



# **European Quality Labelling, Certification, Electronic Health Record systems (EHRs)**

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## AGENDA

1. **The EuroRec Institute**
2. EHR-systems Certification: the QRec Project
3. Rationale for EHRs Certification
4. The EuroRec Repository: Methodology and Tools
5. Archetypes / Templates

## EuroRec (<http://www.eurorec.org> )

- The « European Institute for Health Records »
- A not-for-profit organisation, established April 16, 2003
- **Mission:** the promotion of high quality Electronic Health Record systems (EHRs) in Europe
- **Federation** of national ProRec centres in Europe

## ProRec Centers



### Centres

Belgium  
Bulgaria  
Denmark  
France  
Italy  
Germany  
Ireland  
Romania  
Slovenia  
Spain  
Slovakia

### Applicants

United Kingdom  
Serbia  
The Netherlands  
Poland  
Norway  
Greece  
Hungary  
Portugal  
Sweden  
Austria  
Malta  
Cyprus

*" Differences in languages, cultures and HC-delivery/funding systems "*

## LIAISON



## Q-REC

*European Quality Labelling and Certification of Electronic Health Record systems (EHRs)*



Duration: 2006 - 2008  
Contract No: IST-27370-SSA  
Coordinator: Prof. Georges De Moor

<http://www.eurorec.org/>

## EHR-Implement

*National policies for EHR implementation in the European area: social and organisational issues*

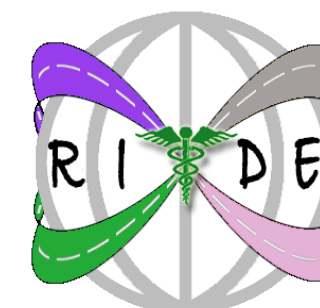


Duration: 2007 - 2010  
Contract No: IST-27370-SSA  
Coordinator: Dr. Laurence Esterle

<http://www.ehr-implement.eu/>

## RIDE

*A Roadmap for Interoperability of eHealth Systems in Support of COM 356 with Special Emphasis on Semantic Interoperability*



Duration: 2006 - 2007  
Contract No: IST-027065  
Coordinator: Prof. Asuman Dogac

<http://www.srdc.metu.edu.tr/>

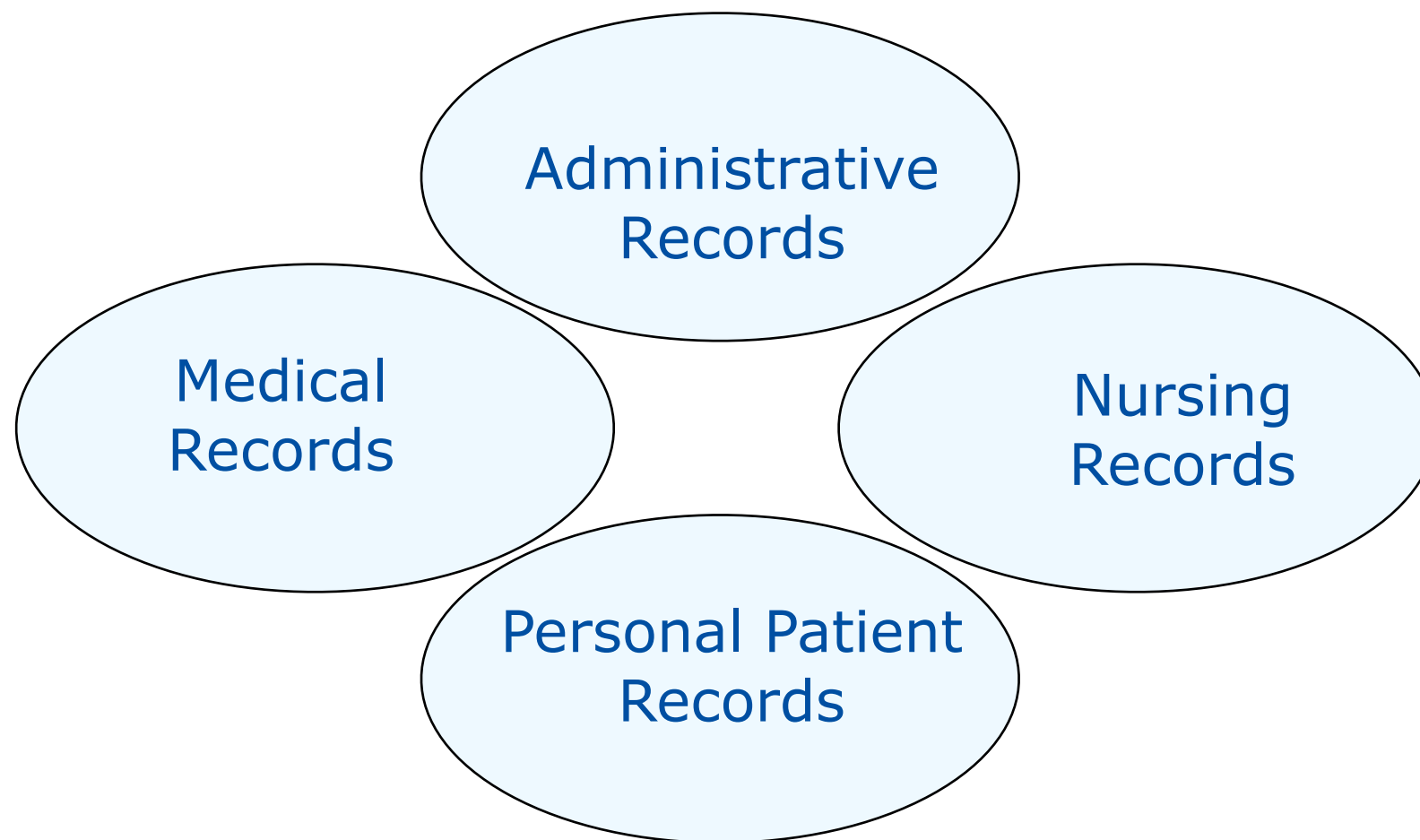
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## EHRs: TRENDS

EHRs start to become:

- transmural, virtual
- multidisciplinary and interactive
- longitudinal and intelligent



*! Integration with other eHealth applications ...!*



## Q-Rec project topics

The Q-Rec repository will comprise several kinds of artefacts relating to the quality labelling and benchmarking of EHR systems:

- EHR system requirements
- EHR system conformance criteria
- EHR system test plan items
- An inventory of quality labelled (certified) EHR systems
- An inventory of EHR related standards
- An inventory of terminology and coding schemes
- A directory of certified EHR archetype repositories
- A directory of reviewed open source specifications and components

### **Initial focus:**

- Functional requirements
- Primary care
- Prescription

## QREC's Objective: Quality Criteria and Certification

To develop **formal methods** and to create a mechanism for the quality labelling and **certification of EHR systems** in Europe, in primary- and in acute hospital-care settings

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**EuroRec Institute** is coordinating partner  
QREC has 12 partners and 2 subcontractors  
Project duration is 30 months (1/1/2006-30/6/2008)

## QREC: ORIGIN

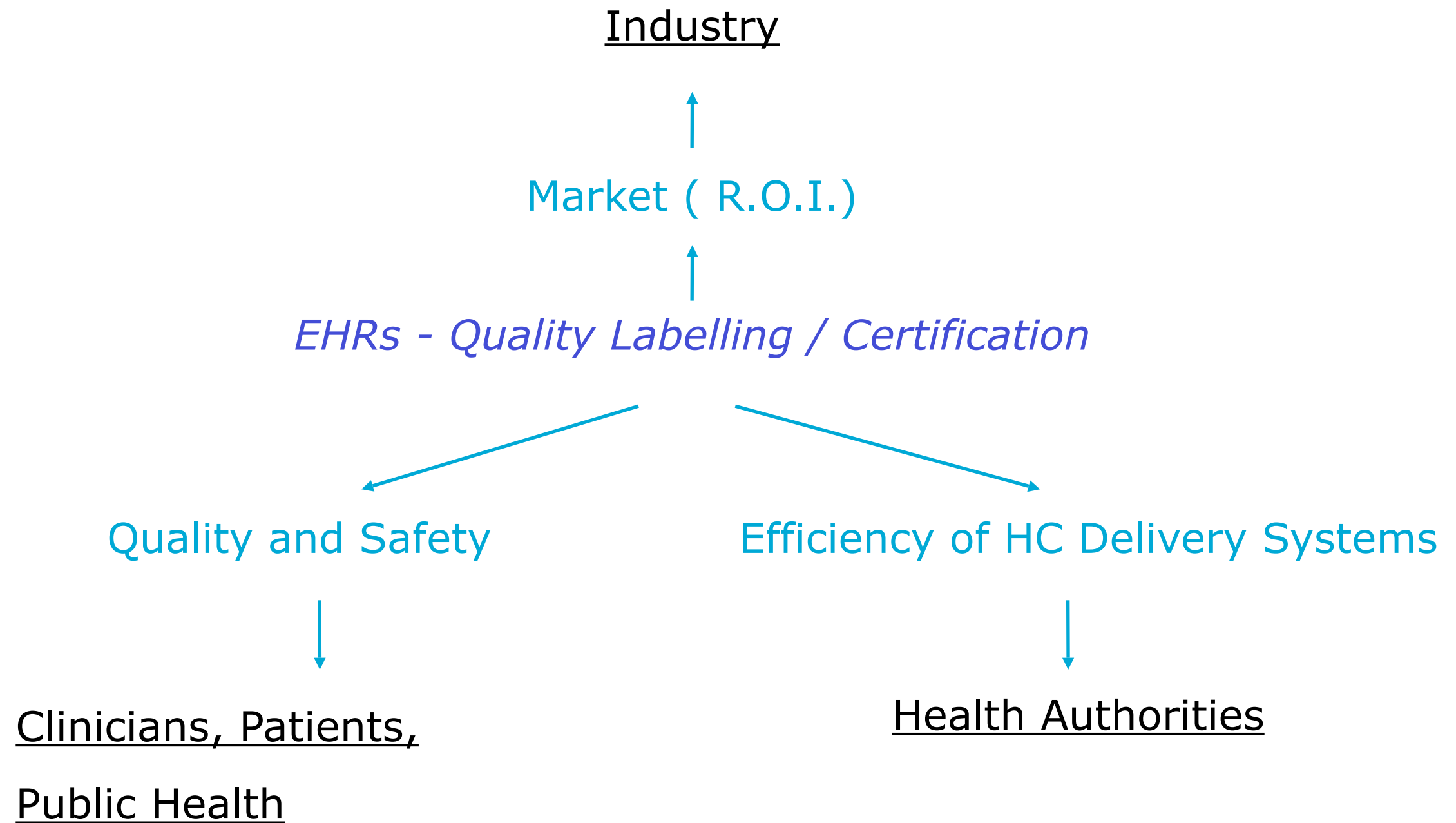
Several EU-member states (Belgium, Denmark, UK, Ireland, ...) have already proceeded since years with (EHRs-) quality labelling and/or certification (more often in primary care) but these differ in scope, in **legal** framework under which they operate, in policies and **organisation**, and perhaps most importantly in the quality and **conformance criteria** used for benchmarking ...

