concepts			Describing what gets documented about: Information components/concepts
			EN13606 representation of DCM		<b>Archetype</b>	Definition of how a topic is stored in a conformant database
Message Reference Information Model to produce statements	<b>RIM</b>					
Model describing a knowledge domain	<b>DMIM</b>		Describing the information needs in a domain for exchange		<b>Archetype Library</b>	Domain Information that can be stored in a database
Model describing according to the scope of the specific messages	<b>RMIM / CDA / (Templates)</b>		Model describing local context the exchange: structure domain content		<b>Template</b>	Description of the structure and content used in a local context for a report, screen
Standard Message Technical respresentation	<b>XML-Schema</b>		Defines the content of the exchange	<b>EHR-Extract</b>	<b>EHR-Extract/ Archetype/Template</b>	Defines the content of the record
Describing model/tech spec of messages with all degrees of freedom removed	<b>IHE profile</b>		Not necessary because of EN13606			Not necessary because of EN13606-1
IT-vendors adapt software in a region/ country leading to database conversions	<b>Implementation</b>		Immediate implementation of the extract without re-programming need. No database conversions are needed	<b>Implementation</b>	<b>Implementation</b>	Immediate implementation of the extract without re-programming need. No database conversions are needed
Install with all users in a region in a country	<b>Roll-out</b>		Immediate automatic implementation of the extract and its describing archetypes/template	<b>Roll-out</b>	<b>Roll-out</b>	I Immediate automatic implementation of the extract and its describing archetypes/template
Not possible	<b>Local adaptability</b>		Possible	<b>Local adaptability</b>	<b>Local adaptability</b>	Possible

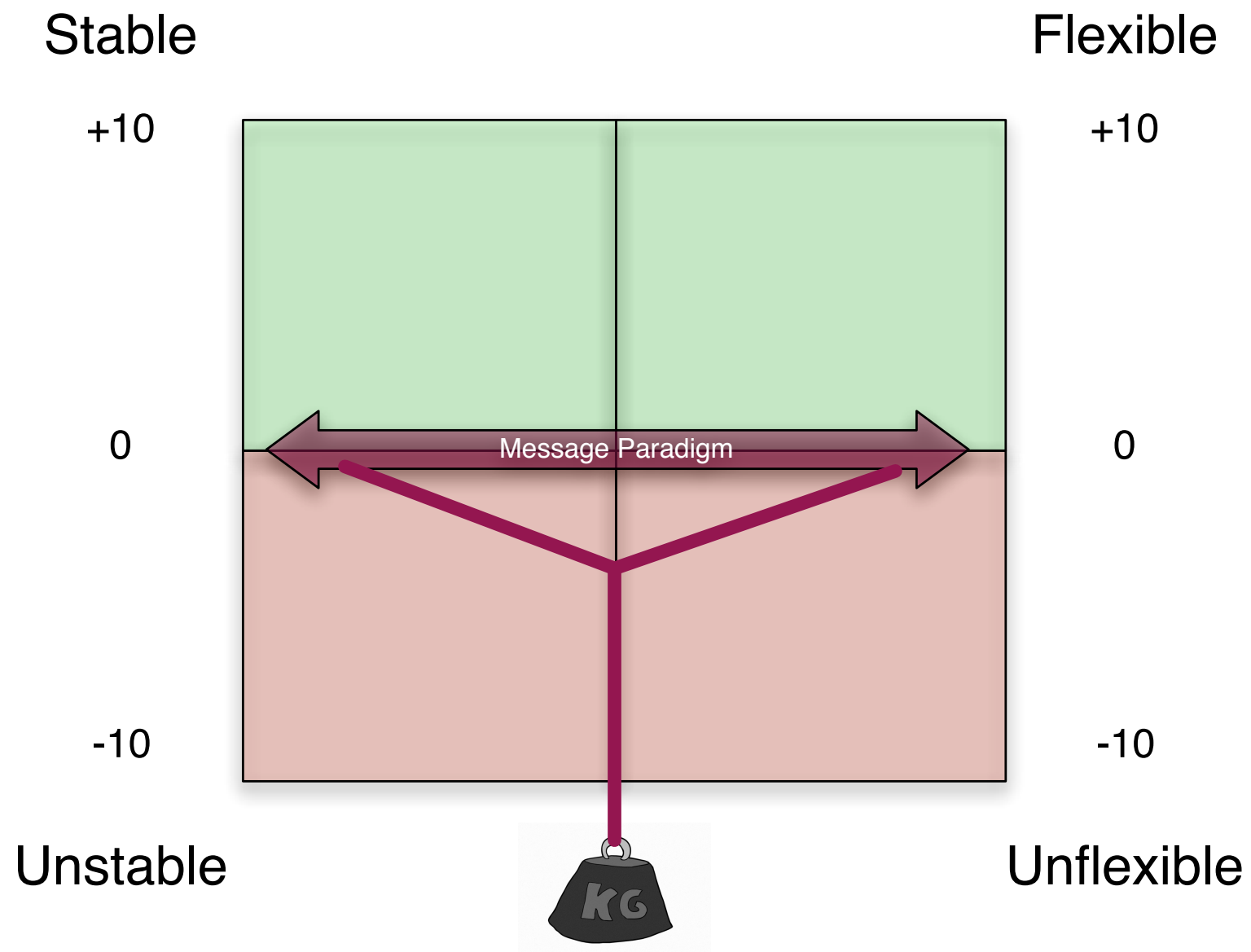
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I tried to reflect the similarities and differences between HL7 artifacts and those of CEN/ISO EN13606

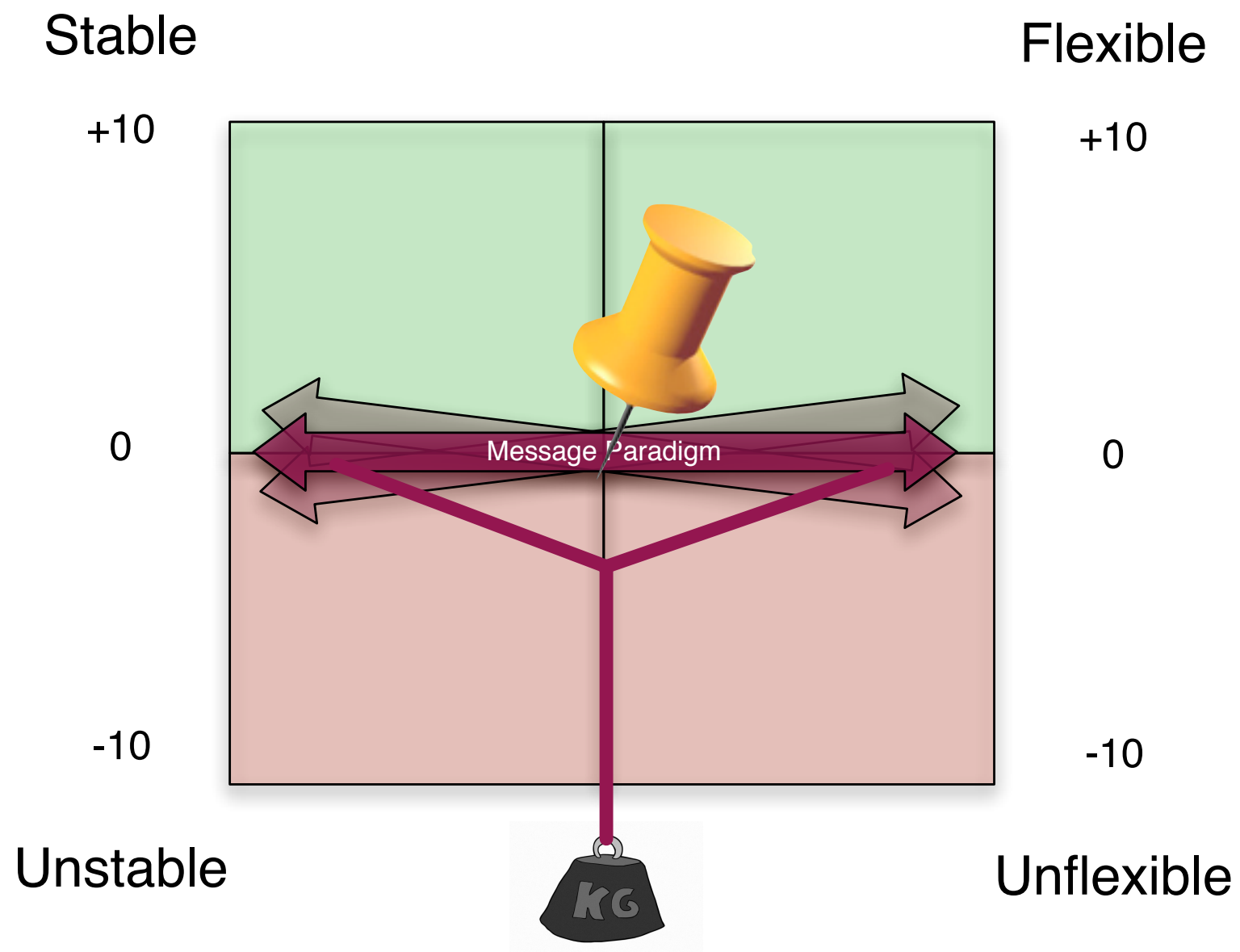
# Message based paradigm versus Archetype based paradigm



