



# Research in Biomedical Informatics

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# Paradigm Shift



# What is a paradigm?

*A reference model of fundamental value widely accepted in a particular field because it is an expression of a comprehensive belief system or world view in that field.*

- Usually a paradigm emphasizes relationships between some fundamental concepts that shape the thinking.
- A paradigm is derived from a specific way of thinking, communicating and viewing the world.
- A paradigm better captures the nature of the differences between different approaches to solve a problem.
- Paradigm shifts are good go-betweens in transferring knowledge to and from knowledge fields.

# Example of Paradigm Shift

- Vitruvius described the human figure as being the principal source of proportion among the classical orders of architecture.

Architecture

- Paradigm:

**Canon of Proportions:**

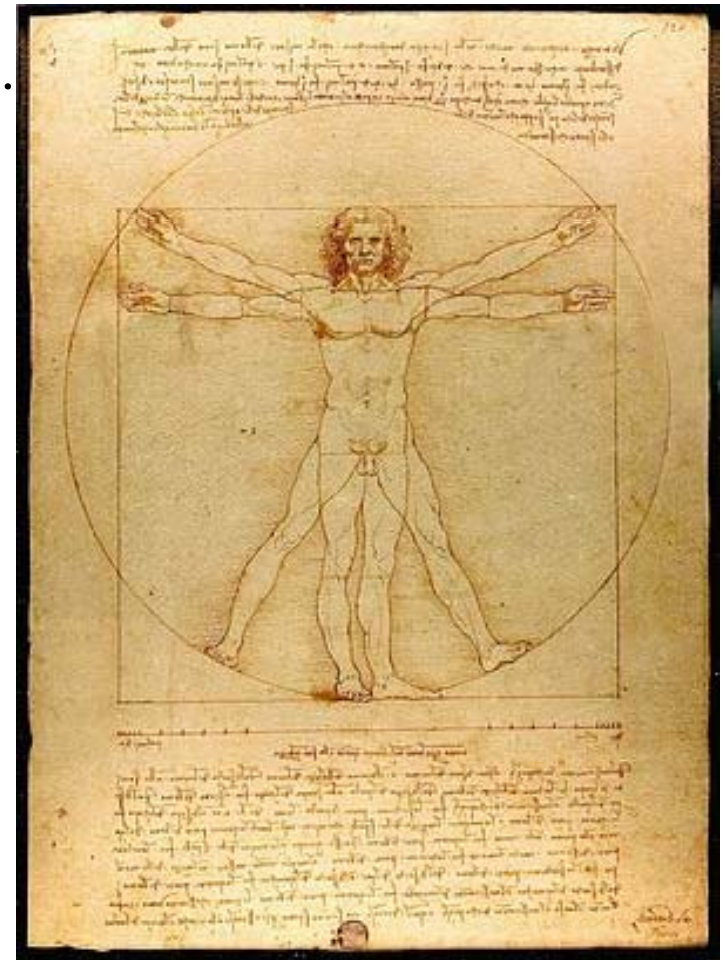
*Human body proportions  
are the golden proportions  
of architectural styles*

Paradigm  
shift

Cosmography of the  
microcosm, Art, Science

- Leonardo da Vinci believed the workings of the human body to be an analogy for the workings of the universe.

**Homo Vitruvianus**



# How to use a paradigm?

- A paradigm influences how an individual perceives an area of the real world or reacts to this perception.
- A paradigm guides research and practice in the field of interest.
- A paradigm is used as:
  - a structuring schema in both teaching and model-driven design processes;
  - a benchmark to assess methods or conceptual tools that are related to the paradigm goal or idea;
  - a means for transferring knowledge across domains.

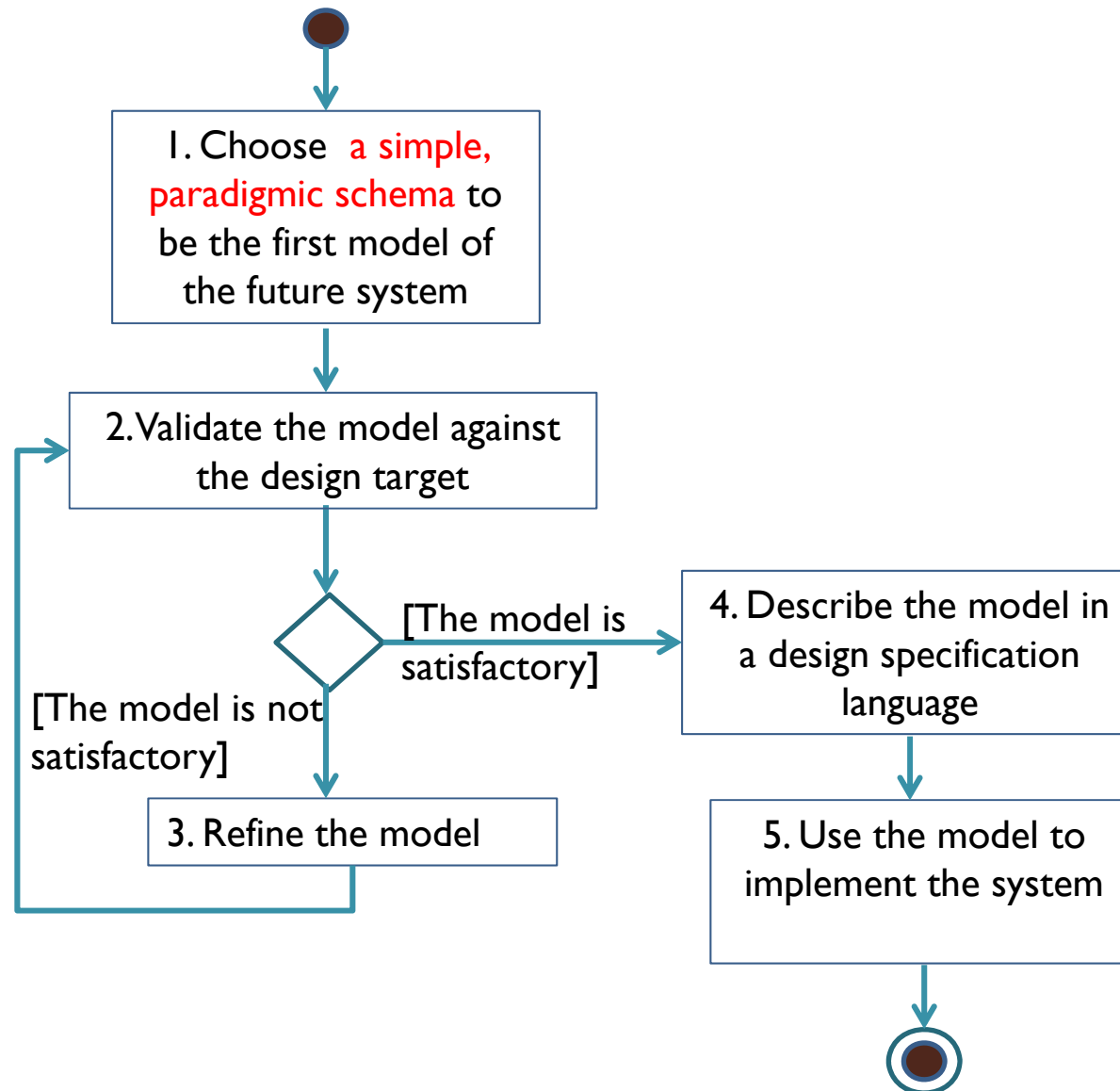
# Using Facets in Systems Development<sup>\*)</sup>

- “By abstracting, we ignore some aspects (usually attributes or properties) of the system and retain the most relevant ones from a certain point of view or at a certain abstraction level. In this way we can create multiple simplified images of the same object, in other words, *models of it*.“
- “Once the relevant aspects are localized in some models, these models may be studied and modified independently and more easily than the original object.”
- “These models can be compared with the facets of a spatial object: from one point in space we see one facet of the object, from another point, another facet, and so on.“
- “... we shall use the term *facets* to designate these simplified views of the complex object. As a result, when we analyze an existing SO, we study it only through its facets.”
- “It is worthy noting that if the facets comprise all known or all interesting properties of the object at analysis time, they represent for us the object itself.“
- “About a nontrivial object we have, as a rule, incomplete knowledge. Even so, our knowledge may be sufficient to study and work with the object at a certain level of interest. This is why we usually assume that our incomplete knowledge represents the object.”
- “The developer’s knowledge is model oriented: his or her mental representation of the object is strongly structured by known *meta-models* of the object .”