*These differences represent a richness but also a risk: harmonisation efforts should help to avoid further **market fragmentation** in Europe*

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## Benefits for the Stakeholders



# Q-REC Rationale – Certification is Essential

To assure the quality of EHR systems, e.g., [patient safety](#) may be at risk due to:

- system design, specification and functional inadequacies,
- poor or confusing presentation of clinical relevant information.

Sharing of information requires a quality assessment of EHR products with a view to ensuring [interoperability with other systems](#) because:

- healthcare information, in particular clinical information, is often scattered over a number of informatics systems
- the structures of these EHRs may significantly differ from one system to the other, depending on the creator and the purpose.
- more and more incentives are being given to share patients' medical data to support high quality care and "continuity of care" in a seamless way.

Certification of EHRs is essential [for purchasers and suppliers](#)

- to ensure that EHR systems are robust enough to deliver the anticipated benefits as EHR systems and related product quality (data portability and interoperability are difficult to judge).
- To reduce the risk for purchasers and therefore accelerate the adoption of high quality and more interoperable EHRs.

## AGENDA

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4. **The EuroRec Repository: Methodology and Tools**
5. Archetypes / Templates

## Central Repository

EuroRec will install a central repository of **validated quality criteria** and other relevant materials that can be used to harmonise European testing, quality labelling and procurement specification of EHR systems.

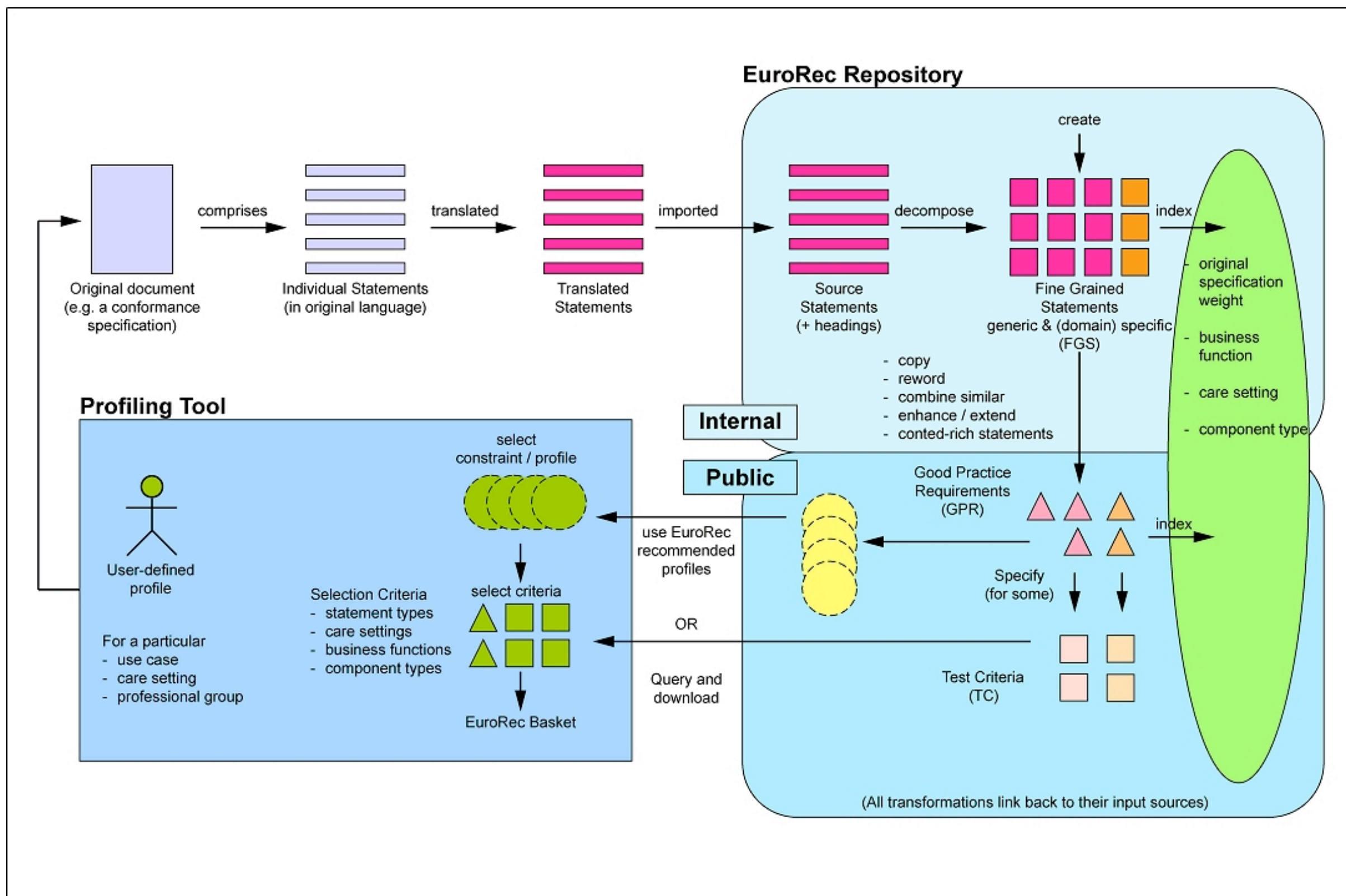
*It will **not impose particular certification models** or **specific criteria** on any member country but will foster, via ProRec centres and other channels, the progressive adoption of consistent and comparable approaches to EHR system quality labelling.*



# Typology of EHR System Statements

- Source Statements
  - faithfully extracted from original EHR system specifications and test plans
  - translated if necessary
- Fine Grained Statements (FGS)
  - usually derived from source statements
  - made more generic, decomposed, reworded, corrected
- Good Practice Requirements (GPR)
  - recomposed from FGS into the more common useful building blocks
  - may enhance or extend the scope of FGS: “push the boat out a bit”
- Generic Test Criteria
  - derived from FGS and/or GPR
  - formally worded as testable functions

# Repository Workflow



## Some statistics

### Fine Grain statements

Total FGS:	1345
Total links Business Functional Indices:	4231
Total links Care setting Indices:	3500
Total links Type of Statement Indices:	2200
Total links Indices:	9931
Total links SS FGS:	1898
Unconnected FGS:	103

### Translations

German: 91
Danish: 39
French: 246
Dutch: 218
Romanian: 30
Slovenian: 74

### Good Practice Requirements

Total GPR:	124
Total links Business Functional Indices:	457
Total links Care setting Indices:	374
Total links Type of Statement Indices:	181
Total links Indices:	1012
Total links FGS GPR:	904
Unconnected GPR:	2

### Translations

Bulgarian: 3
German: 22
Danish: 13
French: 72
Dutch: 53
Romanian: 21
Slovenian: 21

### Initial focus:

- Functional requirements
- Primary care
- Prescription

# EuroRec Use Tools

## ***The EuroRec Composer*** <sup>TM</sup>

To compose user defined, re-usable and exchangeable baskets of Fine Grained Statements.

## ***The EuroRec Certifier*** <sup>TM</sup>

To format a EuroRec Basket content to obtain the basic layer for the certification of EHR systems. This is done by adding structure and attributes to the selected Fine Grained Statements.

## ***The EuroRec Documentor*** <sup>TM</sup>

To document EHR systems and their functions, enhancing their understanding and comparability by using the EuroRec statements.

## ***The EuroRec Procuror*** <sup>TM</sup>

To list and describe, for purchase purposes, required functionalities and product characteristics using EuroRec statements.

## ***The EuroRec Scriptor*** <sup>TM</sup>

To produce and link Test Scenarios to EuroRec Baskets for Certification, Documentation and/or Procurement purposes.

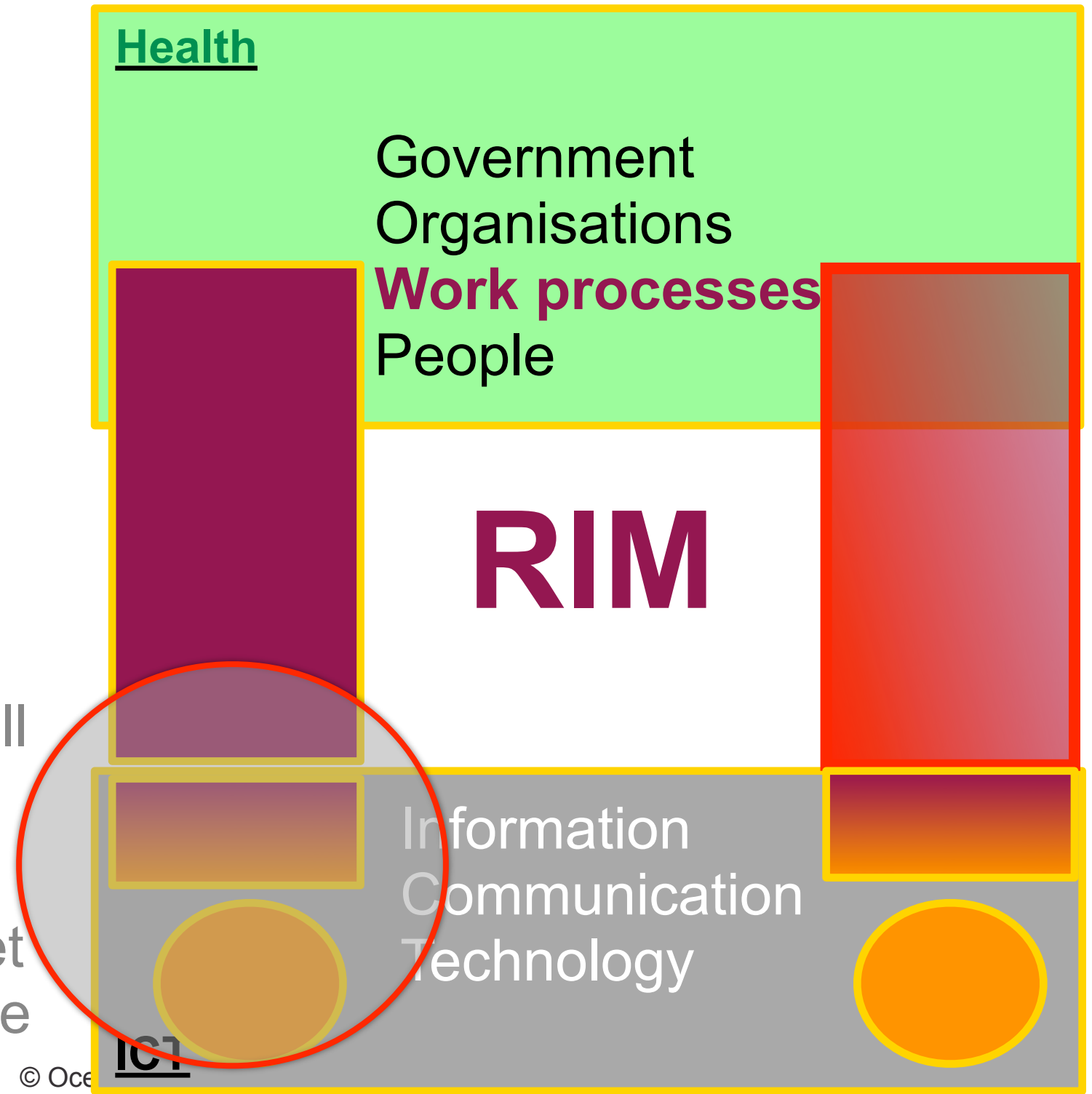
## AGENDA

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4. The EuroRec Repository: Methodology and Tools
5. **Semantic Interoperability: Archetypes / Templates**

# How?

## Messages paradigm

- 1- Standardise a work process
- 2 -Use a RIM  
(Referention Information Model)
- 3- Produce the message specification
- 4- Implement uniformly messages in systems by changing software
- 5- Install the new software in all end-user systems
- 6- Each new version or new set of messages needs the same cycle



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# How?