# Message based paradigm versus Archetype based paradigm



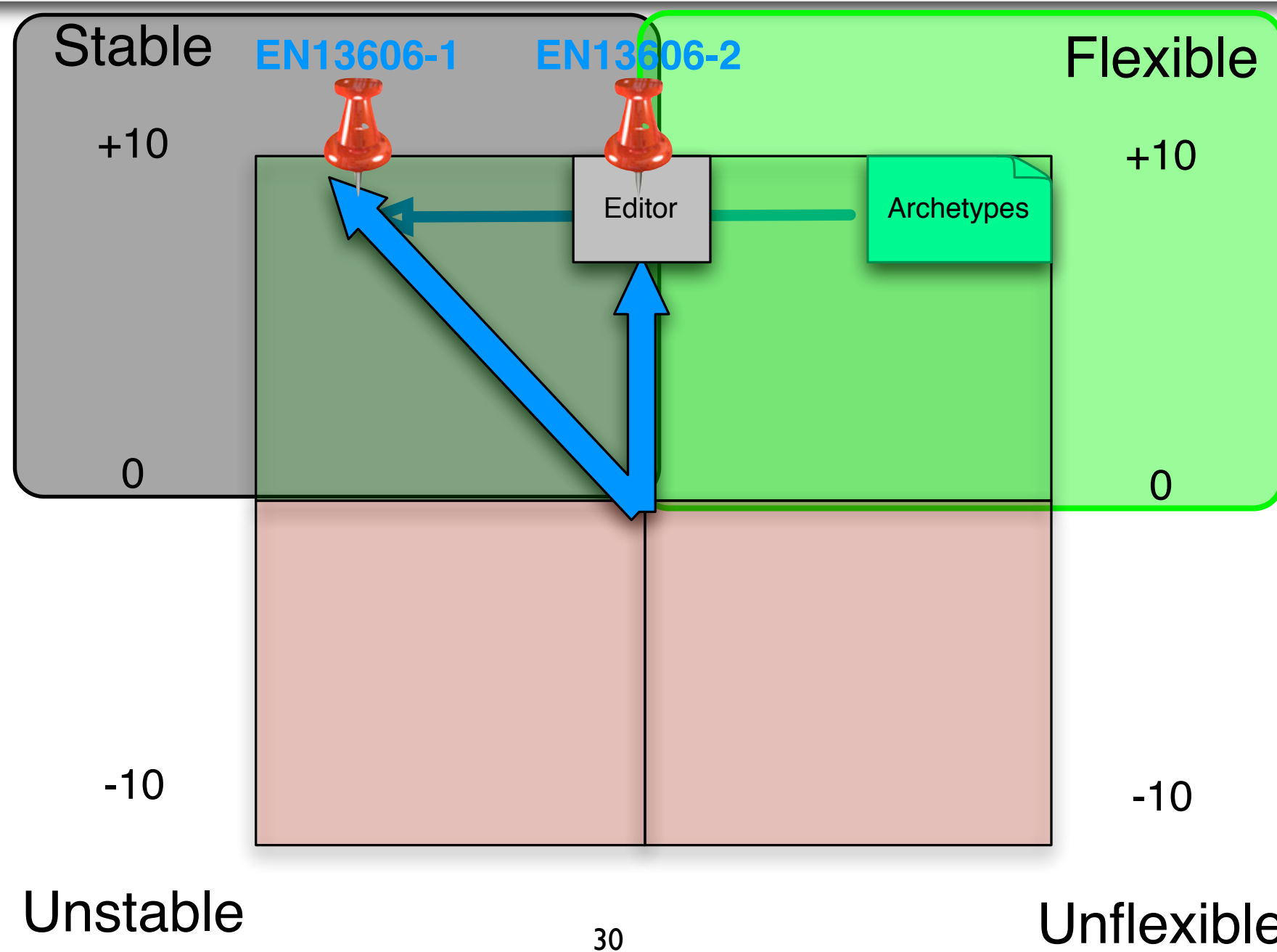
# Message based paradigm versus Archetype based paradigm



One model Message Paradigm

A general optimal situation is created.  
Because of the resources (Time and money) needed it will always be suboptimal and very static.  
Only very small variations are possible. Always the suboptimum will be reached.

# Message based paradigm versus Archetype based paradigm



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## Two Level Model Paragdigm

Stable and flexible at the same time.

How?

Model 1 nails down the EHR-system with a Documentation/ArchivingModel

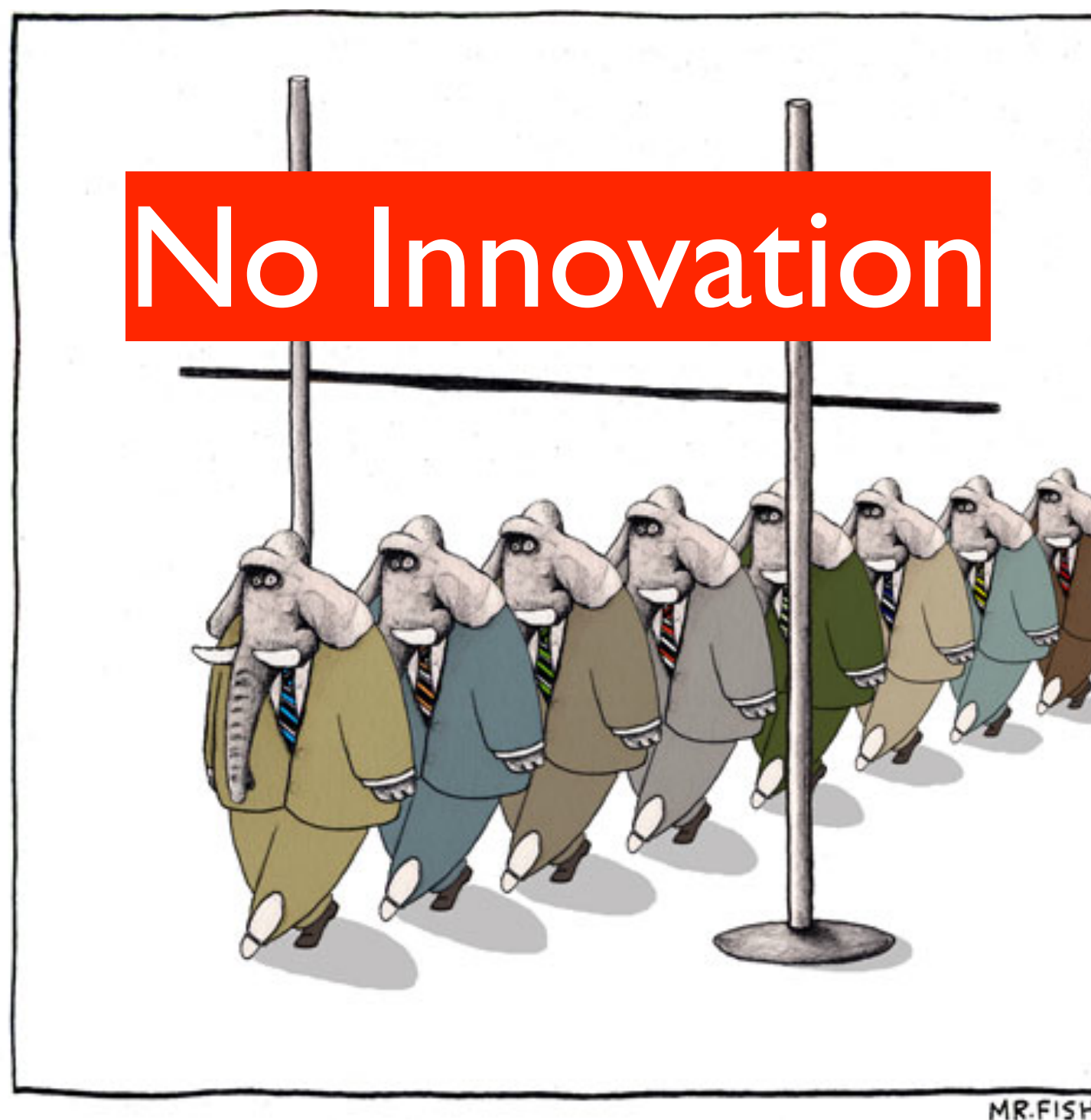
Model 2 allows healthcare to define extremely flexibly anything they want to document, as constraints on the first model.