<sup>\*)</sup>

L. D. Serbanati, *Integrating Tools for Software Development*, Yourdon Computing Series, Prentice Hall, 1992.

# Model-Based Design Process





# New paradigms in healthcare

- New paradigms are arising in healthcare to mark epochal changes in the domain:
  - "pay for performance" focuses on cost control
  - "personalized medicine" and "evidence-based medicine" focus on the quality of services
  - "patient-centered care"- “The right care in the right way at the right time”
  - "patient empowerment" Nothing about me without me”

## Method

Four new communication behaviors:

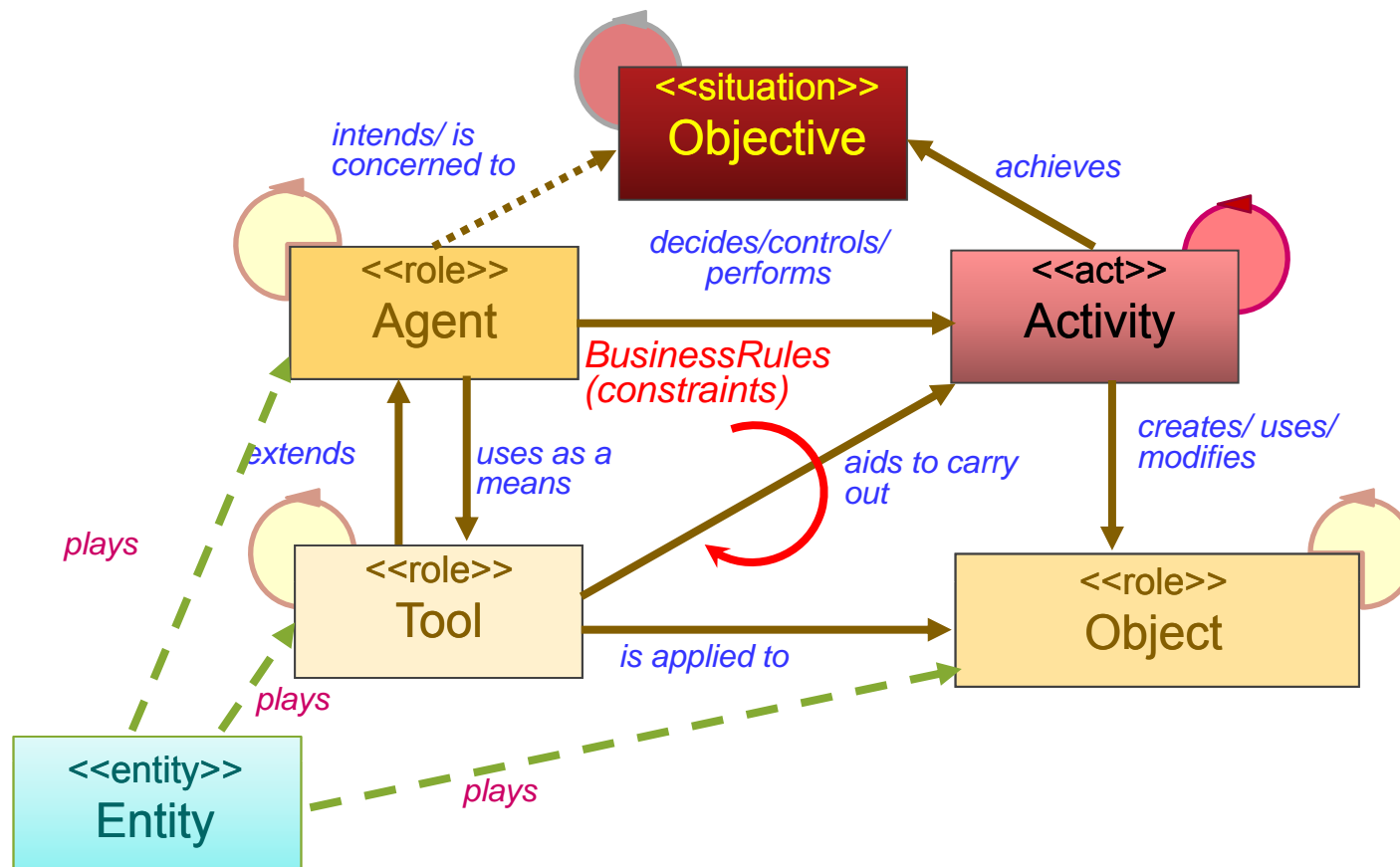
- Understanding and validating the patients' perspective
- Extension of understanding of the patient to his / her global psycho-social context
- Shared understanding with the patient of his / her health problem and its treatment
- Partnership with “empowered” patients in decision making, power and responsibility.



# The “Interconnecting health” paradigm

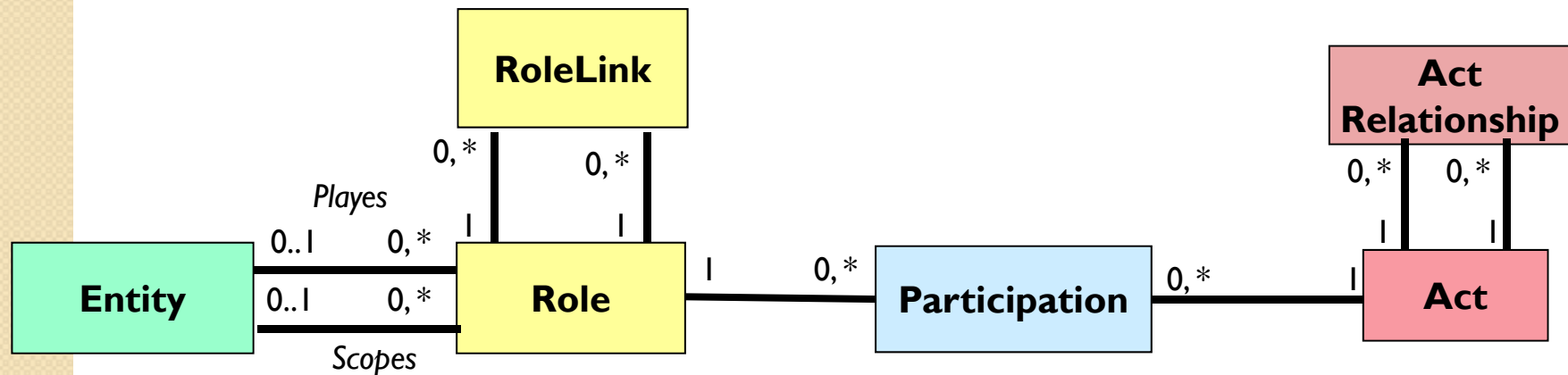
- Progress in IT has made possible the development of some new paradigms in health informatics.
- *Interconnecting health* focuses on the ability to connect health organizations and systems, and the role of IT as an enabler in achieving this connectivity.
  - The growth in importance of *electronic health records* in the last two decades marked a technological but also "cultural" shift.
  - The evolution of “Interconnecting health” was a continuous broadening of the horizon of interoperability in health.

# A business meta-model\*)



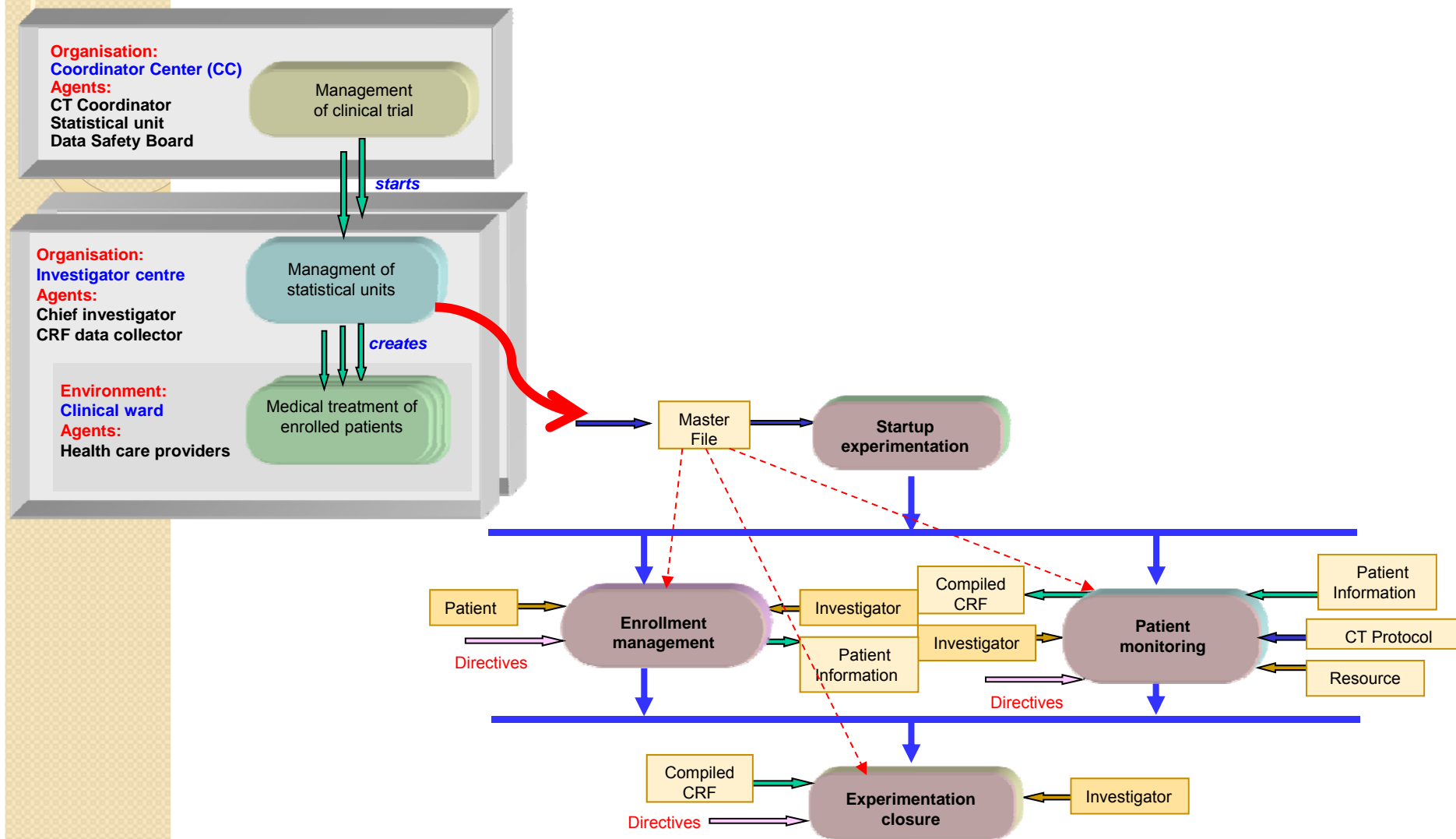
\*) L. D. Serbanati, *Integrating Tools for Software Development*, Yourdon Computing Series, Prentice Hall, 1992.