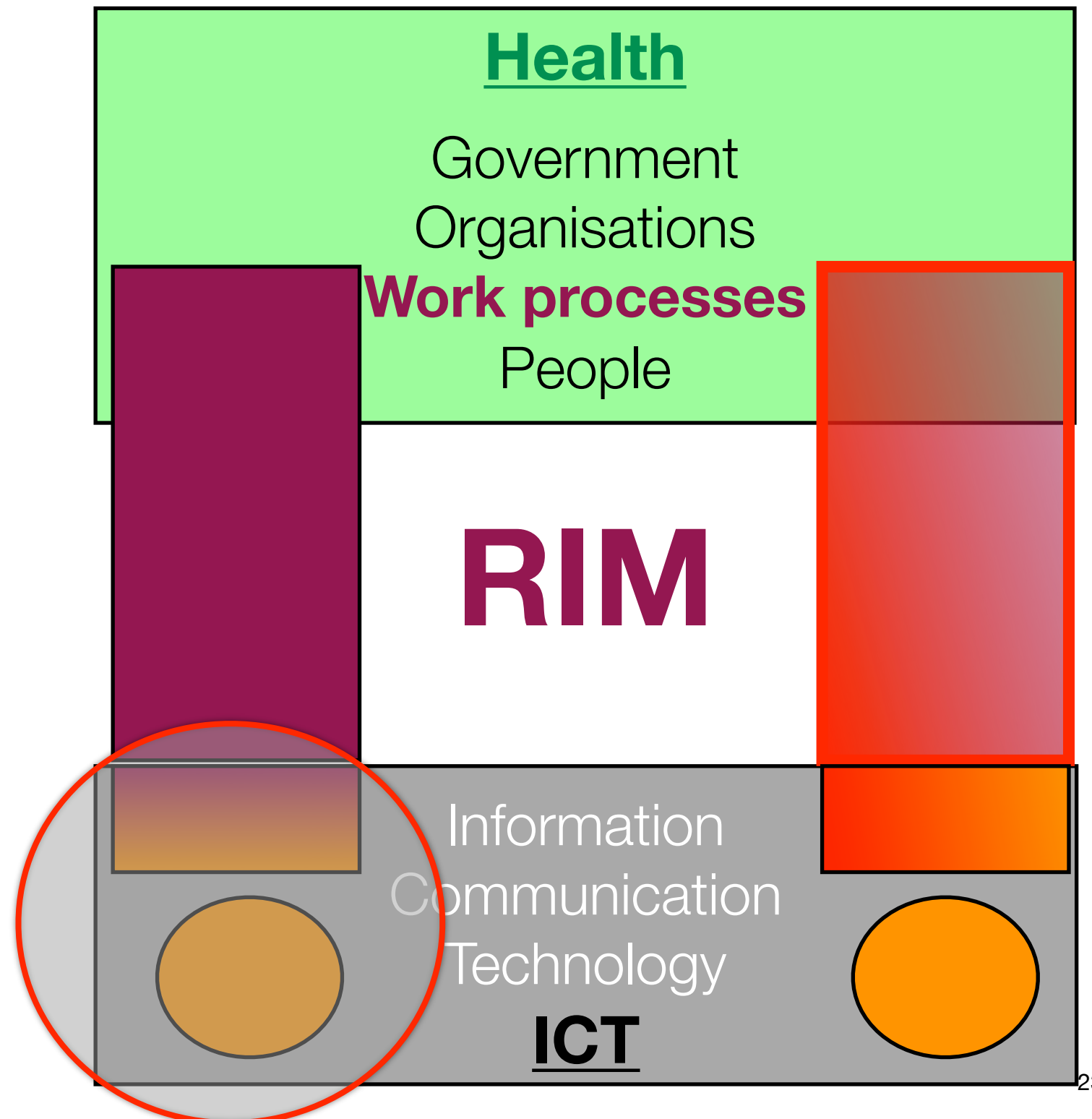
## Messages paradigm



The production of  
standardised messages  
takes 1-2 years  
(3-5 years?)

The production of tested  
implementable messages  
takes according to IHE  
1.5 years

The roll out takes an other  
couple of months till one  
year



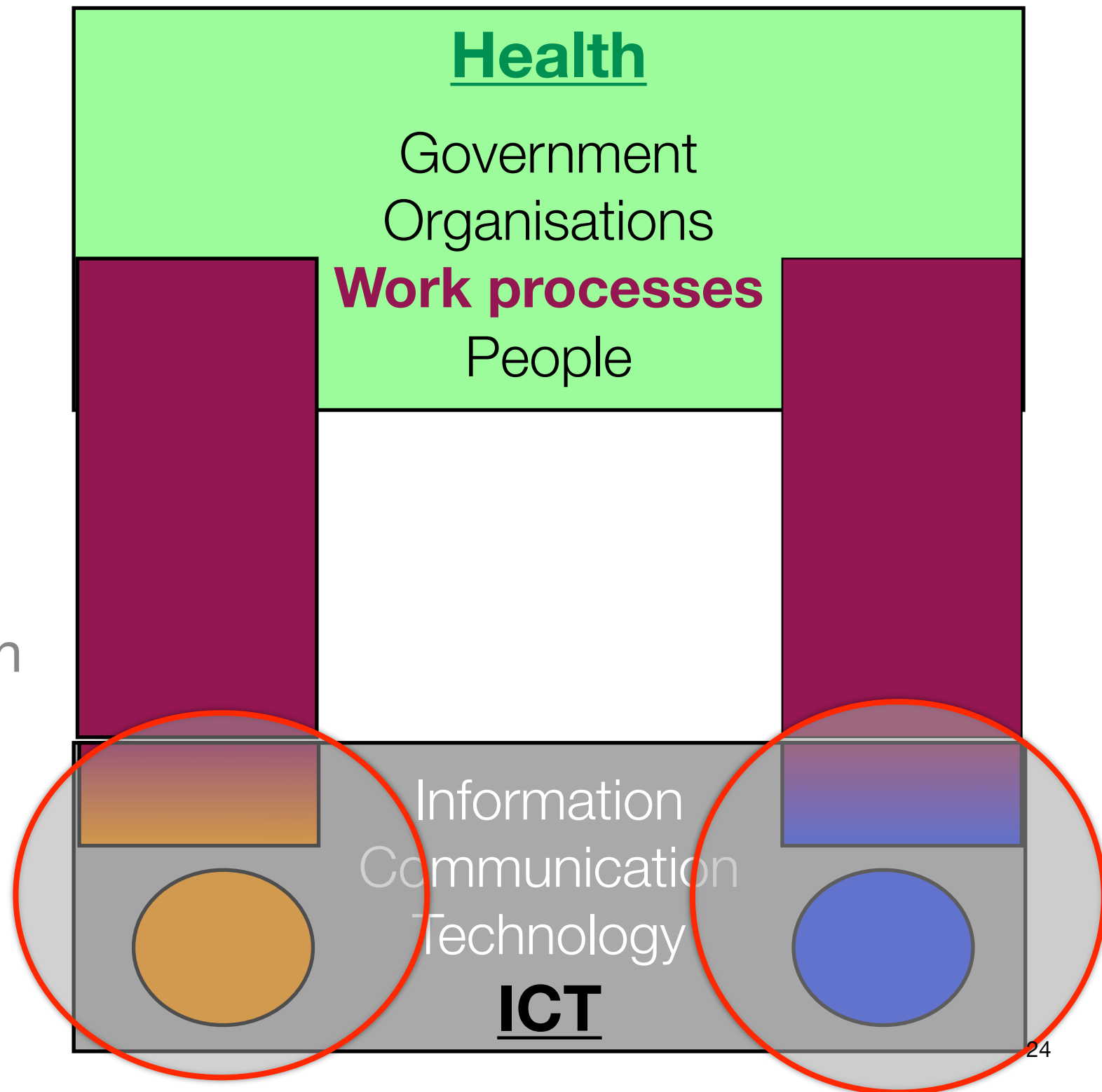
# How?

## Messages paradigm



In the end the systems can exchange data.