The IT-sector will be responsible for the Stable part.

Healthcare for the Flexible part.

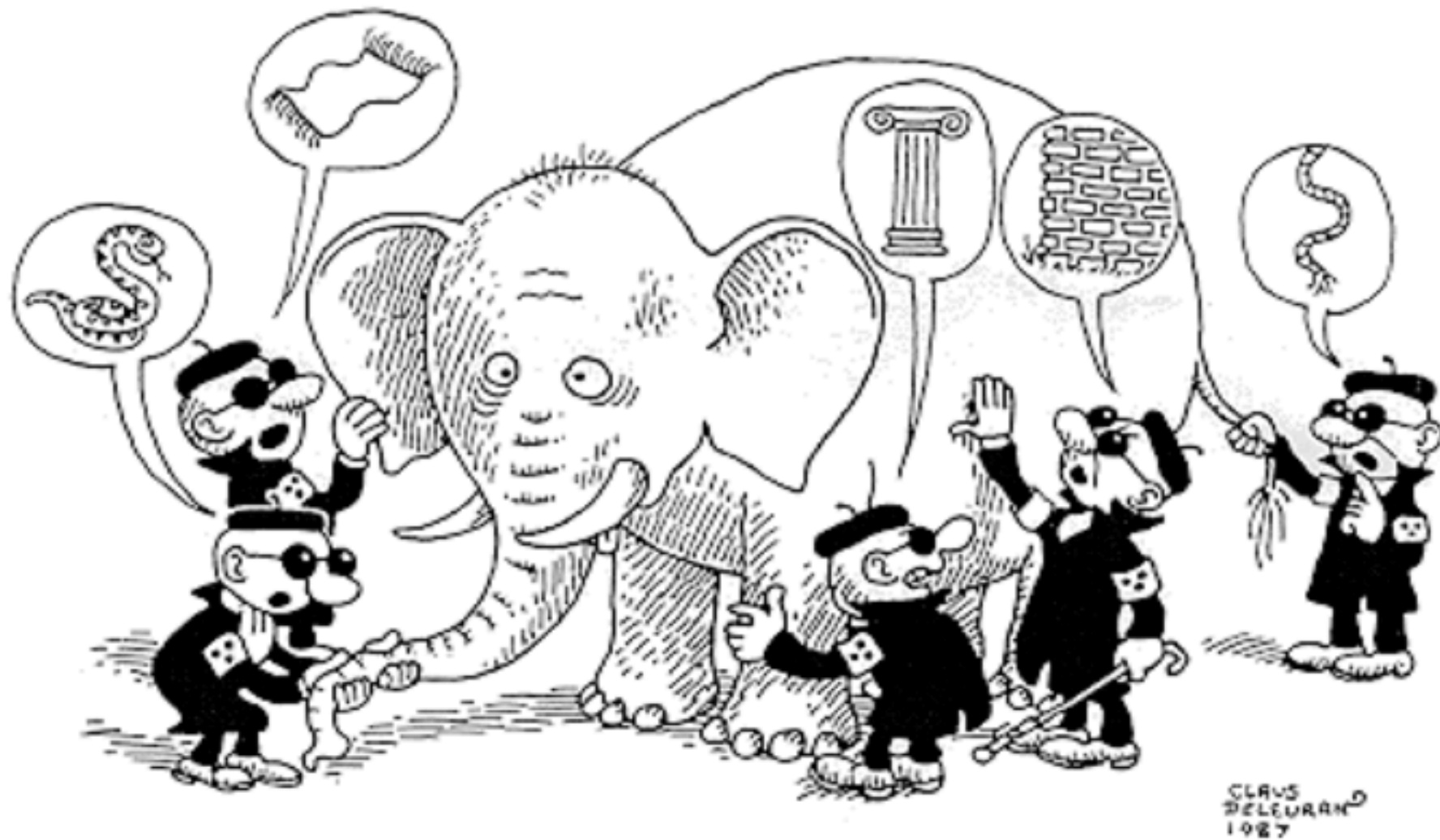
A complete separation of concerns.

# Message standards: Edifact, HL7, IHE





# What is an EHR?



*Slide kindly provided by Søren Vingtoft*

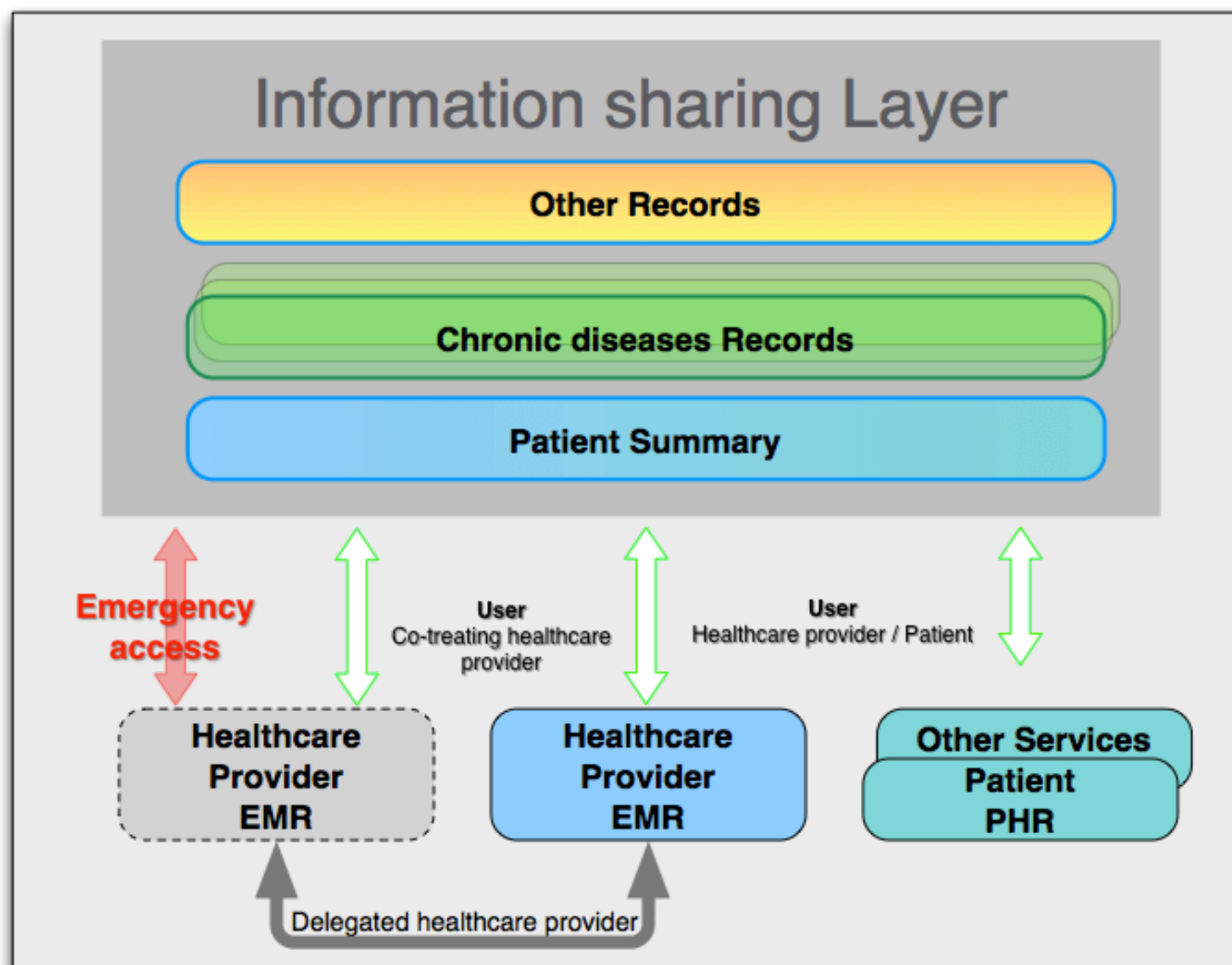
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There are many ideas of what an EHR is.  
I will not discuss reasons why an EHR is essential in this day and age.