# The RIM HL7 V3 Meta-model \*)



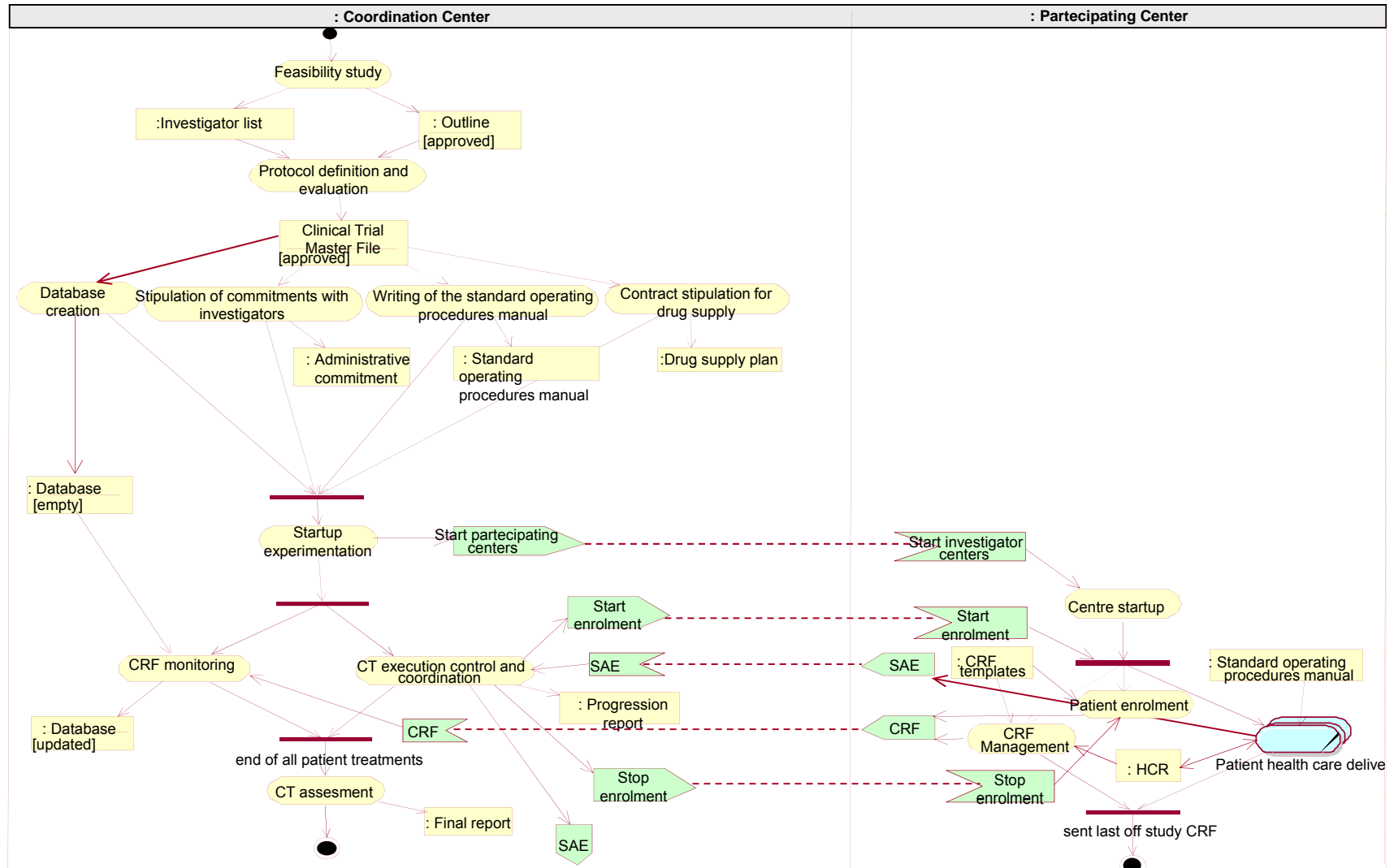
\*) Health Level Seven International, *HL7 version 3*, <http://www.hl7.org>

# A Business Model of Clinical Trials \*)



\*) L. Collada Ali, P. Fazi, D. Luzi, F.L. Ricci, L.D. Serbanati, M. Vignetti, *Toward a Model of Clinical Trials*, ISBMDA 2004, 5th International Symposium of Biological and Medical Data Analysis, Barcelona, 2004.

# Modeling the Clinical Trial with Activity Diagrams





# Concern-Oriented Modeling <sup>\*)</sup>

A concern-oriented approach = obtaining the ontology by conceptualizing the domain from the point of view of stakeholders.

Method:

1. The concerns of all stakeholders partition the knowledge we have on the domain universe in smaller pieces which can be separately analyzed and described.
2. This knowledge is mapped in a comprehensive ontology.
3. The ontology is used to construct facets of the domain that semi-formally describe the concepts and their relations using the UML language.

<sup>\*)</sup> C.M.Bogdan, F.Ricci, D.Luzi, L.D.Serbanati, *A Concern-Oriented and Ontology-Based Approach to Support Clinical Protocols Writing*, EMMIT 2007: Euro-Mediterranean Medical Informatics and Telemedicine, Mangalia, Romania, 2007

<sup>\*)</sup> C. Bogdan, D. Luzi, F.L. Ricci, L.D. Serbanati, *Towards a Clinical Trial Ontology using a Concern-Oriented Approach*, ISBMDA 2006.



# Clinical Trials and their Protocols

- Clinical Trial = “Controlled study performed in human subjects and intended to discover, and/or evaluate, and/or verify safety, effectiveness, clinical and pharmaceutical effects, and adverse reactions of new drugs, devices, treatments, preventive measures, or other medical interventions in treating, preventing or diagnosing a specific disease or condition”<sup>\*</sup>).
- Clinical Protocol = Description conceived by the writing committee, that contains the selection criteria of the subjects, defines or uses medical procedures (e.g. therapeutic procedure) and defines some roles (e.g. investigator, statistician).

\* NCI Thesaurus: <http://nciterms.nci.nih.gov>

# Concern

A **concern** in information system engineering is a *care* related to a problem from the real world of one or more stakeholders involved in the construction or evolution of an information system in its natural environment.

- The care of a stakeholder depends on his/her interest or preoccupation on which he/she has related to a problem from the real world.
- The interest of a stakeholder derives frequently from a need, but can also originate in a desire, another interest or his/her responsibility in the information system evolution process.
- We consider the concern as a state of mind arising from another state of mind of the stakeholder, namely his/her worry or interest in a problem that he/she identified in the real world.

The concerns emerge from a particular perspective to an existing or in development IS that can be:

- social,
- functional,
- informational, or
- technological perspective.