But this only is worthwhile in static (non-changing) situations





# How?

## Messages paradigm

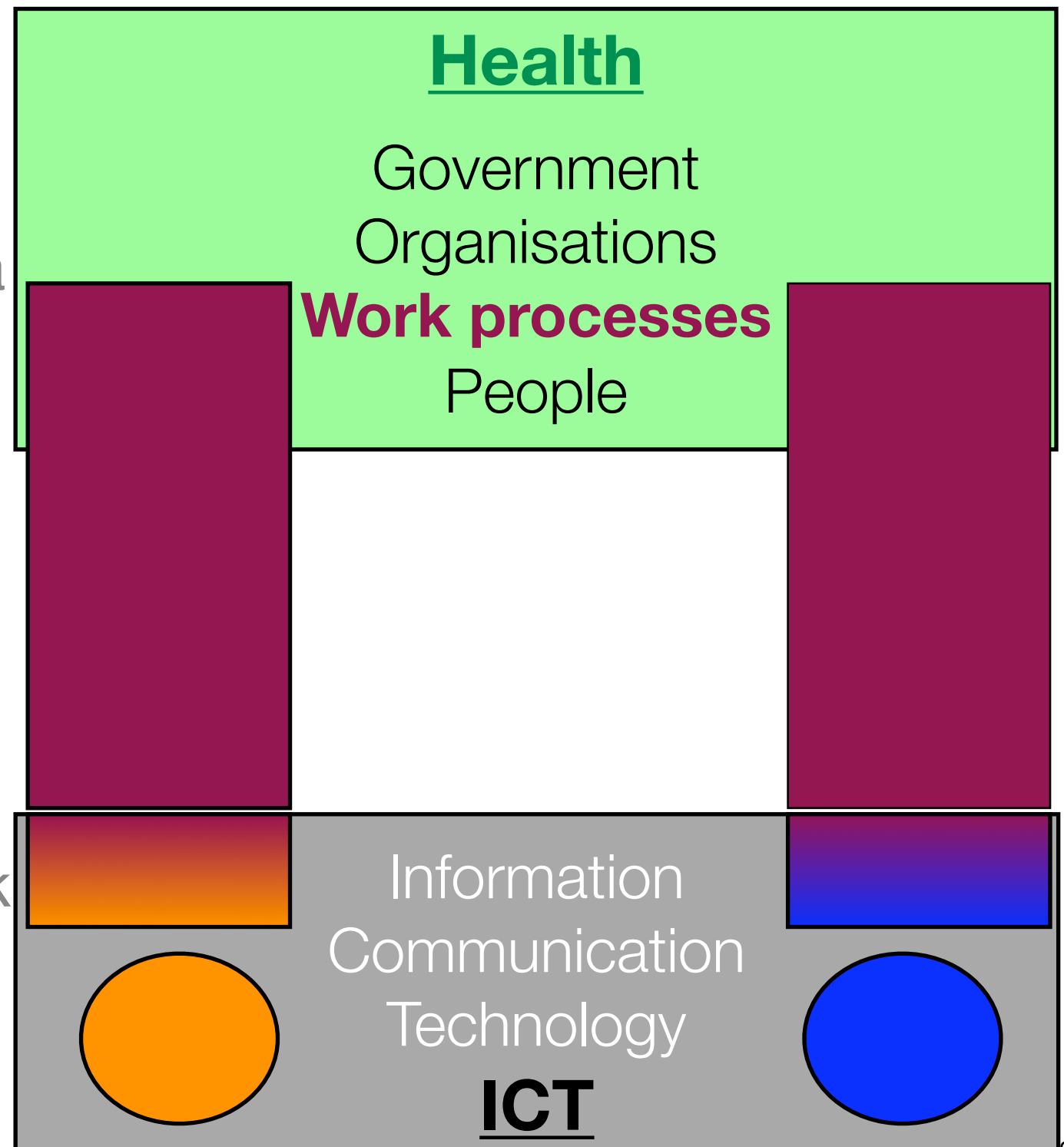


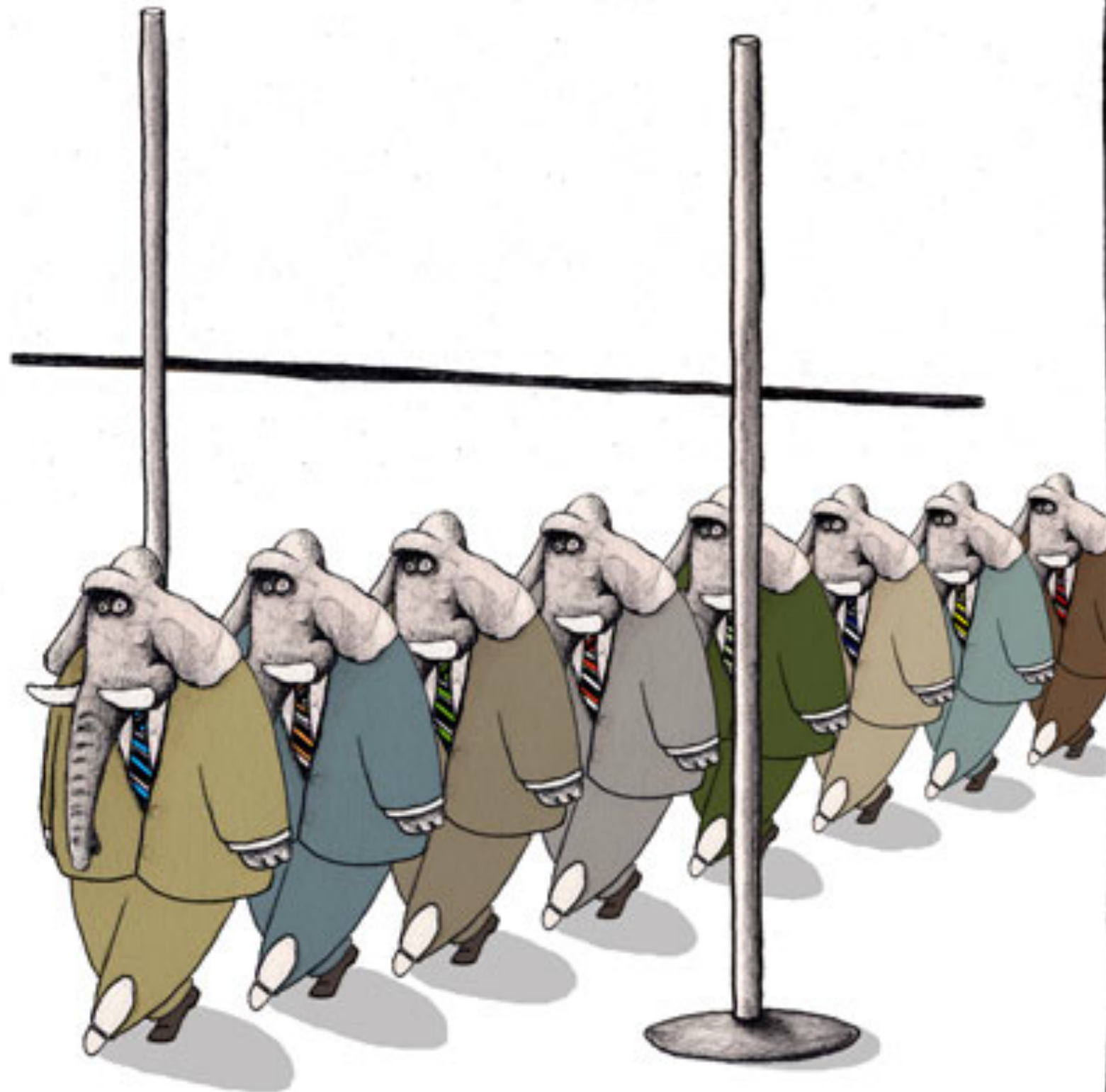
Since ...

Each set of messages takes a lot of resources (time and money) to implement

And ...

When implemented it causes that all users will have to work according to the same standardised work processes





## Standardised healthcare workers

All are not able to adopt to local workflow, local culture, and needs

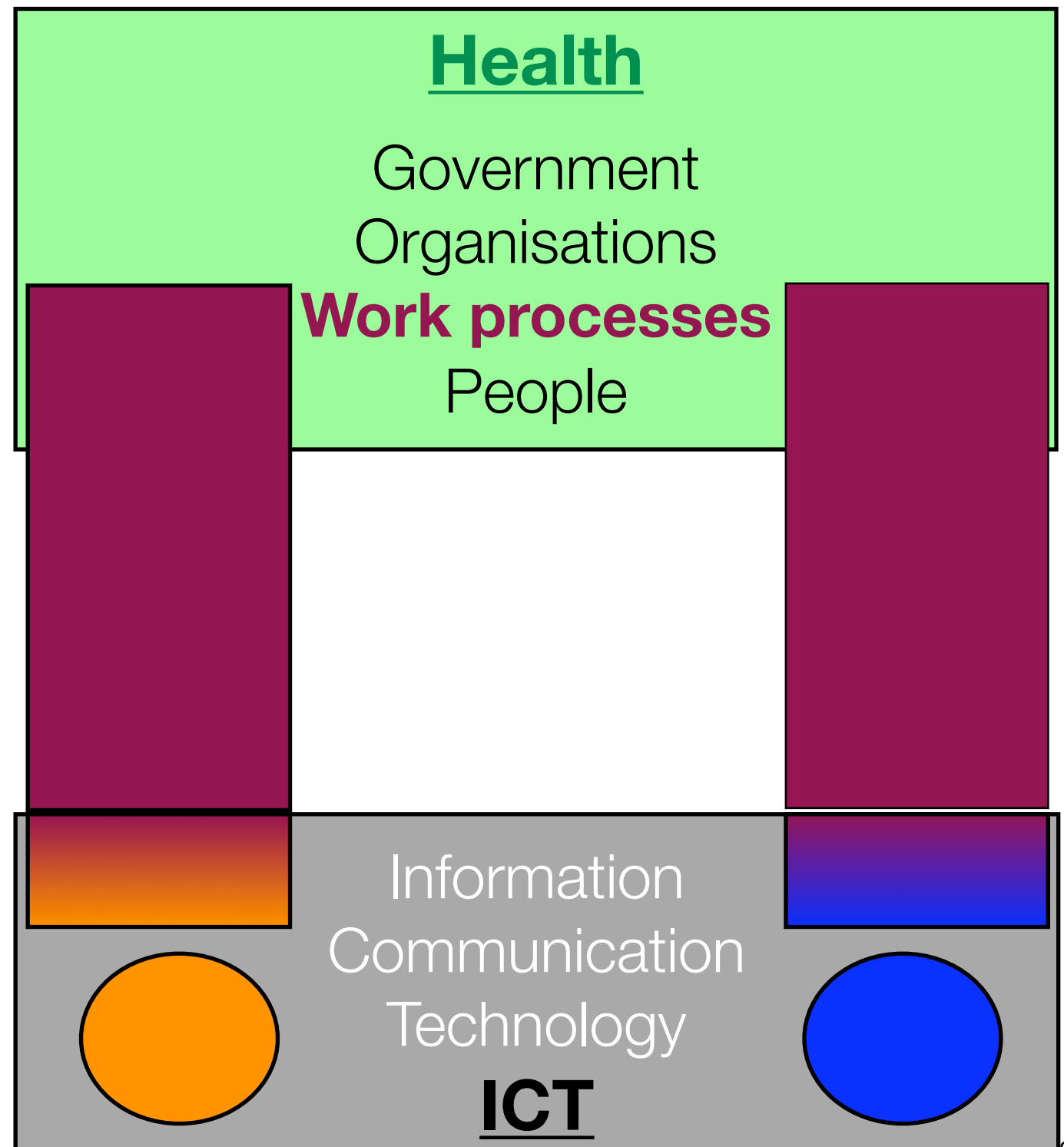
# How?