I will discuss what to my mind IS the EHR.



# What is the EHR? eHealth Infrastructure?



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In Essence the EHR is ALL what you see in this picture.  
It is a high level model I use to think about an eHealth Infrastructure and the EHR.

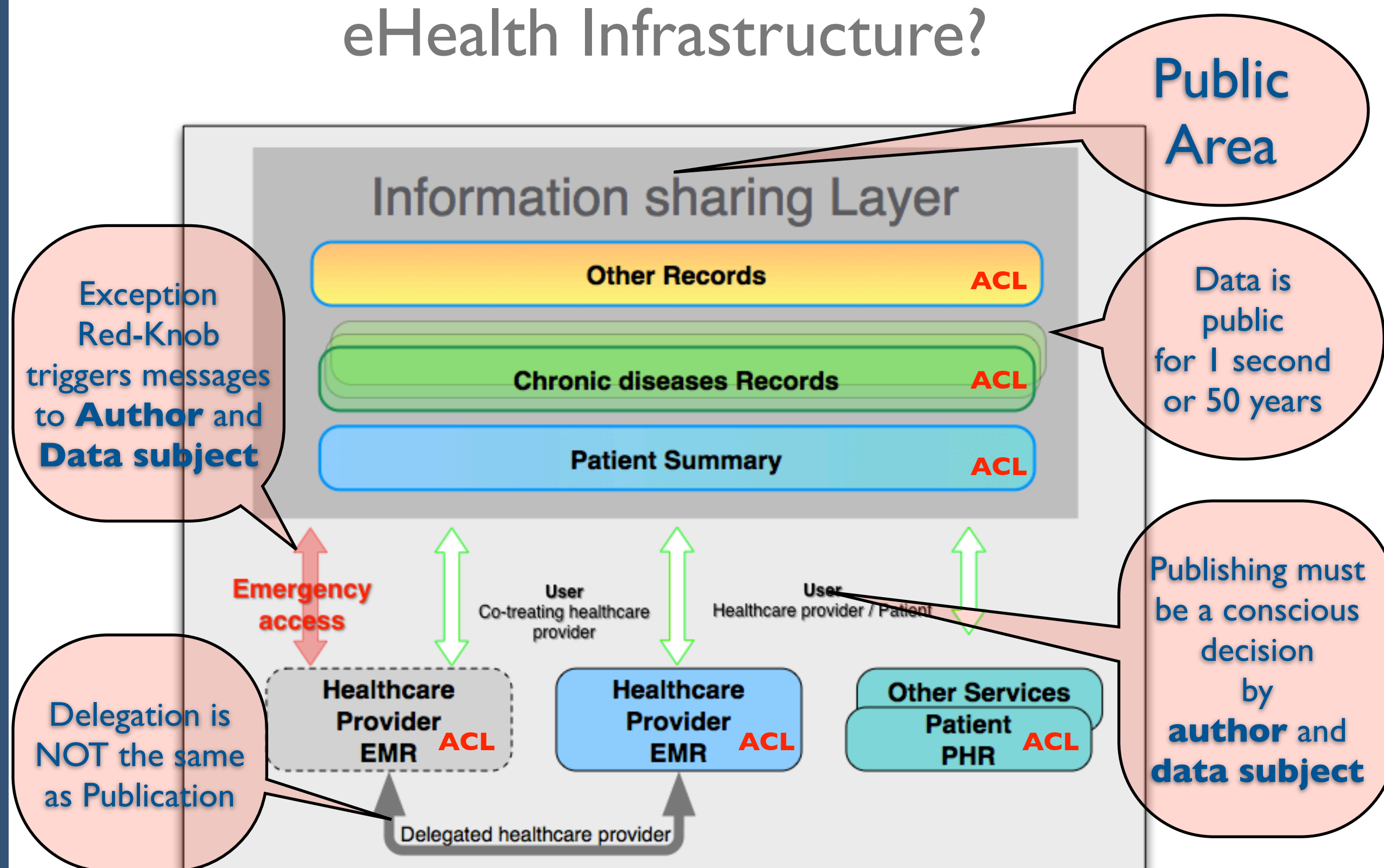
The prime function of the EHR is to document the treatment given to a patient by a healthcare provider  
(Sometimes patients treat themselves and are healthcare provider, also)

Some experiences indicate that any solution that does not fit this picture leads to avoidable discussions and problems in the acceptance.

- 1- the eHealth Infrastructure (and EHR) is about DOCUMENTATION of the care delivered. The author is central. IT must facilitate and document the provision of healthcare. In the context of the EHR it is NOT the patient that is central!  
It is the documentation and archiving of the care delivered.
- 2- Not only the HCP is author. The patient and its surrounding carers have a need to document.
- 3- Each author is responsible for what he documents.
- 4- It is the author (Together with the patient) that decide what will be published in an Information Sharing Layer. They control the Access Control List.
- 5 -E.g. discharge letters will be published for short period of time. The patient summary and the chronic care record will be there permanently. Each artifact needs an accountable person as
- 5- They can add any other to the ACL as a conscious decision they need to take accountability for.
- 6- Delegation must not be confused with data in the Information sharing Layer.
- 7- Seldomly one will need immediate access and has to invoke the Red Button procedure, leading to immediate alerting all authors AND the patient.