Views

# Stages and Steps of the Modeling Process

## **A. Identification and specification of concerns**

1. identification of stakeholders
2. identification of concerns
3. concern classification
4. identification of relations between concerns
5. prioritize of the concern problems solving



## **B. Constructing an ontology of the conceptual domain**

1. identification of semantic rationales associated to concerns
2. identification of the concepts used in the semantic rationales
3. ontological analysis of the intension of the concepts
4. choosing a foundational ontology to be extended by our ontology
5. classification of the concepts conforming the chosen top-level ontology
6. definition of the domain ontology



## **C. Constructing the conceptual domain views**

1. construction of the UML ontological model of each piece of knowledge or belief
2. construction of facets for each concern rationale
3. the analysis of the independence degree of the facets
4. construction of the informational views by grouping facets of related concerns



# The Concern's Problem

- *A problem originating a concern* = a pair composed from two descriptions:
  - a) **hypothesis**, that is the description of the current situation of the problem, as the stakeholder perceives it,
  - b) **conclusion**, that is the description of the situation that matches expectations, interests, or desires of the stakeholder.
- The problem's current situation contains all information and knowledge necessary to obtain a state in which the problem has been solved.
- We can specify the concern of a stakeholder as an association of the concern problem description with the role the stakeholder plays in the system.



# The Concern's (Semantic) Rationale

SR = group of beliefs and knowledge associated to the concern and used for the problem solving.

Properties of a semantic rationale:

- it answers to the question: „Why did appear the problem?”
- it is true for the state of affairs of the problem, and
- it is clear.

**State of mind** = beliefs, concerns, desires, being in pain, etc.

The **beliefs** take are closely related to concerns. They represent convictions a stakeholder holds for true in a given situation, independently of the nature of the source of the conviction.

**Knowledge** = information evaluated, processed, and structured by the human mind. According to current needs it is used in our decisions or explanations.

**Mental representations** = structured knowledge .

**Functionalism:** *the states of mind have solely a functional role: they transform sensory inputs in behavioral outputs, by working in causal relations with other states of mind.*

# Concern Definitions (I)

<b>C1</b>	<b>Name: Care not to worsen the general clinical state of the subjects during the clinical trial and follow-up</b>	
	<i>Problem</i>	<p><i>Hypothesis:</i> Objectives were defined in order to start a clinical research on a new drug and/or procedure.</p> <p><i>Conclusion:</i> The drug or procedure risks were minimized as much as possible and in the case of appearance of adverse events, their gravity was minimized, the safety of the subjects was preserved during the study and follow-up.</p>
	<i>Stakeholders:</i> Sponsor, Scientific Coordinator	
<b>C2</b>	<b>Name: Care to attain the objectives of the clinical trial</b>	
	<i>Problem</i>	<p><i>Hypothesis:</i> Objectives were defined in order to start a clinical research on a new drug or procedure.</p> <p><i>Conclusion:</i> The clinical trial objectives were attained.</p>
	<i>Stakeholders:</i> Sponsor, Scientific Coordinator	
<b>C3</b>	<b>Name: Care to obtain the characteristics of the study population</b>	
	<i>Problem</i>	<p><i>Hypothesis:</i> Following information is available:</p> <ol style="list-style-type: none"> <li>1. Trial objectives, trial design, statistical considerations</li> <li>2. projects and their scientific results</li> </ol> <p><i>Conclusion:</i> Characteristics of the CT subjects are identified and specified as inclusion/exclusion criteria.</p>
	<i>Stakeholders:</i> Writing committee	

# Concerns Definition (II)

Code	Concern name	
C4	<b>Name:</b> Care to find how the clinical manifestation of the disease is related to the objectives attainment and the selection criteria identification	
C5	<b>Name:</b> Care to determine how the components of the study therapeutic procedure and its administration might affect the general state of the subjects and/or influence the attainment of the objectives	
	Problem	<i>Hypothesis:</i> Following information is available: - Trial objectives, trial design, statistical considerations - Previous CT projects and their scientific results
		<i>Conclusion:</i> How the kind of therapeutic procedure and its components affect the general clinical state of the subjects and the attainment of the objectives? The therapeutic procedure and its components have been administrated on the subjects with the age less than 18 years? If so, what effects they had? In this study, might also take part the subjects with the age less than 18 years? Can the therapeutic procedure have effects on the developing of the fetus?
	<i>Stakeholder:</i> Writing Committee	

# Beliefs from the concerns C1-C4

State of mind code	Mental representation description in natural language
B1	There is the risk that the general clinical state of the subjects may become worse during the clinical trial and follow-up
B2	The safety of the subjects is preserved during the clinical trial and follow-up
B3	The objectives of the clinical trial are fulfilled
B4	The study population is formed by subjects.
B5	The study population has characteristics
B6	The characteristics of the study population are defined by the inclusion and exclusion criteria.
B7	The inclusion and exclusion criteria form the selection criteria.
B8	The clinical manifestation of the disease has relation with the attainment of the objectives and the selection criteria identification
B9	The disease in its stage has a diagnostic as it resulted from tests
B10	The existence of the disease and its gravity affect the life expectancy of a person
B11	The life expectancy is a characteristic of study population
B12	The study population has other basic characteristics: gender, race and performance status
B13	The existence of the disease and its gravity affect the performance status of a person
B14	The clinical manifestation of the disease might have some particularities that are important to identify the selection criteria.
B15	Any disease has a pathogenesis.
B16	The pathogenesis of the disease might affect the general clinical state of the subjects and the inference of the selection criteria.

# Beliefs and Knowledge

## Beliefs

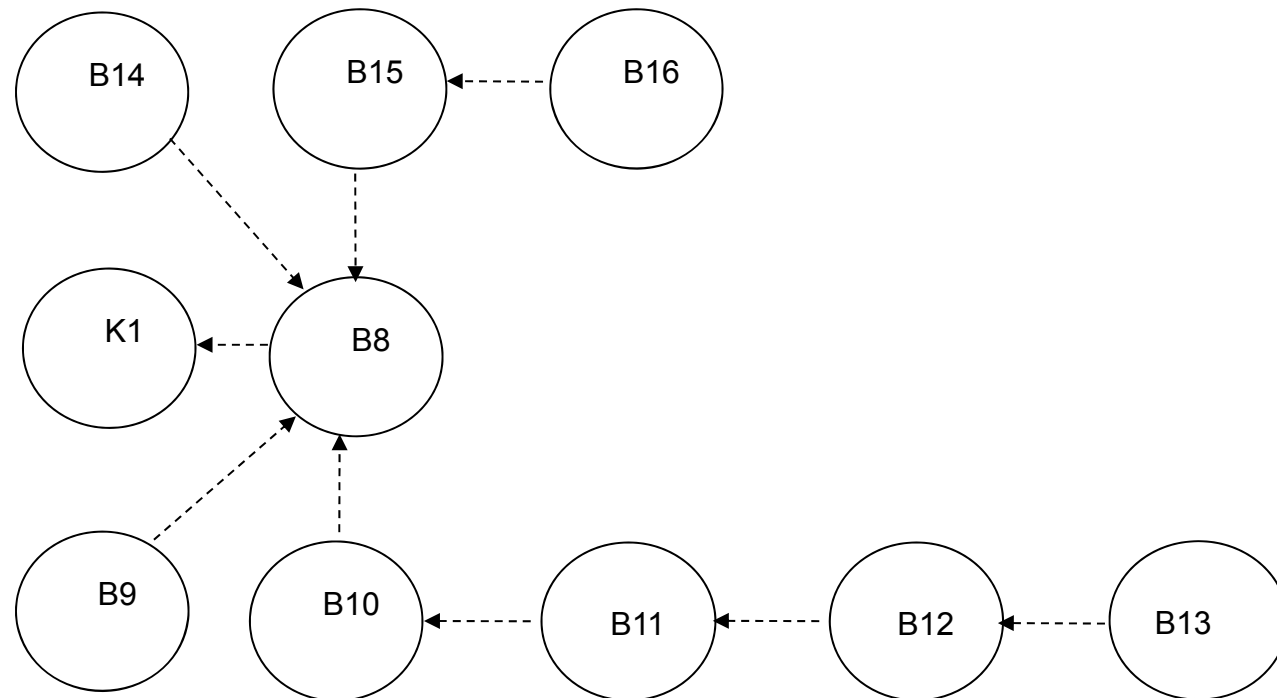
Concern Code	C5	Semantic Rationale Code	SR5
Belief Code	Informal Description of a Mental Representation		
B17	The study therapeutic procedure will affect the clinical manifestation of the disease and the general state of the subjects and/or influence the attainment of the objectives.		
B18	The therapeutic procedure might contain therapeutic agents whose administration might affect the general state of the subjects and/or influence the attainment of the objectives.		
B19	The kind of study therapeutic procedure might affect the general state of the subjects and/or influence the attainment of the objectives.		
B20	The study therapeutic procedure might have been administrated on subject with the age less than 18 years. If so, there are effects of these administrations.		
B21	The therapeutic procedure might have effects on the developing fetus.		

## Knowledge

Know.Code	Mental representation description in natural language
K1	The subjects who have the disease in the stage considered by the study are eligible.
K2	The subjects who have other medical condition that could bias the study compliance and follow-up are not eligible.
K3	The therapeutic procedure administration will affect the clinical manifestation of the disease.
K4	Results of previous phases of the CT or experimental laboratory results are available and a list of ascertained side effects and/or adverse events is known.