## Messages paradigm



### The consequences:

- **No innovation**
- **No healthcare market competition**



# How?

## Archetype Paradigm

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### Health

Government  
Organisations  
Work processes  
People

Language

Technology  
Communication

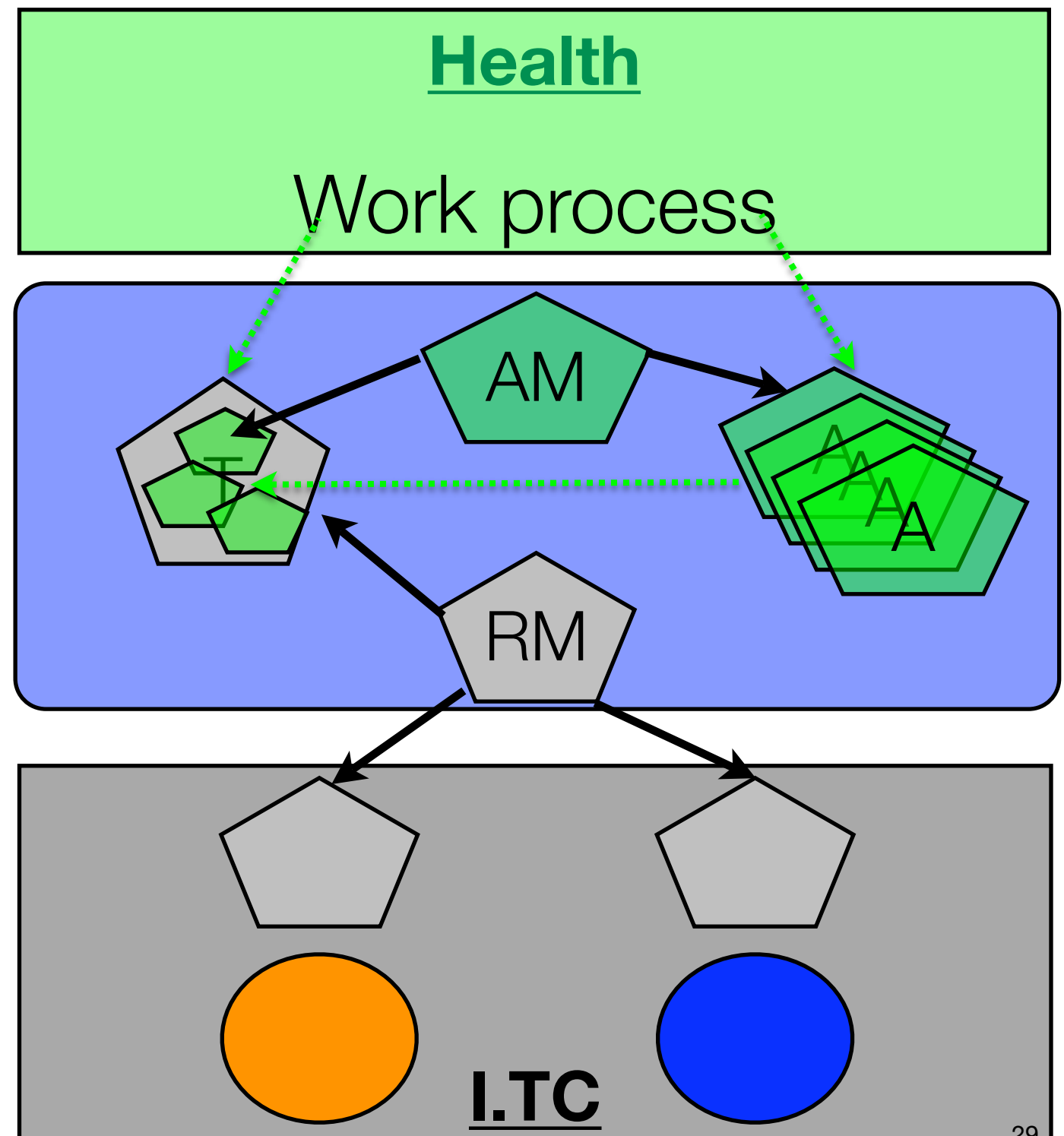
I.TC

# How?

## Archetype Paradigm



- 1- All I.TC-systems implement only once one Reference Model
- 2- Using tools based on the Archetype Model co-operating healthcare providers produce a collection of health concepts (archetypes)
- 3- For a specific work process they define Templates using Archetypes and tools



**Ocean Archetype Editor [Blood pressure measurement]**

File Edit Publish Language Terminology Help

Archetype file name:  
**openEHR-EHR-OBSERVATION.blood\_pressure.v1**

Header Entry model Terminology Display Interface Description

☒ Protocol

**Data** Protocol

☒ Event EventSeries ☒ Person State

**List** Events Person State

☒ Ordered at0004

**+** **Q** systolic  
**-** **Q** diastolic  
**↑** **Q** mean arterial pressure  
**↓** **Q** pulse pressure  
**T** Comment

**Occurrences**  
 Min: 0 Max: 1 ☐ Unbounded

Description: the peak systemic arterial blood pressure over one cycle

Runtime name constraint:

*Quantity*  
 Property: Pressure

Units:  
**+** mm[Hg]  
**-**

*Unit values*  
☒ Set min. value  $\geq$  0.00  
☒ Set max. value  $\leq$  1,000.00

**Ocean Archetype Editor [Blood pressure measurement]**

File Edit Publish Language Terminology Help

Archetype file name:  
**openEHR-EHR-OBSERVATION.blood\_pressure.v1**

Header Entry model Terminology Display Interface Description

☒ Protocol

Data **Protocol**

☒ Ordered at0012

**T** Instrument  
**T** Cuff size  
**T** Location of measurement

Occurrences  
Min: 0 Max: 1 ☐ Unbounded

Description: the instrument used to measure the blood pressure

Runtime name constraint: ...

☒ Free text or coded ☐ Internal codes ☐ Terminology

+  
-  
↑  
↓  
T  
Q  
1 2 3  
1 2  
≡  
✓  
?  
✎

+  
-  
..



**Ocean Archetype Editor [Blood pressure measurement]**

File Edit Publish Language Terminology Help

Archetype file name:  
**openEHR-EHR-OBSERVATION.blood\_pressure.v1**

Header Entry model Terminology Display Interface Description

☒ Protocol

**Data** Protocol

☒ Event EventSeries ☒ Person State

List **Events** Person State

Event list:

☒ open

☐ Fixed

☐ Events at regular time period

☐ ? any event  
☒ baseline reading  
☒ 5 minute reading  
☒ 10 minute reading  
☐ Postural change  
☐ Paradox

Event details

Occurrences

Min:  Max:  ☐ Unbounded

Description:

Blood pressure reading after 5 minutes rest

Runtime name constraint:  ...

☒ Point in time
 ☐ Interval

Offset

☒ Fixed offset







# Example: archetype-based generation of web applications



## HeartBeat

Welcome to HeartBeat, Dr. Dipak Kalra. Your patient is Ahmand Khaliq (29-Jan-1933).

### Users

[Logout](#)

### Patients

[Nota Bene](#)

[Select Patient](#)

### Administration

[Accounts](#)

[Important Dates](#)

### Anticoagulant Control

[Plan](#)

[Clinic Contact](#)

### Medical Summary

[Service Delivery](#)

### Reports and Letters

[Clinic List](#)

[Patient Summary](#)

[Clinician Summary](#)

[Clinical Governance](#)

[Withdrawal Letter](#)

### Additional Links

[British Heart Foundation](#)

[Heart Health](#)

[Anticoagulation Facts](#)

### Allergies

There are no Allergies records for this patient.

[Create new Allergies record](#)

### Clinical Conditions

Date committed:	Name:	Current Problem:	Concerns:	
09-May-2007	Asthma	true	Acute attacks, esp winter	<a href="#">View This Record</a>
08-Jun-2007	Diabetes	true	Fear of needles	<a href="#">View This Record</a>

[Create new Clinical Conditions record](#)

### Regular Drugs

Date committed:	Name:	Actual Start Date:	Actual End Date:	Description:	Dosage:	
13-Jun-2007	Aspirin	02-Apr-2007			1.0	<a href="#">View This Record</a>
13-Jun-2007	Ventolin	07-Jun-2006			1.0	<a href="#">View This Record</a>
13-Jun-2007	Valium	01-Jan-2007	13-Jun-2007		2.0	<a href="#">View This Record</a>

[Create new Regular Drugs record](#)

### Lifestyle Information

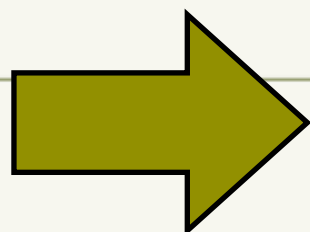
There are no Lifestyle Information records for this patient.

[Create new Lifestyle Information record](#)

### Services And Needs

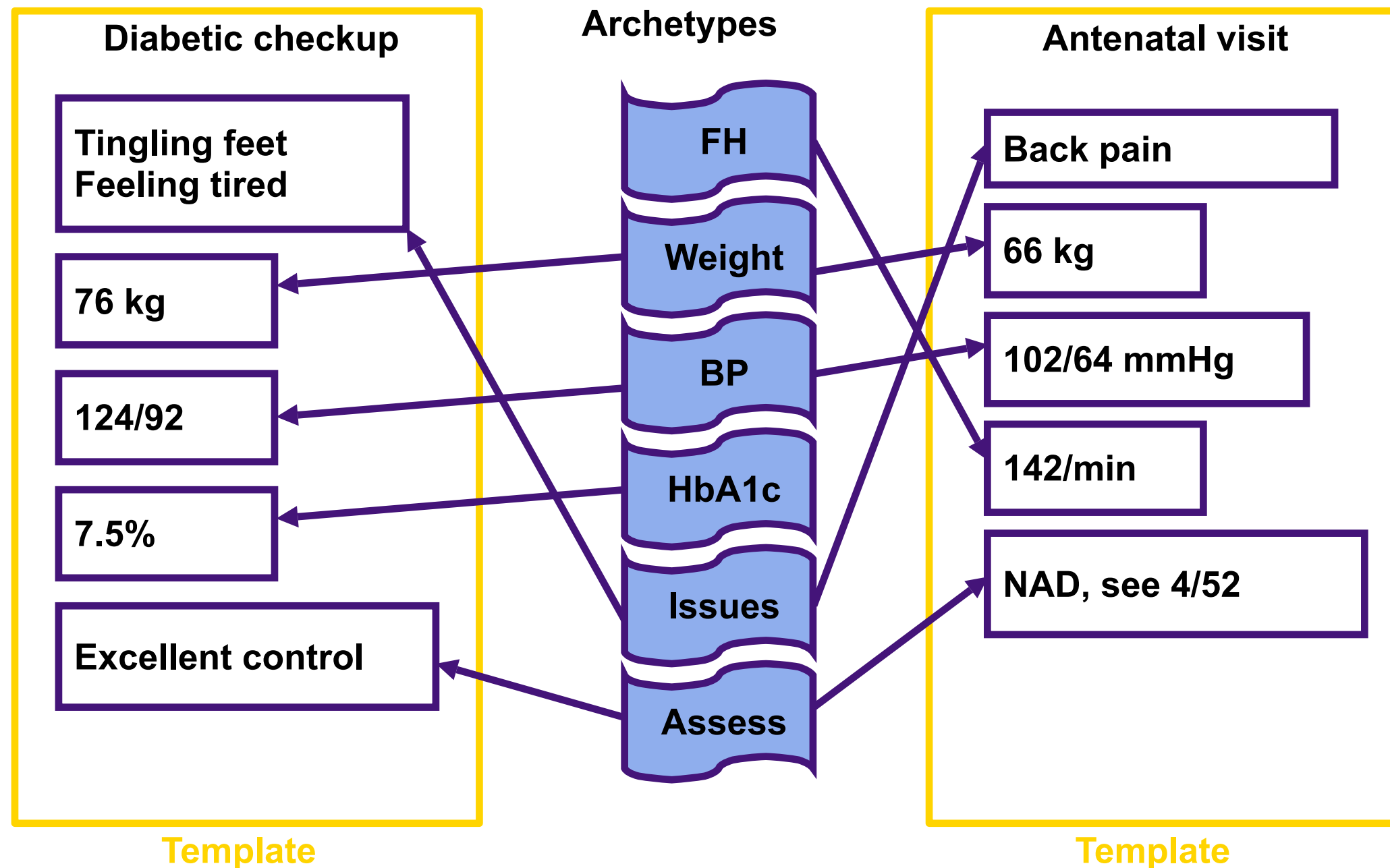
There are no Services and Needs records for this patient.