# What is the EHR?

## eHealth Infrastructure?



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In Essence the EHR is ALL what you see in this picture.  
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-4-

# What is missing?

a semantic interoperability  
supporting **infrastructure**

# **1. Legislation**

## **2. the Semantic Stack as a (European) Service**

a shared quality assured library of:

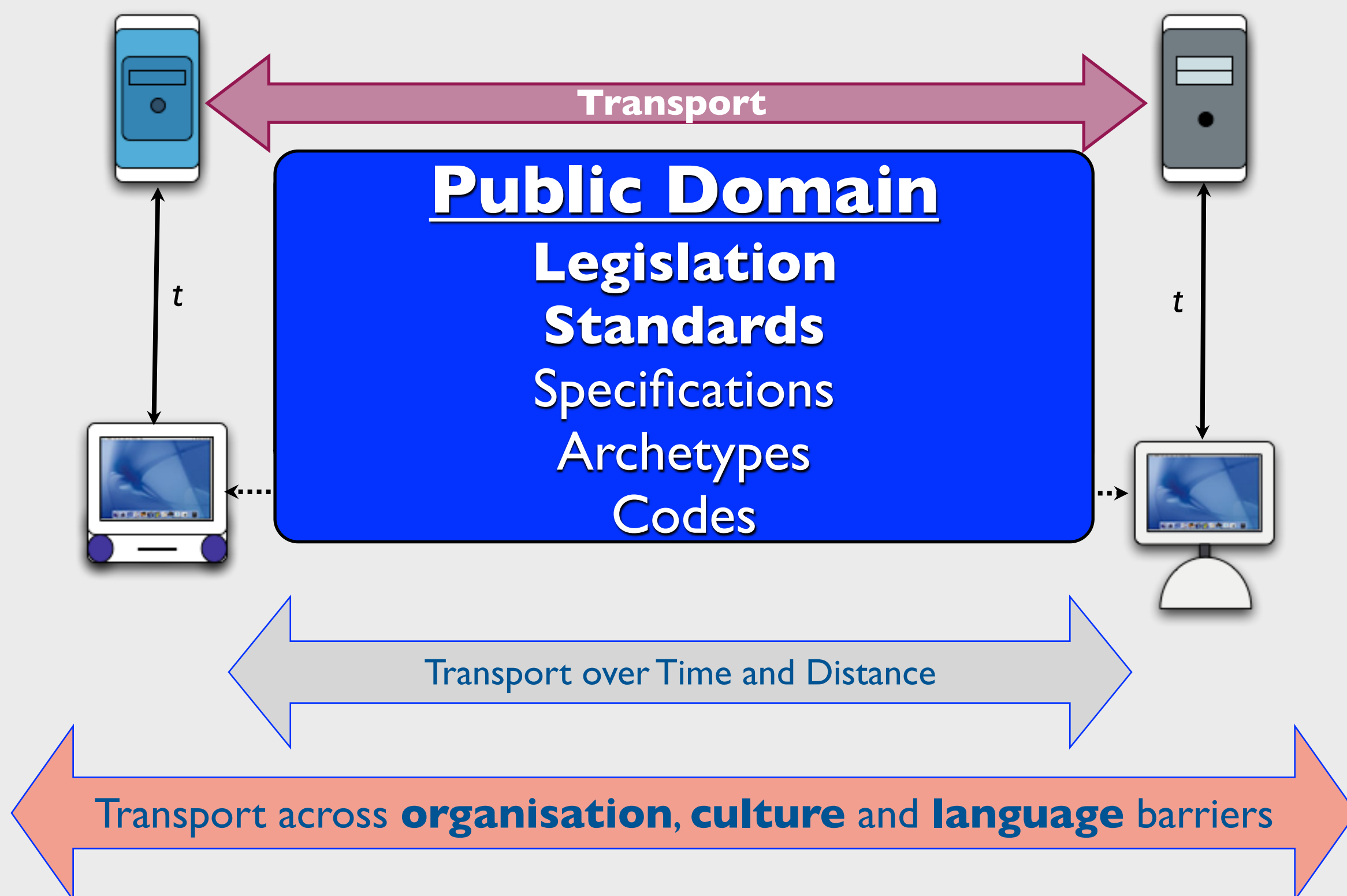
- Archetypes, Templates
- Terminologies/Codes and
- Ontologies

## **3. Quality Assurance**

## **4. Shared IPR and Licenses**

## **5. Accountable organisation(s)**

# What is needed



# R&D - Innovation Digital Agenda

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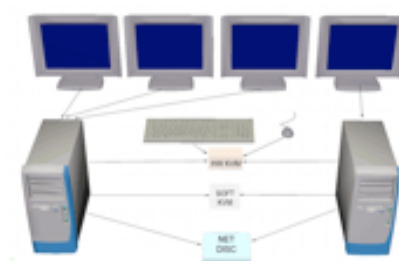


Digital  
Agenda

Infrastructure  
Infostructure

Legislation  
Standards

Effect on society	-	Innovation
Infrastructure	-	Infrastructure
R&D - New products	One-off	Commodity



EMR



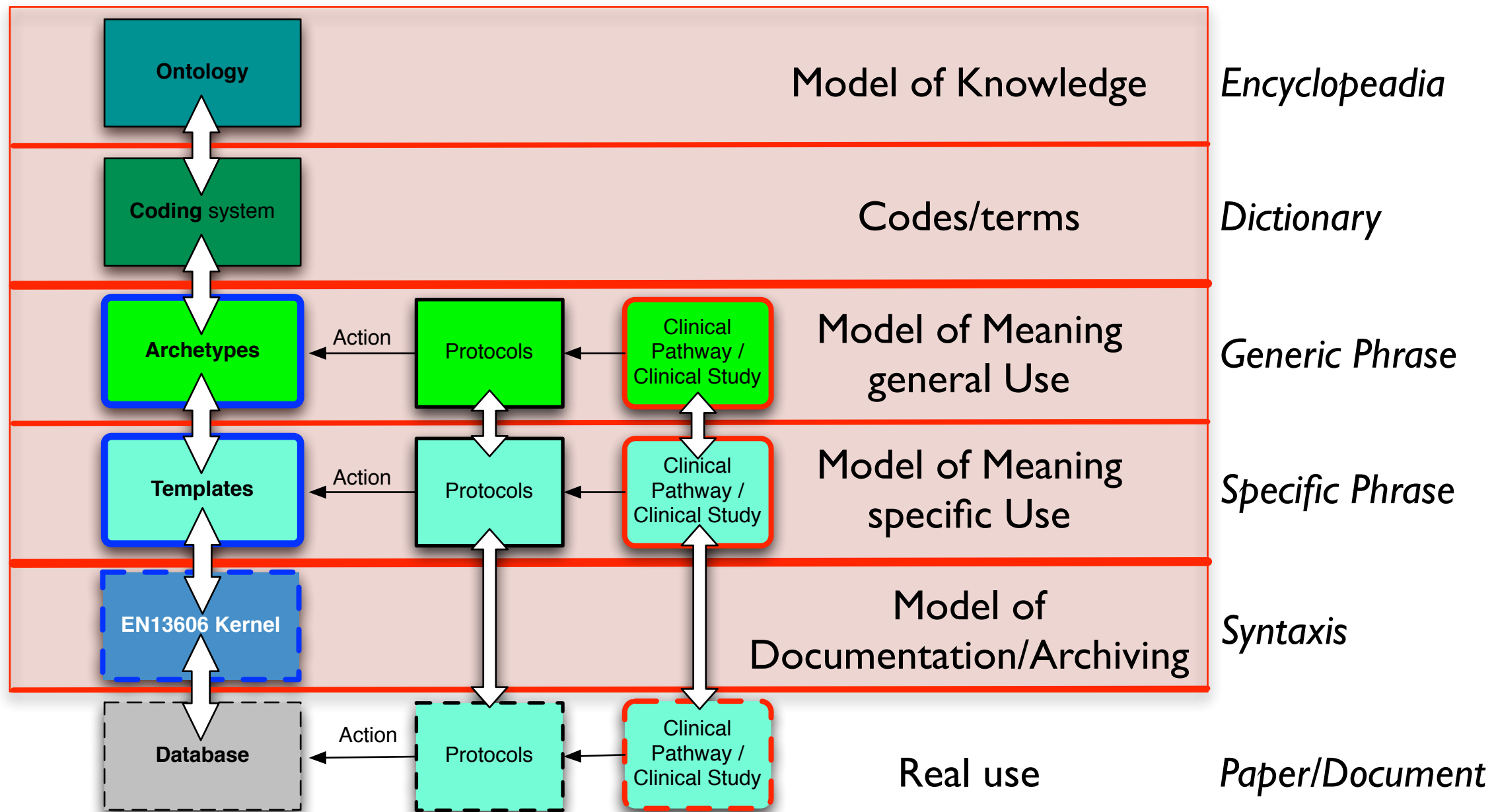
EHR



# What is needed

## Semantic Interoperability Stack

**DCM**



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Semantic stack.