# Direct dependency relationship between beliefs

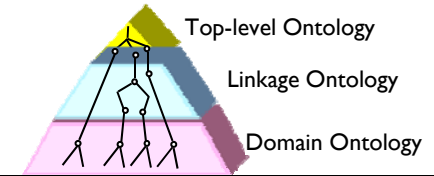
- Direct dependency indicates a causal relation describing that the origin of one component of the relation resides in the other component. The relation may relate: a) a concern and its relative belief, preoccupation, interest; and b) two beliefs, preoccupations, interests, and knowledge.



# Excerpt from the ontology of the “Subject selection criteria” concept in Clinical Trial

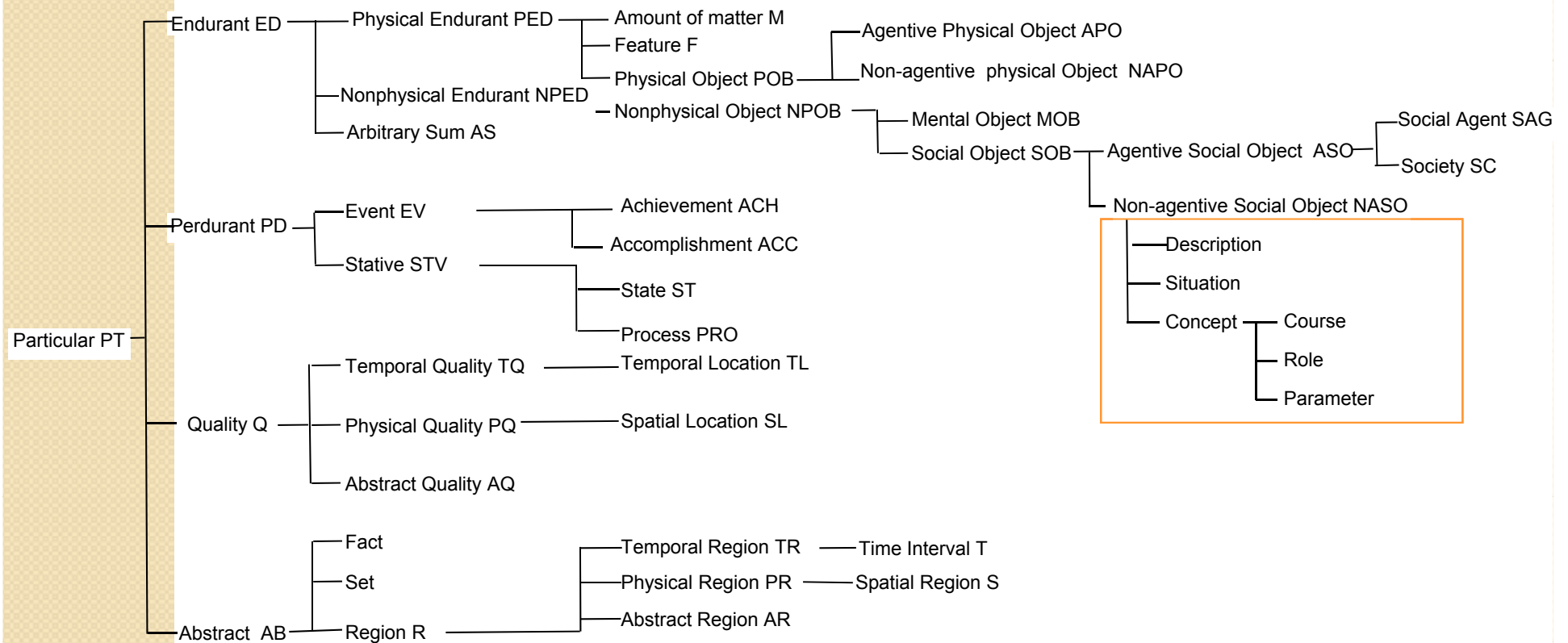
Concept	Formal semantic	Description
person	$\text{Person}(p) =_{df} \text{APO}(p) \wedge \exists c (\text{DNA}(c) \wedge \text{OSD}(p,c))$	Agentive physical object that specifically and one-side depends on DNA.
selection criteria	$\text{SelectionCriteria}(c) =_{df} \text{Description}(c) \wedge \exists w,t (\text{WritingCommittee}(w) \wedge \text{Conceives}(w,c,t)) \wedge \exists i1,i2,e,t (\text{InclusionCriterion}(i1) \wedge \text{InclusionCriterion}(i2) \wedge \text{ExclusionCriterion}(e) \wedge \text{TimeInterval}(t) \wedge K(i1,c,t) \wedge K(i2,c,t) \wedge K(e,c,t))$	Description conceived by the writing committee and constituted by the inclusion and exclusion criteria. The description has two parts: inclusion and exclusion criteria. Moreover, the persons have to have signed and dated an informed consent, K1 and .
variable	$(A) \text{Variable}(v) \rightarrow \text{Description}(v)$ $(A) \text{Variable}(v) \wedge \forall p1,s1 (\text{Particular}(p1) \wedge \text{Situation}(s1) \wedge \text{SAT}(s1,v)) \rightarrow \exists p2,s2, t (\text{Particular}(p2) \wedge \text{TimeInterval}(t) \wedge (\text{P}(p1,p2) \vee \text{PC}(p2,p1,t) \vee \text{qt}(p1,p2)) \wedge \text{Situation}(s2) \wedge \text{P}(s1,s2) \wedge \text{SettingFor}(s2,p2) \rightarrow \exists d (\text{Description}(d) \wedge \text{SAT}(s2,d) \wedge \text{PP}(d,v)))$	Generic description of various situations of a particular (namely enduring, perduring or quality) used in the description of another particular. Such variable exists due to a kind of relation between the two particulars. The relation can be: parthood, participation, or quality.
value of variable	$(D) \text{ValueOf}(s, v) =_{df} \text{Situation}(s) \wedge \text{Variable}(v) \wedge \text{SAT}(s,v)$ $(A) \text{Variable}(v) \rightarrow \exists s1,s2 (\text{Situation}(s1) \wedge \text{Situation}(s2) \wedge \text{ValueOf}(s1,v) \wedge \text{ValueOf}(s2, v) \wedge \forall x1,x2 (\text{Particular}(x1) \wedge \text{SettingFor}(s1,x1) \wedge \text{Particular}(x2) \wedge \text{SettingFor}(s2,x2) \rightarrow x1 \neq x2))$	A situation that satisfies a Variable description. A variable can take different values.
maximal domain	$\text{MaximalDomain}(v) =_{df} \text{Variable}(v) \wedge \forall s (\text{Situation}(s) \wedge \text{SAT}(s,v) \rightarrow \text{valueOf}(s,v))$	Domain of all values of a variable.
characteristic of persons	$(A) \text{CharacteristicOfPerson}(p,v) \rightarrow \text{Person}(p) \wedge \text{Variable}(v)$ $(A) \text{CharacteristicOfPerson}(p,v) \rightarrow \exists v1 (\text{Variable}(v1) \wedge \text{CharacteristicOfPerson}(p,v1) \wedge \text{PP}(v1,v))$ $(A) \neg \forall p, v (\text{Person}(p) \wedge \text{Variable}(v) \wedge \text{CharacteristicOfPerson}(p,v) \rightarrow \exists v1 (\text{Variable}(v1) \wedge \text{CharacteristicOfPerson}(p,v1) \wedge \text{PP}(v1,v)))$	Variable that applies on a person. In addition, the characteristics of a person can be parts of other characteristics.
assessment domain	$(A) \text{AssessmentDomain}(v) \rightarrow \exists d (\text{Variable}(d) \wedge \text{MaximalDomain}(d) \wedge \text{PP}(v,d))$ $(A) \text{AV}(s,v) \rightarrow \text{ValueOf}(s,v)$ $(A) \exists s,v (\text{Situation}(s) \wedge \text{Variable}(v) \wedge \text{ValueOf}(s,v) \rightarrow \neg \text{AV}(s,v))$	Sub-domain of the maximal domain which contains the values that are considered in the study.
inclusion criteria	$(D) \text{InclusionCriteria}(d, p) =_{df} \text{Description}(d) \wedge \text{Person}(p) \wedge \exists v (\text{Variable}(v) \wedge \text{CharacteristicOfPerson}(p,v) \wedge \text{PP}(v,d))$ $(A) \forall d,p (\text{Description}(d) \wedge \text{Person}(p) \wedge \text{InclusionCriteria}(d, p) \rightarrow \exists s (\text{Situation}(s) \wedge \text{AV}(s,d))$	Description conceived by the writing committee of a non-empty group of assessment domain for a selection list of characteristics of persons. It is used to select (eligible) persons for the CT.
exclusion criteria	$(D) \text{ExclusionCriteria}(d, p) =_{df} \text{Description}(c) \wedge \text{Person}(p) \wedge \exists v (\text{Variable}(v) \wedge \text{CharacteristicOfPerson}(p,v) \wedge \text{PP}(v,d))$ $(A) \forall d,p (\text{Description}(d) \wedge \text{Person}(p) \wedge \text{ExclusionCriteria}(d, p) \rightarrow \exists s (\text{Situation}(s) \wedge \neg \text{AV}(s,d))$	Description conceived by the writing committee of a non-empty group of assessment domain for a selection list of characteristics of persons. It is used to eliminate persons from the eligible ones.