[Create new Services and Needs record](#)





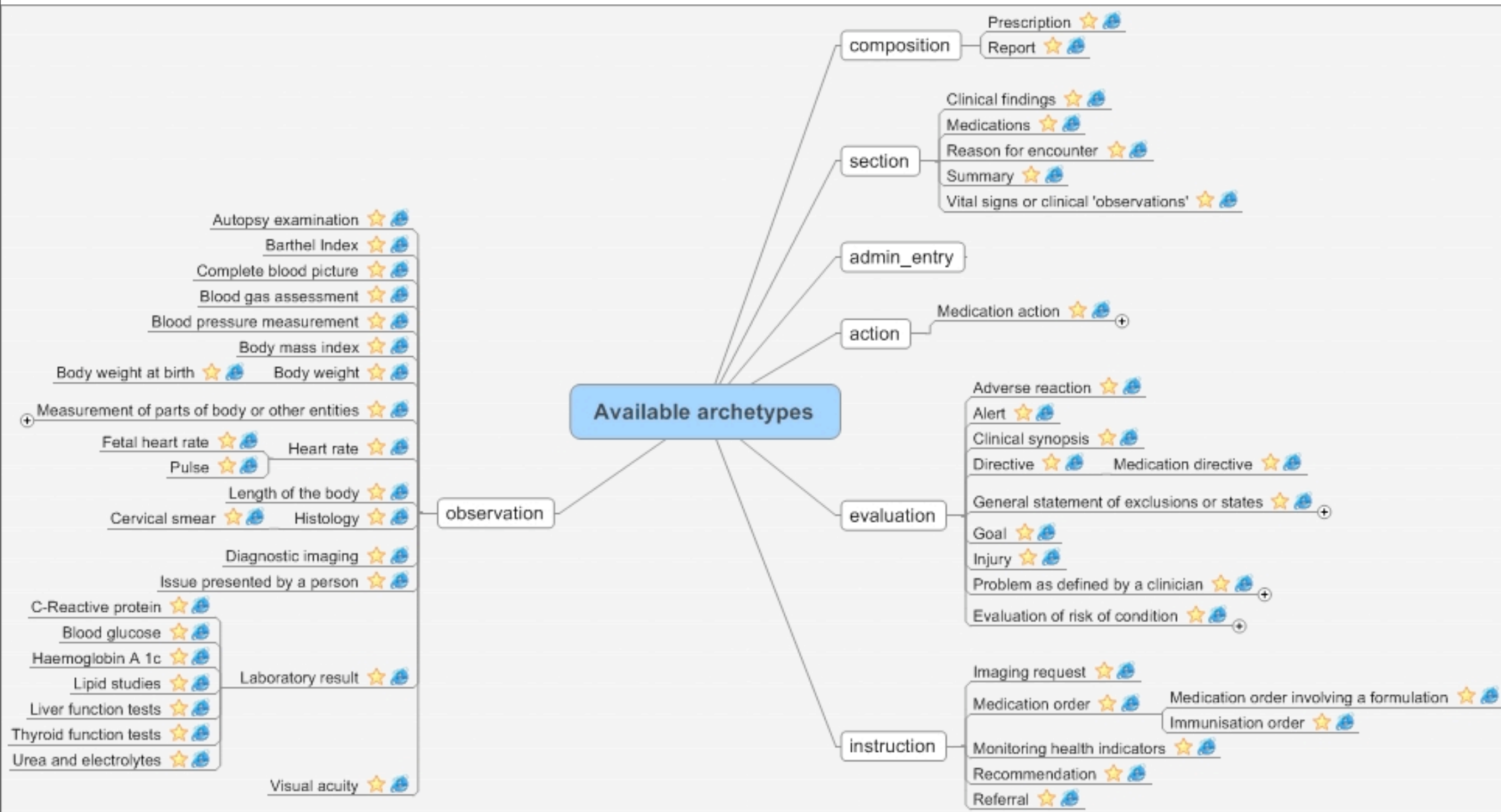
# Archetypes and Templates



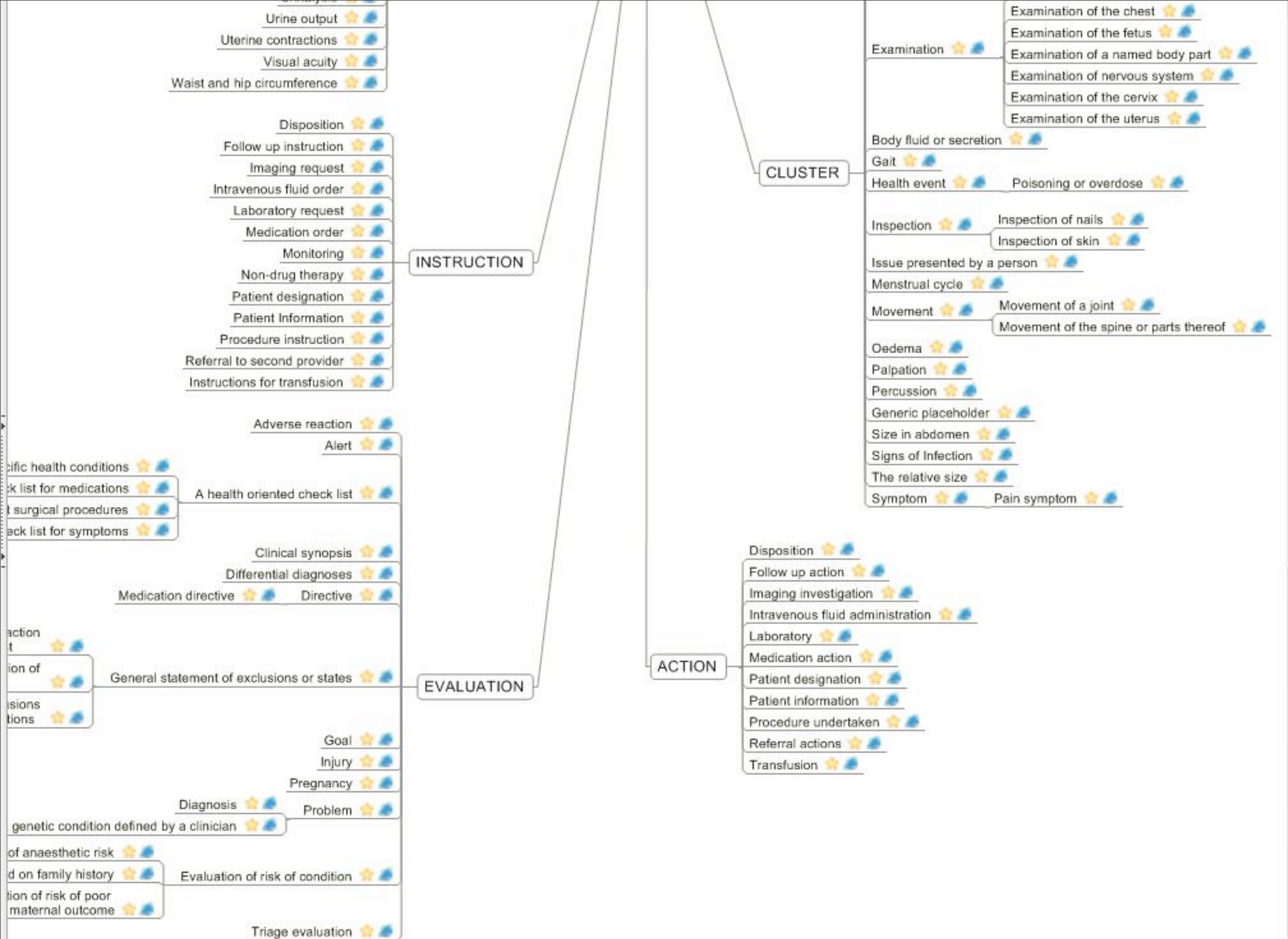
# Over 200 NHS Archetypes

<u>Short concept label</u>	<u>Version</u>	<u>Date</u>	<u>ADL</u>
<a href="#">Auscultation of the chest</a>	v1	11/05/2007	<a href="#">openEHR-EHR-CLUSTER.auscultation-chest.v1.adl</a>
<a href="#">Auscultation</a>	v1	11/05/2007	<a href="#">openEHR-EHR-CLUSTER.auscultation.v1.adl</a>
<a href="#">Balance</a>	v1draft	11/05/2007	<a href="#">openEHR-EHR-CLUSTER.balance.v1draft.adl</a>
<a href="#">Change</a>	v1draft	11/05/2007	<a href="#">openEHR-EHR-CLUSTER.change.v1draft.adl</a>
<a href="#">Circulation</a>	v1draft	11/05/2007	<a href="#">openEHR-EHR-CLUSTER.circulation.v1draft.adl</a>
<a href="#">Coordination</a>	v1draft	11/05/2007	<a href="#">openEHR-EHR-CLUSTER.coordination.v1draft.adl</a>
<a href="#">Cranial Nerves</a>	v1draft	23/05/2007	<a href="#">openEHR-EHR-CLUSTER.cranial_nerves.v1draft.adl</a>
<a href="#">Cranial Nerves</a>	v2draft	23/05/2007	<a href="#">openEHR-EHR-CLUSTER.cranial_nerves.v2draft.adl</a>
<a href="#">Delivery of infant</a>	v1draft	25/05/2007	<a href="#">openEHR-EHR-CLUSTER.delivery_of_infant.v1draft.adl</a>
<a href="#">Dimensions - cervix (v1 draft)</a>	v1draft	21/05/2007	<a href="#">openEHR-EHR-CLUSTER.dimensions-cervix.v1draft.adl</a>
<a href="#">Circumference</a>	v1	11/05/2007	<a href="#">openEHR-EHR-CLUSTER.dimensions-circumference.v1.adl</a>
<a href="#">Dimensions - fetus</a>	v1	17/05/2007	<a href="#">openEHR-EHR-CLUSTER.dimensions-fetus.v1.adl</a>
<a href="#">Dimensions</a>	v1	11/05/2007	<a href="#">openEHR-EHR-CLUSTER.dimensions.v1.adl</a>
<a href="#">Examination of the abdomen - newborn</a>	v1draft	30/05/2007	<a href="#">openEHR-EHR-CLUSTER.exam-abdomen-newborn.v1draft.adl</a>
<a href="#">Examination of the abdomen</a>	v1	22/05/2007	<a href="#">openEHR-EHR-CLUSTER.exam-abdomen.v1.adl</a>
<a href="#">Examination of the abdomen</a>	v2draft	25/05/2007	<a href="#">openEHR-EHR-CLUSTER.exam-abdomen.v2draft.adl</a>
<a href="#">Examination of skull</a>	v1	23/05/2007	<a href="#">openEHR-EHR-CLUSTER.exam-bone-skull.v1.adl</a>
<a href="#">Examination of bone</a>	v1	23/05/2007	<a href="#">openEHR-EHR-CLUSTER.exam-bone.v1.adl</a>
<a href="#">Examination of nervous system of a newborn</a>	v1	30/05/2007	<a href="#">openEHR-EHR-CLUSTER.exam-cardiovascular_system-newborn.v1.adl</a>
<a href="#">Examination of cardiovascular system of a newborn</a>	v1draft	30/05/2007	<a href="#">openEHR-EHR-CLUSTER.exam-cardiovascular_system-newborn.v1draft.adl</a>
<a href="#">Examination of the chest</a>	v1	22/05/2007	<a href="#">openEHR-EHR-CLUSTER.exam-chest.v1.adl</a>
<a href="#">Examination of the eyes of a newborn</a>	v1	23/05/2007	<a href="#">openEHR-EHR-CLUSTER.exam-eyes-newborn.v1.adl</a>
<a href="#">Examination of the eyes</a>	v1	23/05/2007	<a href="#">openEHR-EHR-CLUSTER.exam-eyes.v1.adl</a>
<a href="#">Examination of the face</a>	v1	23/05/2007	<a href="#">openEHR-EHR-CLUSTER.exam-face.v1.adl</a>
<a href="#">Examination of the fetus</a>	v1	31/05/2007	<a href="#">openEHR-EHR-CLUSTER.exam-fetus.v1.adl</a>