This is an idealised picture of what is needed for real semantic interoperability.

We have to deal with:

- a- Model of Documentation/Archiving (Syntaxis)
- b- Codes/terms (Dictionary)
- c- Model of Knowledge (Encyclopedia) to allow systems to reason about the data and information in the future and build correct coding systems.
- d- Models of Meaning in general and in specific local contexts.

Archetypes/templates are needed because without it is possible to construct correct but meaning less sentences:

- the Moon drank the mountain

Or express the opposite of what it states literally

- Once upon a time ...

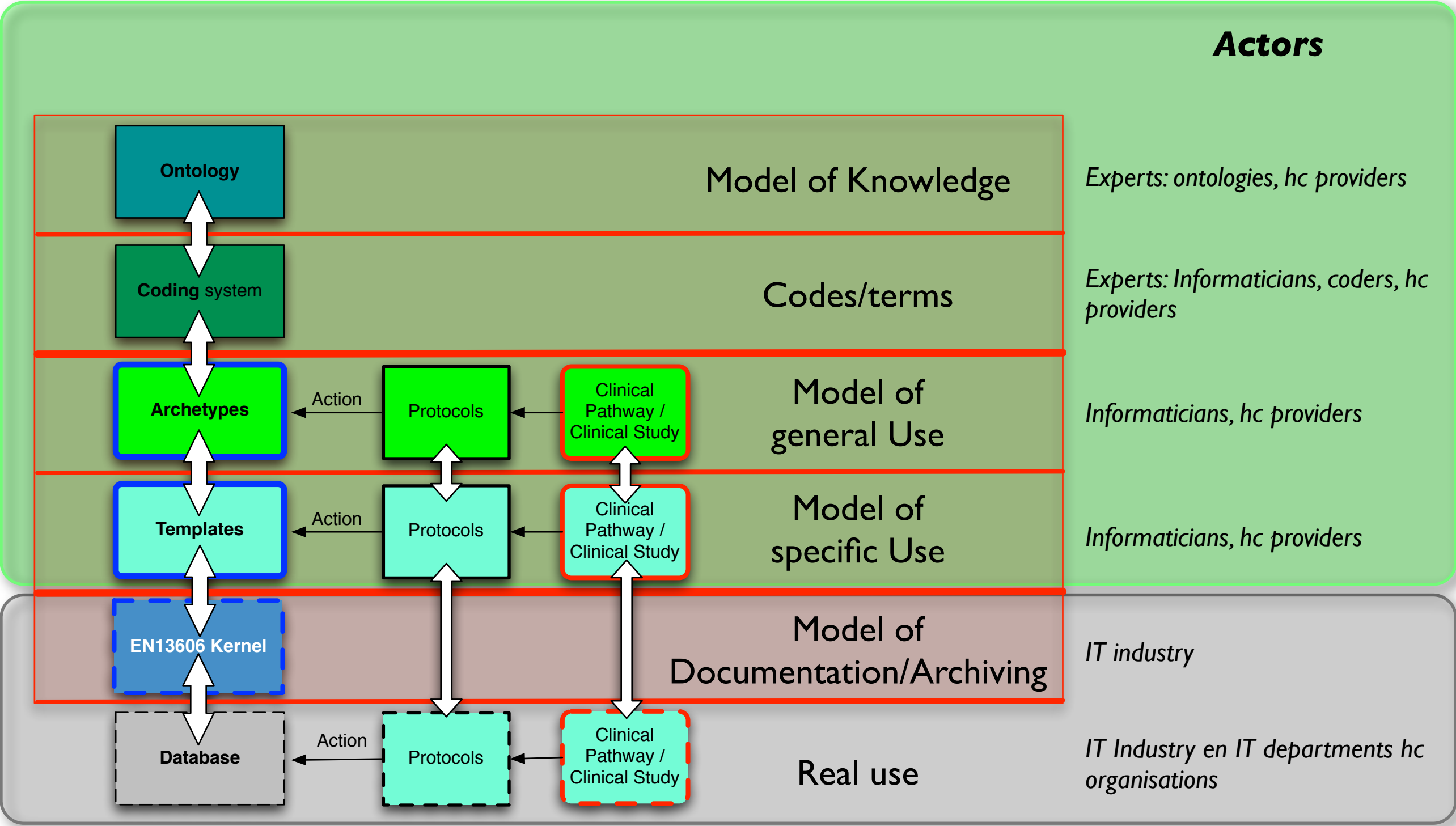
Archetypes and Templates are produced on the basis of local agreements.

And can not be considered Universals like Codes or elements of the Ontology.

It must be possible to express that locally in a specific context a Blood Pressure of 120 mm/Hg is abnormal because it is a new born baby.

Archetypes and Templates define what is at this moment and in that context considered the interpretation of 'normal'.

# What is needed



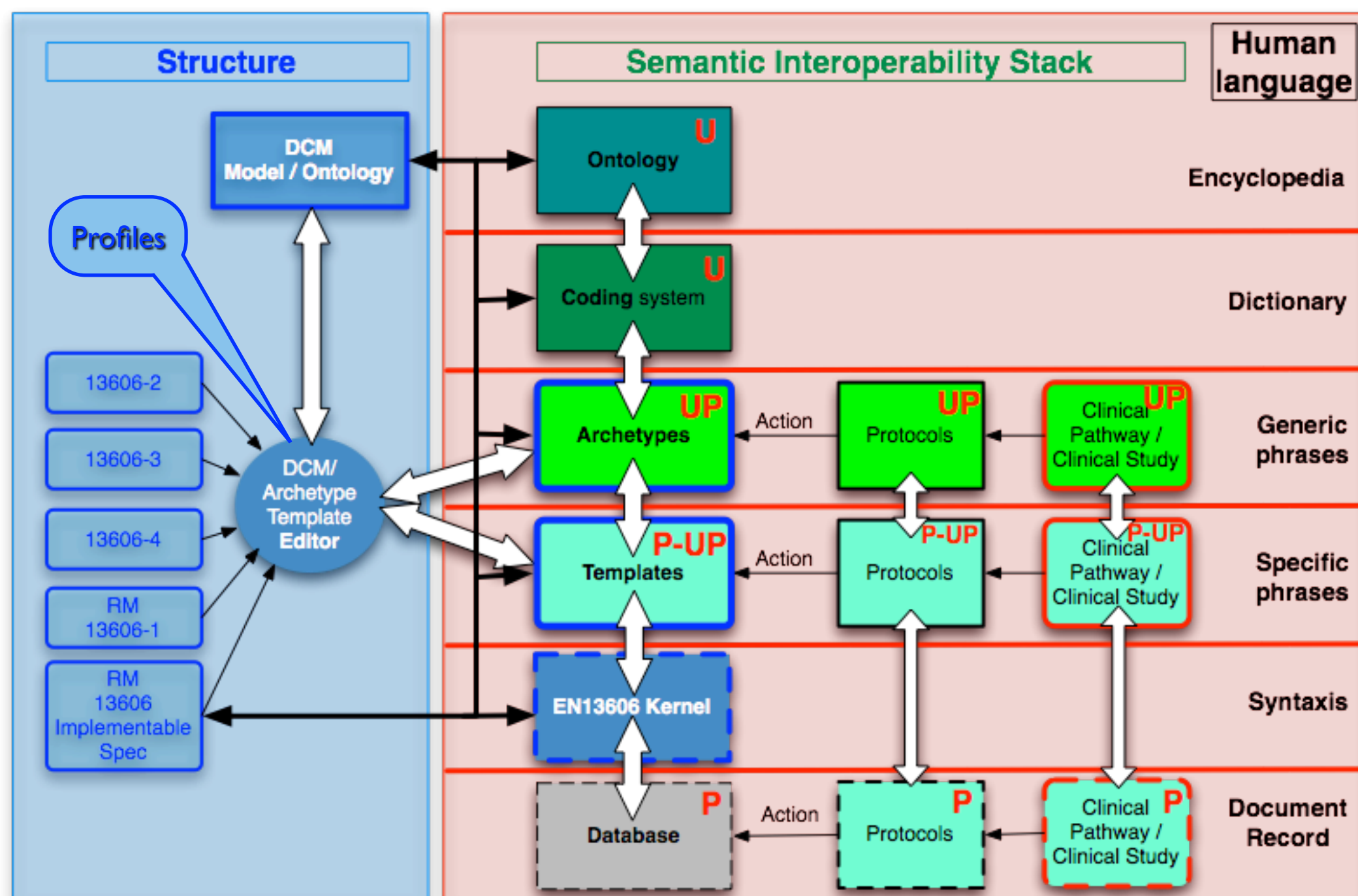
The Healthcare domain will be responsible for the GREEN parts.  
The IT-industry will be responsible aand active in the GREY domain.