# Domain Ontology Definition

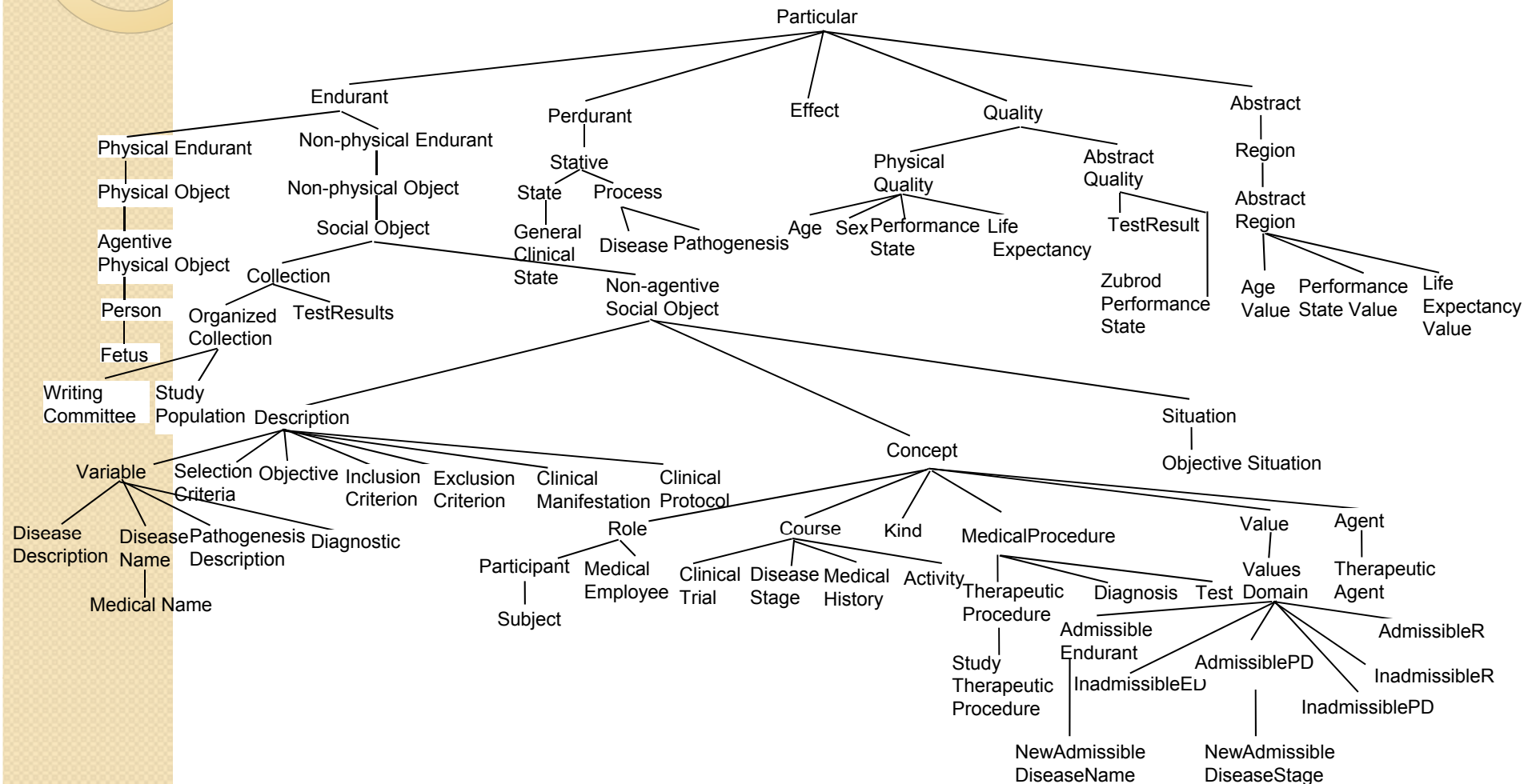


Concept Name	Formal Semantic
Variable	$(D) \text{Variable}(x) =_{df} \text{Description}(x) \wedge \exists y, t (\text{Particular}(y) \wedge T(t) \wedge \text{Refers}(x, y, t))$ $(A) \text{Refers}(x, y, t) \rightarrow \text{Variable}(x) \wedge (\text{Endurant}(y) \vee \text{Perdurant}(y) \vee \text{Quality}(y)) \wedge T(t)$ $(A) \text{Refers}(x, y, t) \wedge \text{Endurant}(y) \rightarrow \exists z, t (\text{Concept}(z) \wedge T(t) \wedge (\text{Uses}(x, z) \vee \exists u (\text{Description}(u) \wedge \text{PP}(u, x) \wedge \text{Uses}(u, z)) \wedge \text{Classifies}(z, y, t))$
Value	$(A) \text{Value}(x) \rightarrow \text{Concept}(x)$ $(A) \text{Variable}(x) \rightarrow \exists y (\text{Value}(y) \wedge \text{Has}(x, y))$ $(A) \text{Has}(x, y) \rightarrow \text{Variable}(x) \wedge \text{Value}(y) \wedge \exists \phi ((\phi(x) \rightarrow \text{Concept}(x)) \wedge \text{Uses}(x, y))$
Person	$(D) \text{Person}(p) =_{df} \text{APO}(p) \wedge \exists c (\text{DNA}(c) \wedge \text{OSD}(p, c))$
Disease	$(A) \text{Disease}(x) \rightarrow \text{Process}(x) \wedge \exists p, t (\text{Person}(p) \wedge T(t) \wedge \text{PC}(p, x, t))$ $(A) \text{Body}(x) \rightarrow \text{NAPO}(x) \wedge \exists p (\text{Person}(p) \wedge \text{GK}(p, x))$ $(A) \text{AffectedBodyPart}(c) \rightarrow \text{NAPO}(c) \wedge \exists x (\text{Body}(x) \wedge \text{P}(c, x))$ $(A) \text{Disease}(x) \rightarrow \exists c (\text{AffectedBodyPart}(c) \wedge \text{P}_s(c, x))$ $(A) \text{DiseaseState}(s) \rightarrow \text{ST}(s)$ $(A) \text{Disease}(x) \rightarrow \exists s (\text{DiseaseState}(s) \wedge \text{P}_T(s, x))$
Clinical Manifestation	$(A) \text{ClinicalManifestation}(x) \rightarrow \text{Description}(x) \wedge \exists y (\text{Disease}(y) \wedge \text{OSD}(x, y))$ $(A) \text{ClinicalManifestation}(x) \rightarrow \exists y, z, m, t (\text{Disease}(y) \wedge \text{Concept}(z) \wedge \text{Uses}(x, z) \wedge \text{Classifies}(z, m, t) \rightarrow \text{PD}(m) \wedge \text{PT}(m, y))$
General Clinical State	$(A) \text{ClinicalGeneralState}(x) \rightarrow \text{State}(x) \wedge \exists p, c, t (\text{Person}(p) \wedge \text{Body}(c) \wedge T(t) \wedge \text{PC}(p, x, t) \wedge \text{GK}(p, c) \wedge \text{P}_s(c, x))$ $(A) \text{ClinicalGeneralState}(x) \wedge \text{Person}(p) \wedge \text{Disease}(y) \wedge \text{PC}(p, x, t) \wedge \text{PC}(p, y, t) \rightarrow \exists s (\text{DiseaseState}(s) \wedge \text{K}(x, s))$
Clinical Protocol	$(A) \text{ClinicalProtocol}(x) \rightarrow \text{Description}(x) \wedge \forall y, t (\text{Person}(y) \wedge \text{Conceives}(y, x, t) \wedge T(t) \rightarrow \exists z (\text{WritingCommittee}(z) \wedge \text{Membership}(y, z, t))$ $(A) \text{ClinicalProtocol}(x) \rightarrow \exists y (\text{SelectionCriteria}(y) \wedge \text{P}(x, y))$ $(A) \text{ClinicalProtocol}(x) \rightarrow \exists y (\text{Objective}(y) \wedge \text{P}(x, y))$ $(A) \text{ClinicalProtocol}(x) \rightarrow \exists y (\text{MedicalProcedure}(y) \wedge \text{Uses}(x, y))$
Clinical Trial	$(A) \text{ClinicalTrial}(x) \rightarrow \text{Course}(x) \wedge \forall y, t (T(t) \wedge \text{Classifies}(x, y, t) \rightarrow \text{Process}(y))$ $(A) \text{ClinicalTrial}(x) \rightarrow \exists y (\text{ClinicalProtocol}(y) \wedge \text{Defines}(y, x))$ $(A) \text{ClinicalTrial}(x) \rightarrow \exists y, z, t (\text{Process}(y) \wedge T(t) \wedge \text{Classifies}(x, y, t) \wedge \text{MedicalProcedure}(z) \wedge \text{Classifies}(z, y, t))$
Subject	$(A) \text{Subject}(x) \rightarrow \text{Participant}(x) \wedge \forall y, t (T(t) \wedge \text{Classifies}(x, y, t) \rightarrow \text{Person}(y) \wedge \text{PlayedBy}(x, y, t))$ $(A) \text{Subject}(x) \rightarrow \exists y, z, t, p (\text{ClinicalTrial}(y) \wedge \text{Process}(z) \wedge T(t) \wedge \text{Classifies}(y, z, t) \wedge \text{Person}(p) \wedge \text{PlayedBy}(x, p, t) \wedge \text{PC}(p, z, t) \rightarrow \exists z1, p1 (\text{TrialTherapeuticProcedure}(z1) \wedge \text{Classifies}(z1, z, t) \wedge \text{Person}(p1) \wedge \text{Executes}(p1, z1, t)))$