<a href="#">Examination of the fetus - v2</a>	v2draft	21/05/2007	<a href="#">openEHR-EHR-CLUSTER.exam-fetus.v2draft.adl</a>
<a href="#">Examination of the fetus - v3</a>	v3draft	25/05/2007	<a href="#">openEHR-EHR-CLUSTER.exam-fetus.v3draft.adl</a>
<a href="#">Examination of a named joint</a>	v1	11/05/2007	<a href="#">openEHR-EHR-CLUSTER.exam-generic-joint.v1.adl</a>
<a href="#">Examination of lymph nodes</a>	v1	11/05/2007	<a href="#">openEHR-EHR-CLUSTER.exam-generic-lymphnode.v1.adl</a>
<a href="#">Examination of a mass</a>	v1	11/05/2007	<a href="#">openEHR-EHR-CLUSTER.exam-generic-mass.v1.adl</a>
<a href="#">Examination of abdomen for a newborn</a>	v1	23/05/2007	<a href="#">openEHR-EHR-CLUSTER.exam-generic-newborn-abdomen.v1.adl</a>
<a href="#">Examination of the chest of a newborn</a>	v1	23/05/2007	<a href="#">openEHR-EHR-CLUSTER.exam-generic-newborn-chest.v1.adl</a>
<a href="#">Examination of spine, hips, genitalia and anus</a>	v1	29/05/2007	<a href="#">openEHR-EHR-CLUSTER.exam-generic-newborn-lower_body.v1.adl</a>
<a href="#">Examination of mouth and throat of newborn</a>	v1	23/05/2007	<a href="#">openEHR-EHR-CLUSTER.exam-generic-newborn-mouth_and_throat.v1.adl</a>
<a href="#">Examination of palette and lips of a newborn</a>	v1	23/05/2007	<a href="#">openEHR-EHR-CLUSTER.exam-generic-newborn-palette_and_lips.v1.adl</a>
<a href="#">Examination of a named body part for a newborn exam</a>	v1	23/05/2007	<a href="#">openEHR-EHR-CLUSTER.exam-generic-newborn.v1.adl</a>
<a href="#">Examination of a named body part</a>	v1	11/05/2007	<a href="#">openEHR-EHR-CLUSTER.exam-generic.v1.adl</a>
<a href="#">Examination of a mass lesion</a>	v1	11/05/2007	<a href="#">openEHR-EHR-CLUSTER.exam-mass.v1.adl</a>
<a href="#">Examination of mouth</a>	v1	23/05/2007	<a href="#">openEHR-EHR-CLUSTER.exam-mouth.v1.adl</a>
<a href="#">Examination of the musculoskeletal system - newborn</a>	v1draft	30/05/2007	<a href="#">openEHR-EHR-CLUSTER.exam-musculoskeletal-newborn.v1draft.adl</a>
<a href="#">Examination of nervous system of a newborn</a>	v1	23/05/2007	<a href="#">openEHR-EHR-CLUSTER.exam-nervous_system-newborn.v1.adl</a>
<a href="#">Examination of nervous system of a newborn (v2 draft)</a>	v2draft	30/05/2007	<a href="#">openEHR-EHR-CLUSTER.exam-nervous_system-newborn.v2draft.adl</a>
<a href="#">Examination of nervous system</a>	v1	11/05/2007	<a href="#">openEHR-EHR-CLUSTER.exam-nervous_system.v1.adl</a>
<a href="#">Examination of ears and hearing of newborn</a>	v1	29/05/2007	<a href="#">openEHR-EHR-CLUSTER.exam-newborn_ears_and_hearing.v1.adl</a>
<a href="#">Examination of nose</a>	v1	23/05/2007	<a href="#">openEHR-EHR-CLUSTER.exam-nose.v1.adl</a>
<a href="#">Examination of respiratory system of a newborn</a>	v1draft	30/05/2007	<a href="#">openEHR-EHR-CLUSTER.exam-respiratory_system-newborn.v1draft.adl</a>

# Previous *open*EHR Archetypes





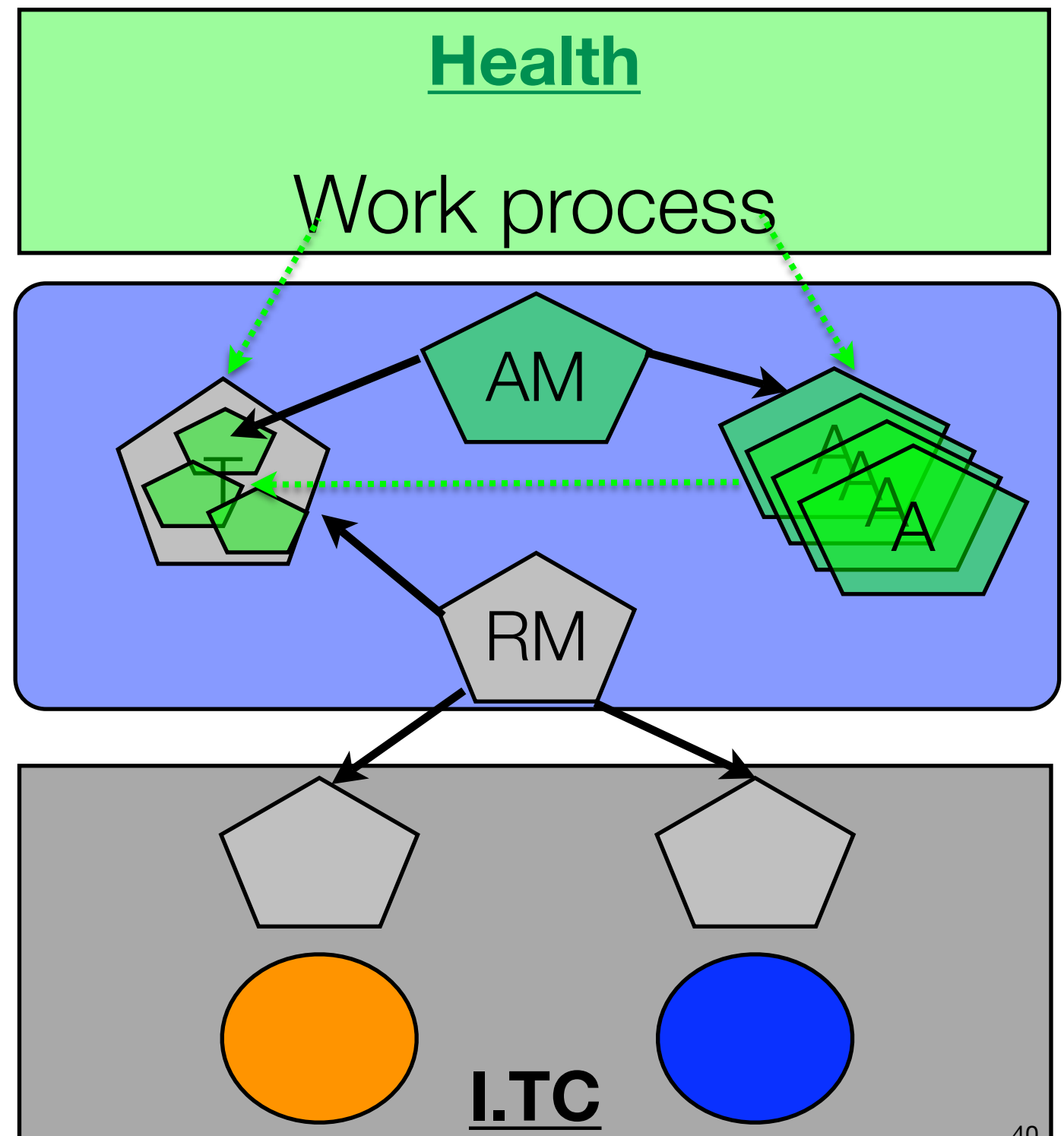


# How?

## Archetype Paradigm



1. Templates are implemented immediately and without any cost
2. Each work process can change and lead to new Templates
3. Local adaptations are always possible
4. Healthcare is no longer dependent on the co-operation of the ICT industry
5. Communication with legacy systems is always possible