IT-systems will be able to deal with all archetypes/templates the Healthcare Domain produces.  
IT-vendors no longer are responsible for the data/information content.



# Concept

## Semantic Interoperability Stack



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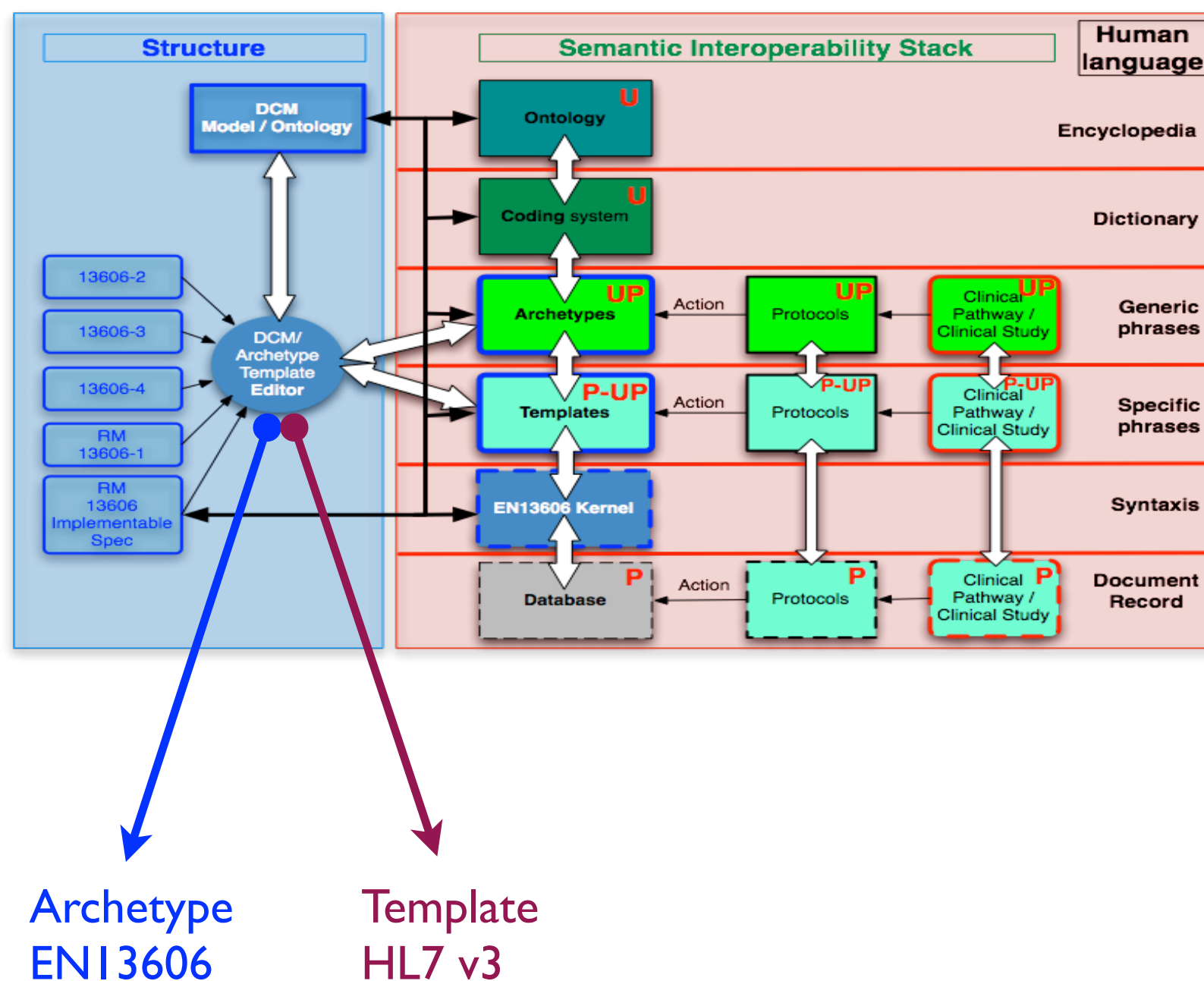
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The future of Semantic Interoperability

For Semantic Interoperability now and in the future it will be essential to have an Ontology define health knowledge. The Ontology must drive the DCM Tooling but also the Coding systems used.

# Concept

## Semantic Interoperability Stack



-6-

# **ENI 3606**

## **Consortium/Association**

# EN I 3606 Consortium-Association

The CEN/ISO EN13606 Information Site

Home

search...

**Main Menu**

- Home
- About this site
- Semantic interoperability
- CEN/ISO EN13606 standard
- Archetypes and DCM
- Resources
- Discussion forum
- EN13606 Workshop, Madrid, June 2010

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- [Forgot your username?](#)
- [Create an account](#)

**The CEN/ISO EN13606 Information Site**

Welcome to the EN13606 Information site

The main aim of this website and community is to become the prime source of information about the CEN/ISO EN13606 EHR standard for healthcare providers, hospitals, IT-vendors and regional and national projects. At the same time, to pave the way for a next release of the CEN/ISO EN13606 EHR standard based on existing implementation experiences.

We can think of many topics that can be discussed:

- Creation of a user community around EN13606
- Sharing of experiences, implementations and tools
- Extension of the present EN13606 with implementable specifications like an XML-schema
- Addition of new features like: genomics, service interfaces
- Detailed Clinical Models and documentation (modeling) patterns for DCM's (Archetypes)
- Governance and certification of specifications and produced Archetypes/DCM's/Templates
- Documentation
- Archetype modeling
- Renewal of the present EN13606
- Development roadmap for the CEN/ISO EN13606 EHR standard

We invite you to sign-up for a discussion, start-up a discussion yourself or contribute texts and opinions.

The EN13606 Information Site Team

**Supporters**

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Electronic Record Services

**New EN13606 wiki**

Written by Administrator  
Monday, 06 September 2010 10:40

A wiki for the EN13606 community has been created and has free access for all users. Main contents and organisation of the wiki is still in development.

You can visit it at <http://wiki.en13606.org>

**CEN/ISO EN13606 invitational workshop, Madrid, June 2010**

Written by Administrator  
Tuesday, 20 April 2010 09:51

 **Helmholtz Zentrum München**  
German Research Center for Environmental Health

**CEN/ISO EN13606 Invitational Workshop**  
June 2nd and 25th 2010  
Madrid, Spain

We are delighted to present CEN/ISO EN13606 invitational workshop to be held in Madrid in June 2010 by invitation only. Limited capacity.