# DOLCE+ Ontology



# Taxonomy of the Selection Criteria Ontology of the Semantic Rationales SR1-SR5



# Views

**View** = simplified model of an IS related to a particular set of concerns homogeneous from a logical point of view. The particularity is due to the fact that the concerns emerge from a particular perspective of the IS developing process: social, functional, informational, or technological.

**Perspective & Role  $\Rightarrow \{C_1, \dots, C_n\} \Rightarrow \text{View}$**

**Informational View** = UML model of structural type (class diagram, package diagram, etc.). It contains the categories of information of the conceptual domain, their relations, as well as the constraints regarding the model interpretation.

# Facets

**Facet** = simplified model of a view and represents a projection of view “filtered” from a stakeholder’s point of view<sup>\*)</sup>.

We consider an informational view as a cluster of facets. Each facet is a simplified model of the informational view and conceptually represents a concern-driven abstraction of the informational view according to a paradigm that one or more stakeholders shaped in time by playing the same role or having the same responsibilities.

## **Facet Pattern:**

- Facet code
- Concern code
- Dependency graph of beliefs and knowledge that form the semantic rationale
- Facet structure

<sup>\*)</sup> L. D. Șerbănați, *Integrating Tools for Software Development*, Prentice Hall, 1993

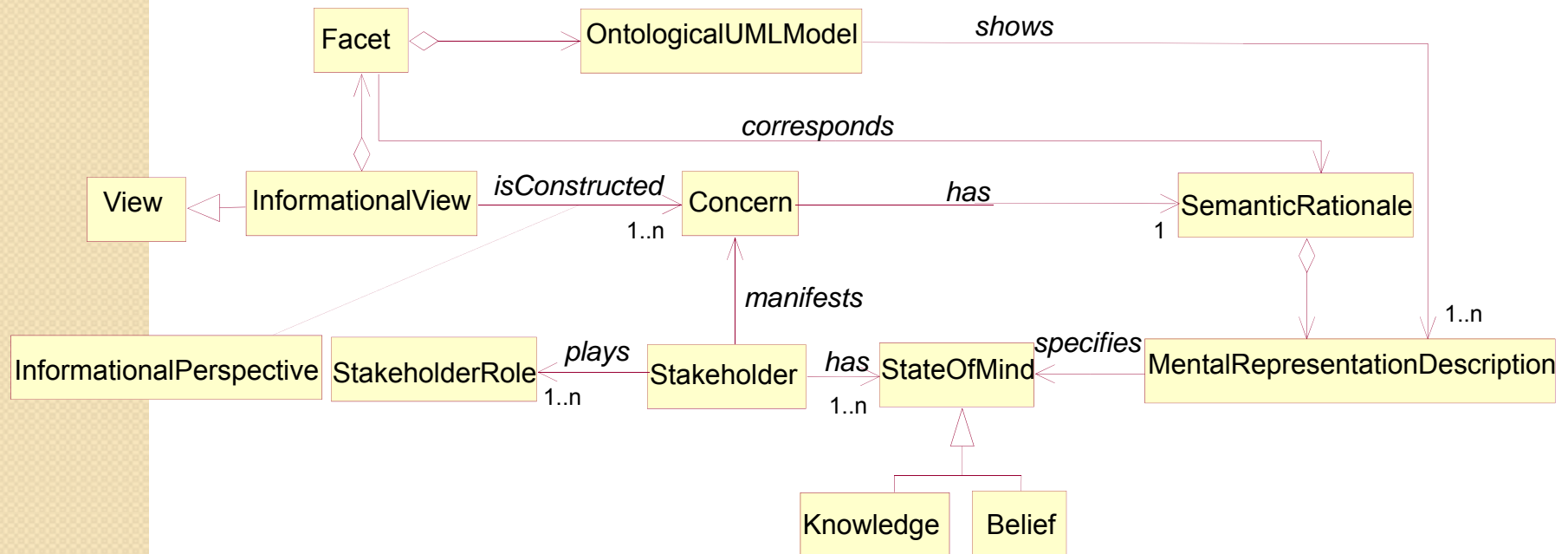
# UML Ontological Models

**UML Ontological Model** = a UML class diagram that semi-formally describes the semantics of a piece of knowledge or belief of a concern's rationale.

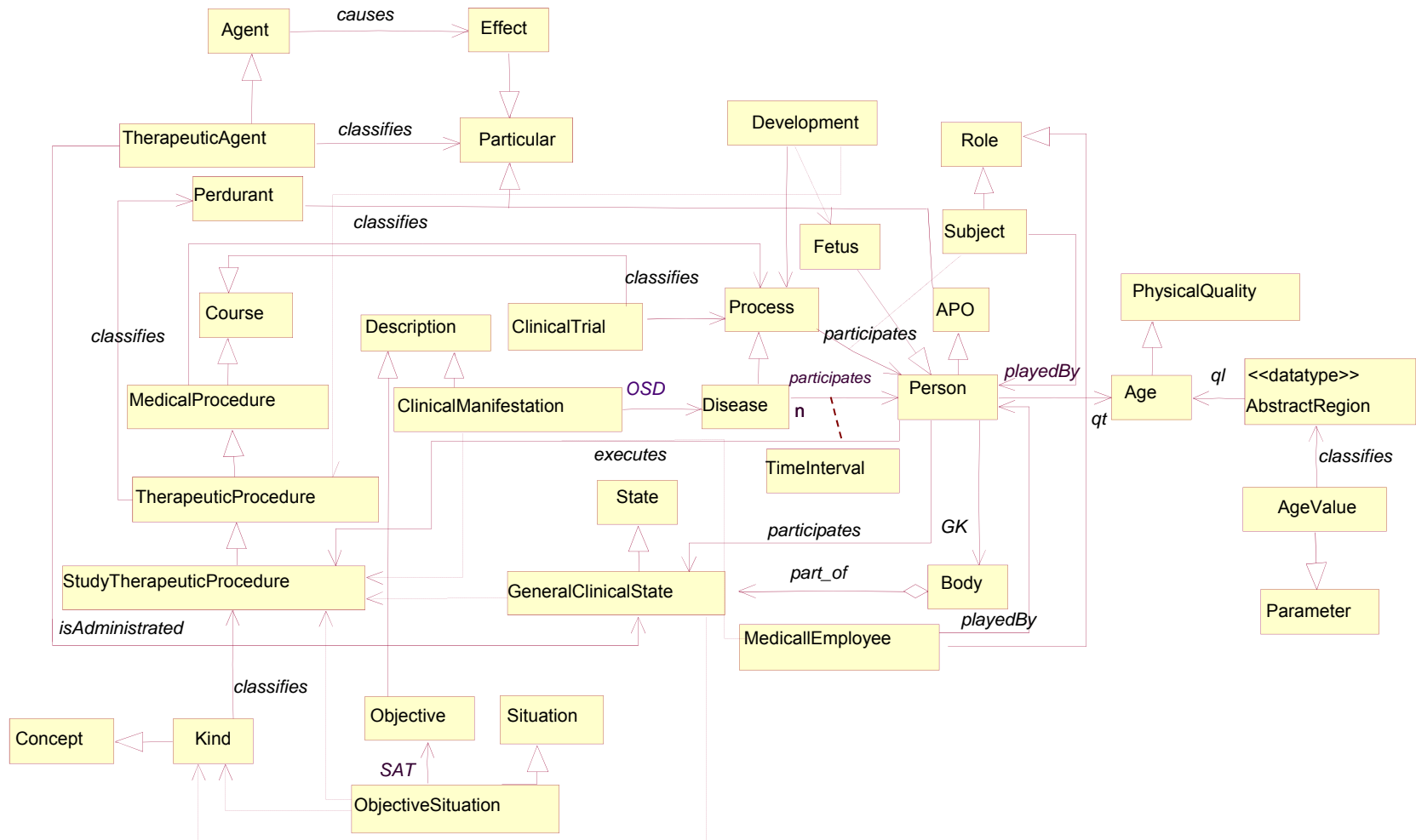
## **Construction rules of UML ontological models using DOLCE+ ontology:**

- any ontological category, excepting abstracts and formal roles, is represented as a class;
- the material roles are mapped to the association classes, and the formal ones are mapped to the association roles;
- the subsumption relation is mapped to the UML generalization/specialization relation;
- the ontological relations, excepting subsumption, parthood, and constitution, are mapped in UML associations;
- temporal and temporary parthood, also constitution relations are mapped in UML aggregation relations.