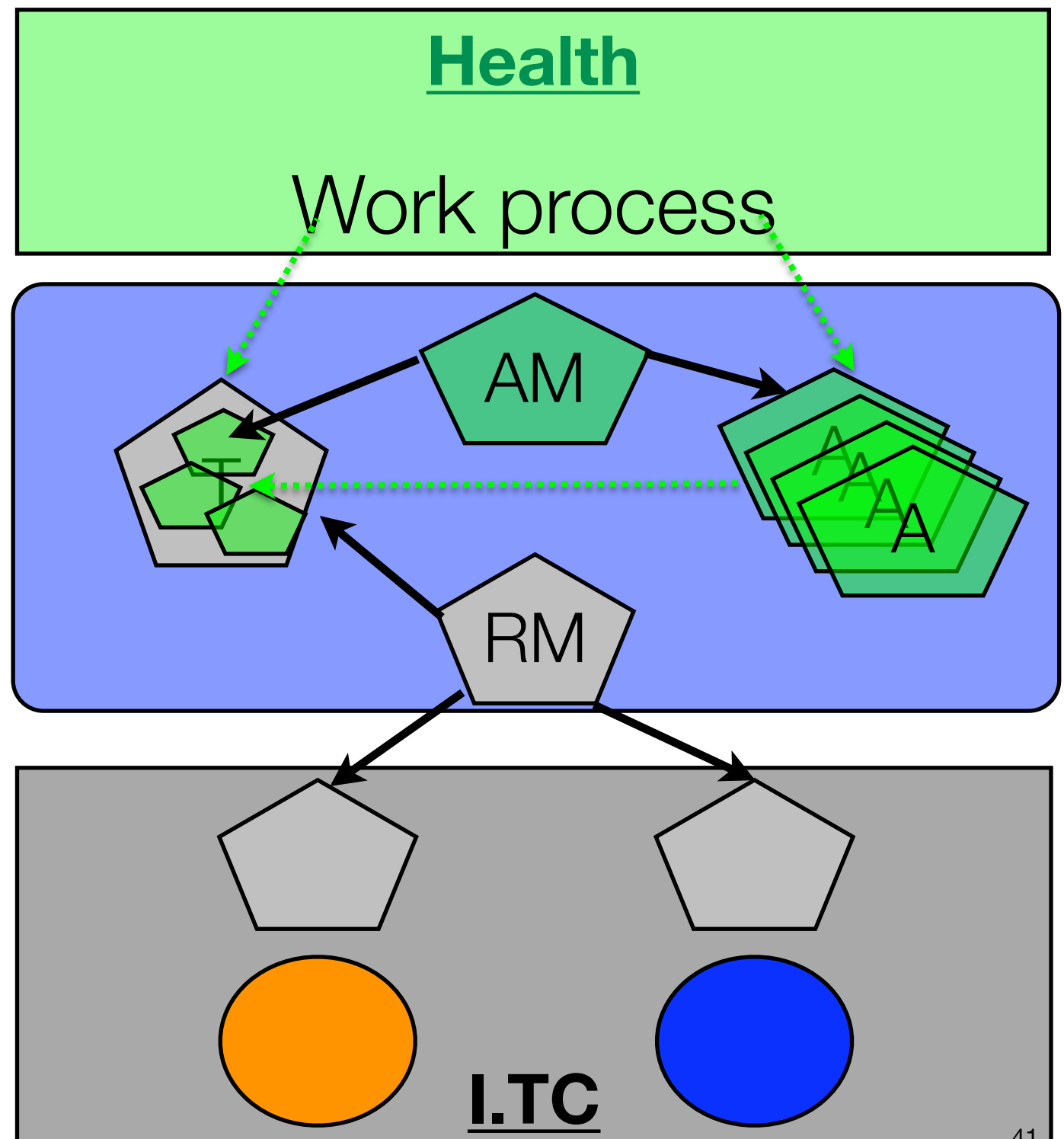
# How?

## Archetype Paradigm



### Consequences:

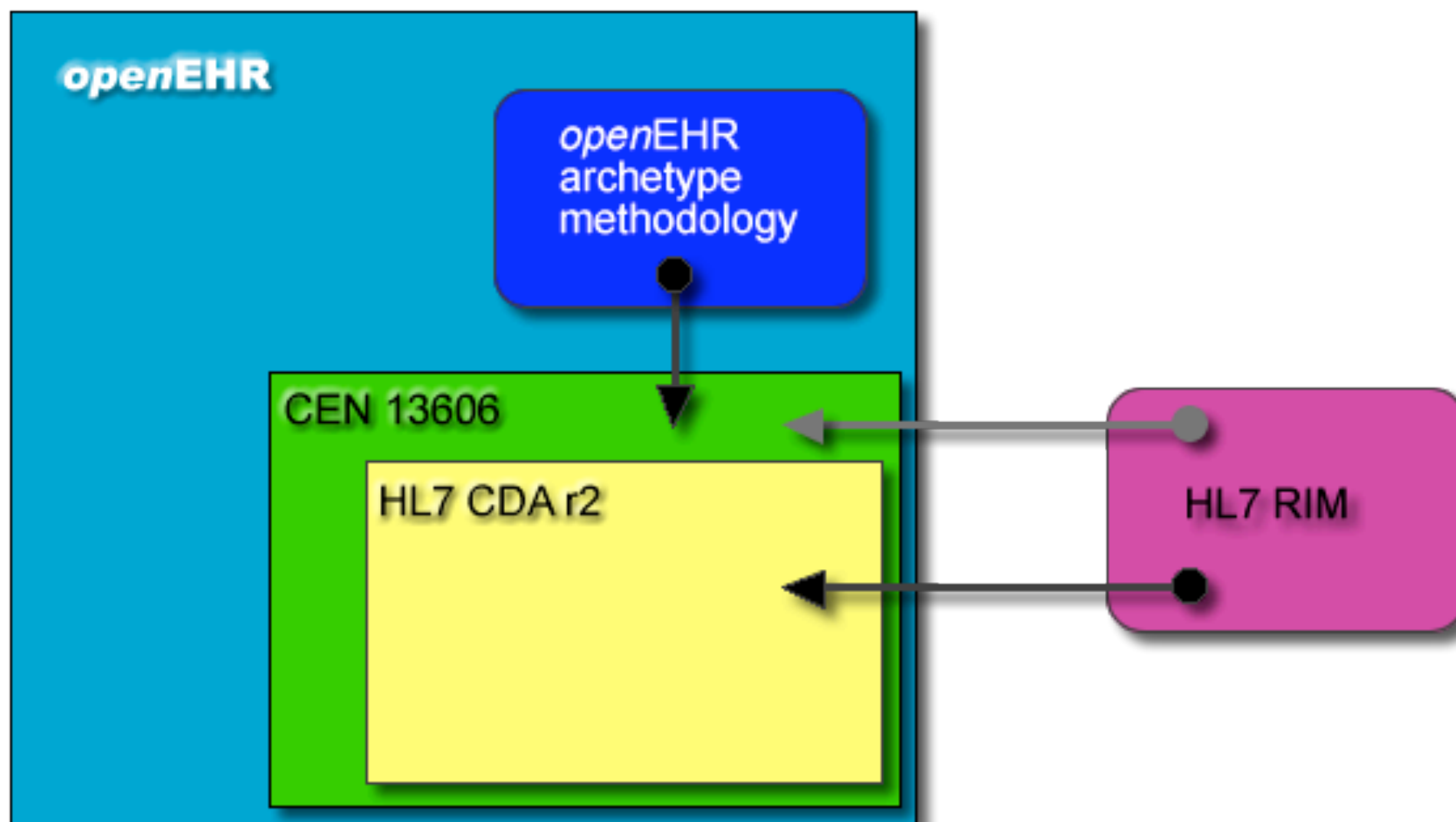
- Innovation
- Health Market Competition
- Evolution



# Parts of CEN/tc251 (ISO) EN 13606 (EHRcom)



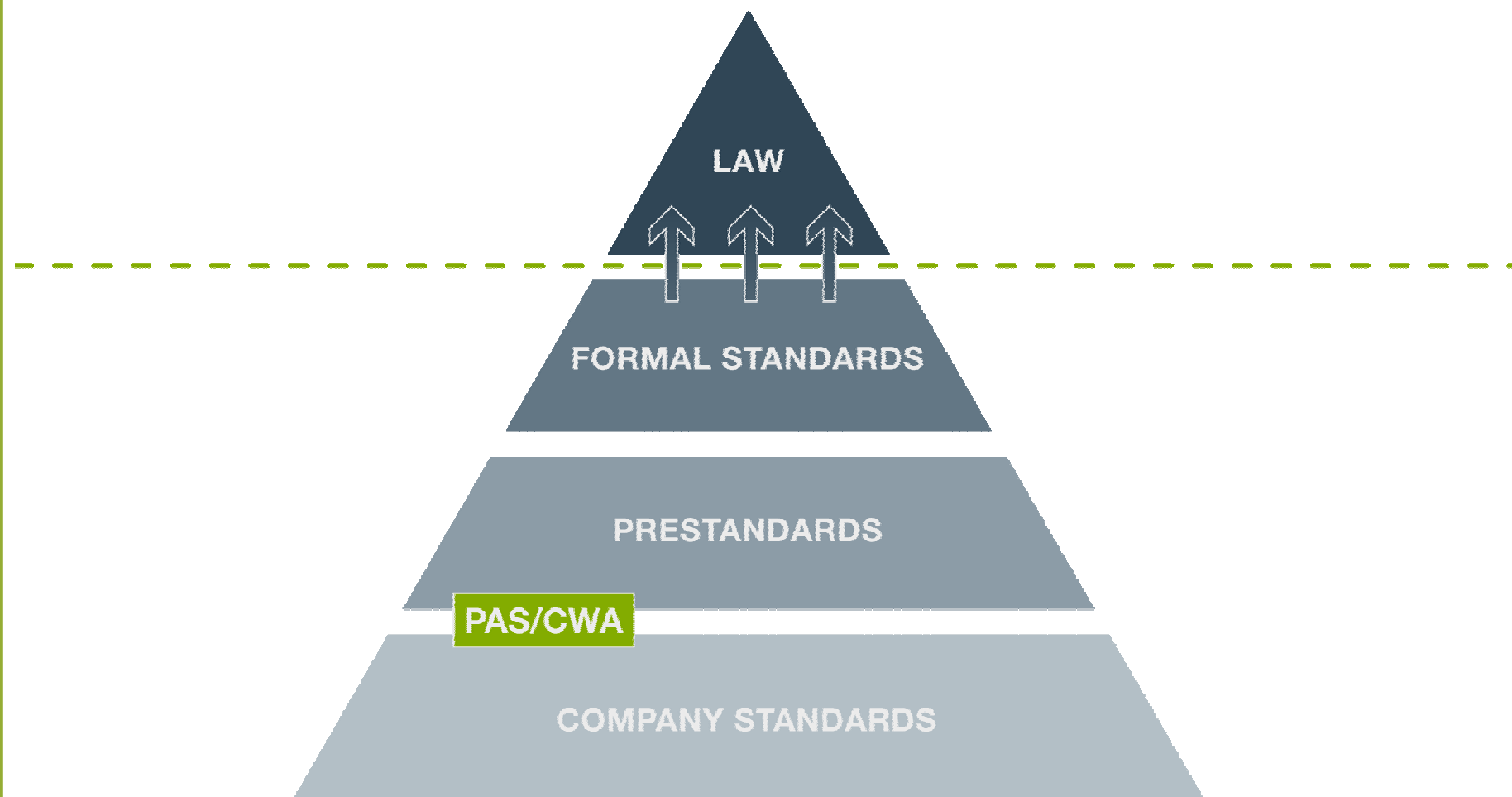
- Part 1: Reference Model
  - comprehensive, generic model for communicating part or all of an EHR
- Part 2: Archetype Specification
  - constraint-based approach for defining clinical “business objects” that are built from the Reference Model - adopted from openEHR
- Part 3: Reference Archetypes and Term Lists
  - initial set of archetypes mapping to other relevant standards
  - micro-vocabularies for the Part 1 model
- Part 4: Security
  - measures to support access control, consent and auditability of EHR communications
- Part 5: Exchange Models
  - message and service interfaces to enable EHR and archetype communication



# The role of European standards



## Strengths of the European system



# The role of European standards



## Trading within the European Union

### → Four basic freedoms:

- Free movement of goods
- Free movement of persons
- Free movement of capital
- Freedom of establishment and free movement of services

### → Barriers to trade:

- Traditional barriers such as tariffs or quotas
- Technical barriers such as differences in standards and conformity assessment



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# Summary



European standards play a specific role in **legislation** and **procurement**

the European Institute for Health Records (**EuroRec**) together with national **ProRec** centers will play a role in quality labeling and certification of EHR-systems

But in the **Governance** of Clinical Archetypes and Templates as well.



**European Institute for Health Records**