**www.ENI3606.org**

# ENI 3606 Consortium-Association

**ERS**

Electronic Record Services BV

**UK**

**Sweden**

**Spain**

**Slovakia**

**Australia**

**Germany**

**Norway**

**Ireland**

**USA**

Netherlands

Brazil

New Zealand

Serbia

USA

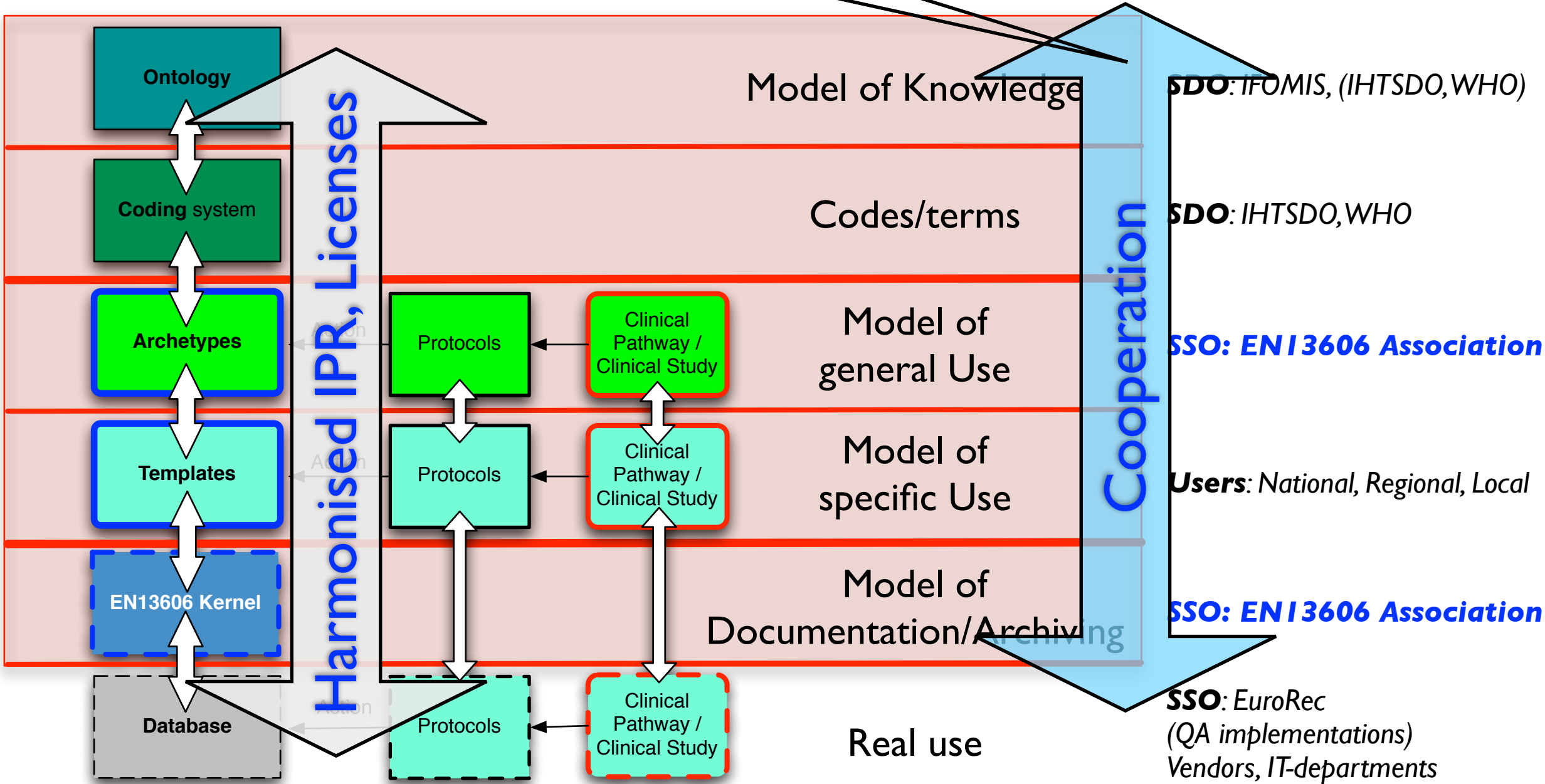
Singapore

# What is needed

## Consequences for

- Standardisation
- Funding

## Actors



The Healthcare domain will be responsible for the RED parts= the Semantic Interoperability Stack.  
The IT-industry will be responsible and active in the bits and bytes domain.

IT-systems will be able to deal with all archetypes/templates the Healthcare Domain produces.  
IT-vendors no longer are responsible for the data/information content.



# SDO's and EN I 3606 Consortium

## Proposal: IPR, Licensing and the EN13606 Consortium

- 1.The EN13606 Consortium is founded to own, produce, maintain and publish artefacts derived from the **Open Standards CEN/ISO EN13606** and needed for the implementation of the Two Level Modelling paradigm.
- 2.Authors of original works -to their discretion- can hand over IP Rights to the EN13606 Consortium.
- 3.The EN13606 Consortium publishes artefacts, with an IP owned by others or itself, that pertains to the ***human readable parts***, only.
- 4.The Licensing policy that will be used by the EN13606 Consortium for all artefacts owned, produced, maintained and published will be the **Creative Commons license: CC-BY-SA**.
- 5.The EN13606 Consortium needs a legal entity that can hold IP Rights and execute the Licensing policy and be able to enter into agreements with SDO's and SSO's.
- 6.The EN13606 Consortium will establish an **Association** as the legal Public entity.



# **Europe**

# **Digital Agenda**

# **FP7**

# European Digital Agenda

**ERS**

Electronic Record Services BV

## **Communication: A Digital Agenda for Europe**

1.Lack of investment in networks: ...

2.**Fragmented digital markets:** Europe is still a patchwork of national online markets even though the problems are fixable.

3.Lack of skills: ...

4.**Fragmented answers to societal challenges:** Europe misses out on much of the potential of ICT because it does not give common answers to challenges facing society (such as the ageing population, rising health costs, climate change).

5.Rising cybercrime and low trust:...

6.Insufficient research and innovation efforts: ...

7.**Lack of interoperability:** Europe does not yet reap the maximum benefit from interoperability. Weaknesses in standard-setting, public procurement and coordination prevent digital services and devices used by Europeans from working together as well as they should.

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# European Digital Agenda

## Communication: A Digital Agenda for Europe

### ACTIONS

The Commission will work with Member States competent authorities and all interested stakeholders to:

- **Key Action 13:** Undertake **pilot actions** to equip Europeans with **secure online access to their medical health data** by 2015 and to achieve by 2020 widespread deployment of telemedicine services;
- **Key Action 14:** Propose a **recommendation** defining a **minimum common set of patient data** for interoperability of patient records to be accessed or exchanged electronically across Member States by 2012;
- **Other actions:**
  - **Foster EU-wide standards, interoperability testing and certification of eHealth systems** by 2015 through stakeholder dialogue;
  - Reinforce the AmbientAssisted Living (AAL) Joint Programme to allow older people and persons with disabilities to live independently and be active

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# European Commission

**Recommendation** of the Commission (July 2, 2008):

**On on cross-border interoperability of Electronic Health Record systems**

**Announcement** COM(2004) 356 (April 30, 2004) of the Commissssion to the Council:

**e-Health - making healthcare better for European citizens:**

**An action plan for a European e-Health Area**

**Announcement COM(2008) 689** (November 4, 2008) of the Commissie to the European Parliament, The Council:

**On telemedicine for the benefit of patients, healthcare systems and society**

# Europe FP7

## A Network of Excellence on semantic interoperability and European Health Infostructure

- The aim is to **engage leaders** and **organisations**, including professional organisations, national competence centres, industrial associations and standards development organisations to **define** and **implement** a **research agenda** on the **semantic interoperability** of health information systems and particularly electronic health records.
- European and international organisations** in the domains of **medical terminology, record architecture, medical logic** and **workflow** are expected to participate.
- The work will also include **set up of** the **governance** of a **European virtual organisation for multilingual, multicultural adaptation of international classifications and terminology** and propose means for the **sustainability** and **governance** of **health information info-structure**.



# *Semantic Interoperability Stack*

## INFORMATION

## DOCUMENTATION

## *Archiving*

# END