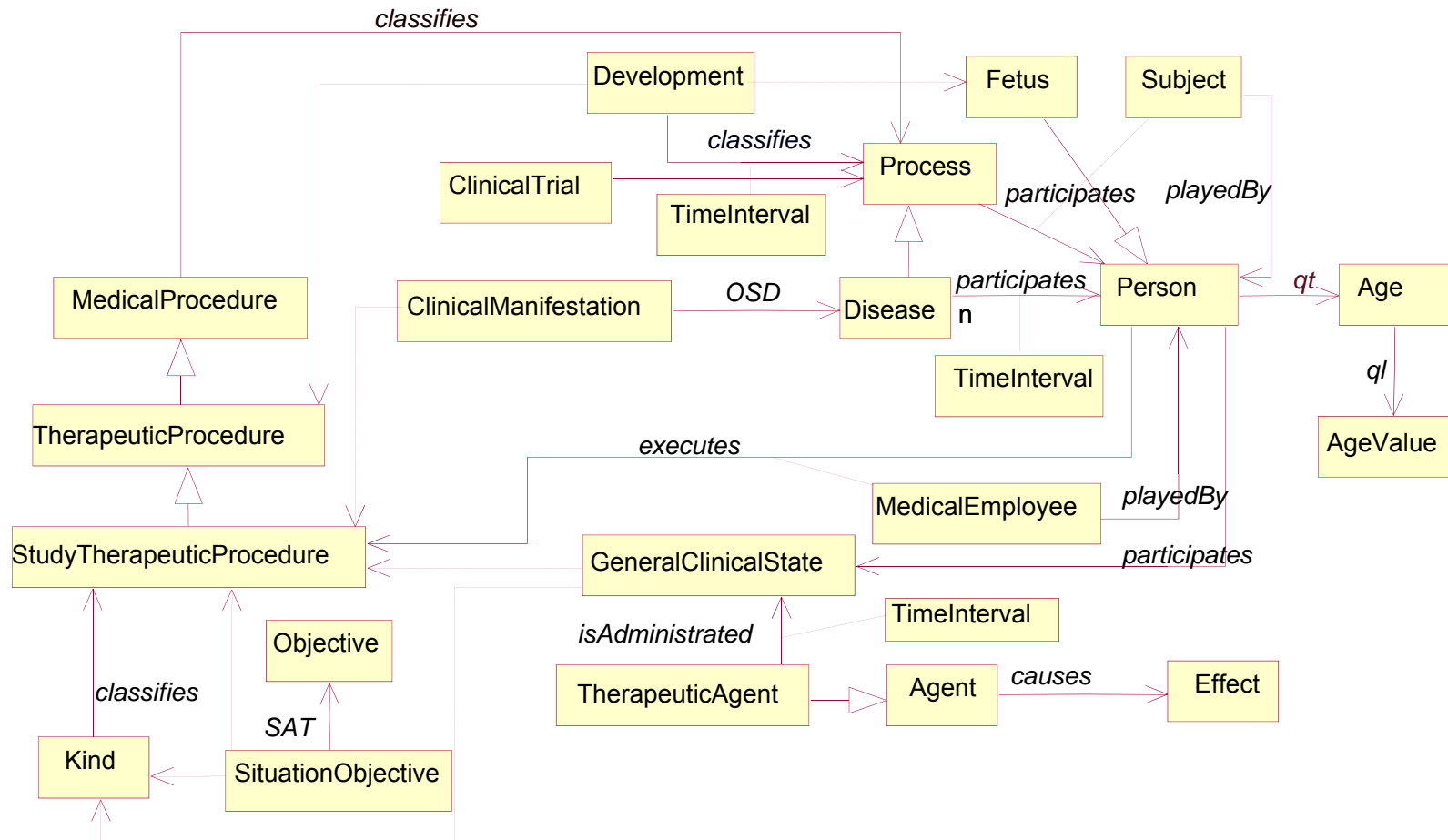
# Concepts Needed for Construction of a View



# UML Ontological Model of the belief O17



# Facet Structure of the Concern C5

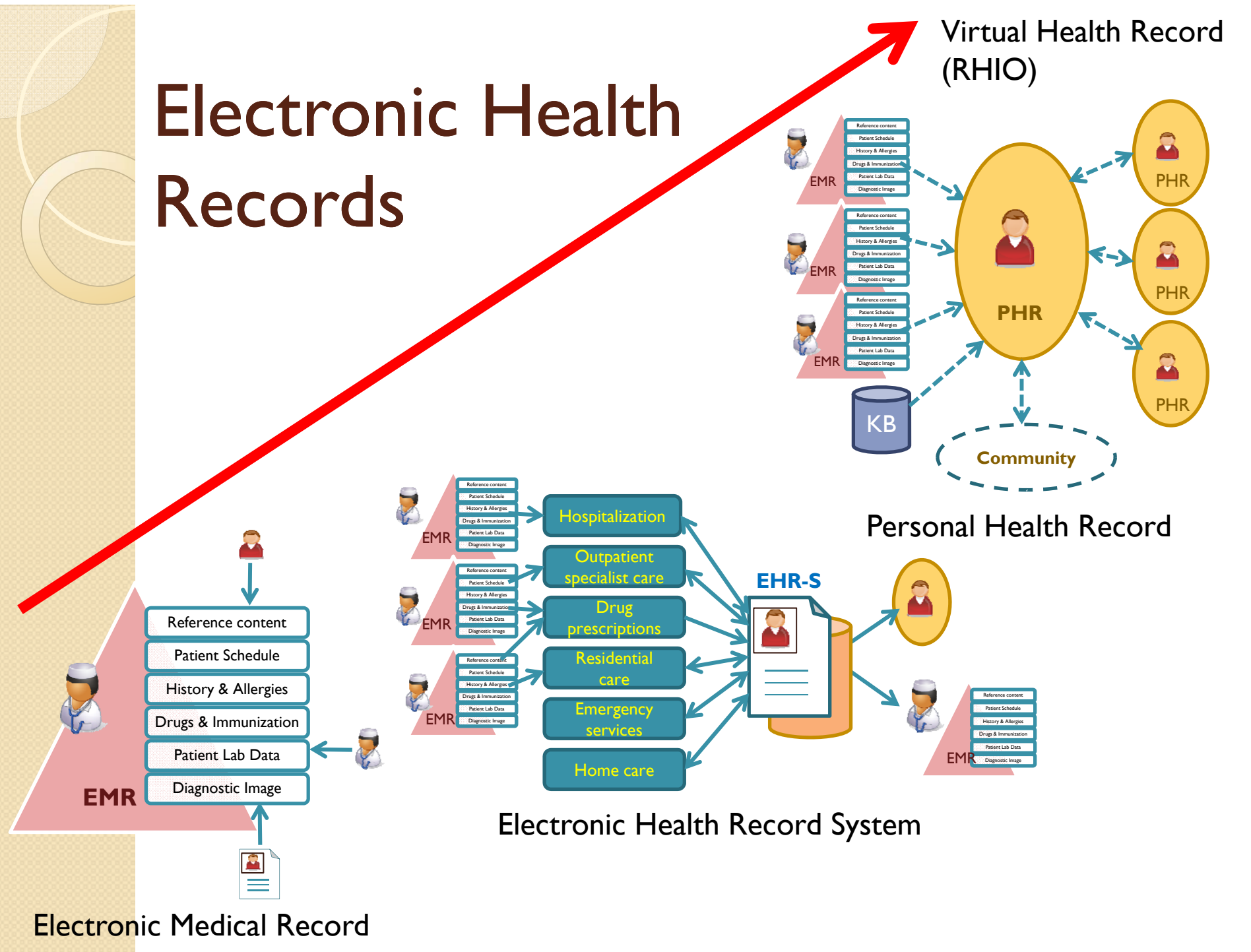




# Interconnecting Health

# Electronic Health Records

Virtual Health Record (RHIO)





# Virtual Health Record

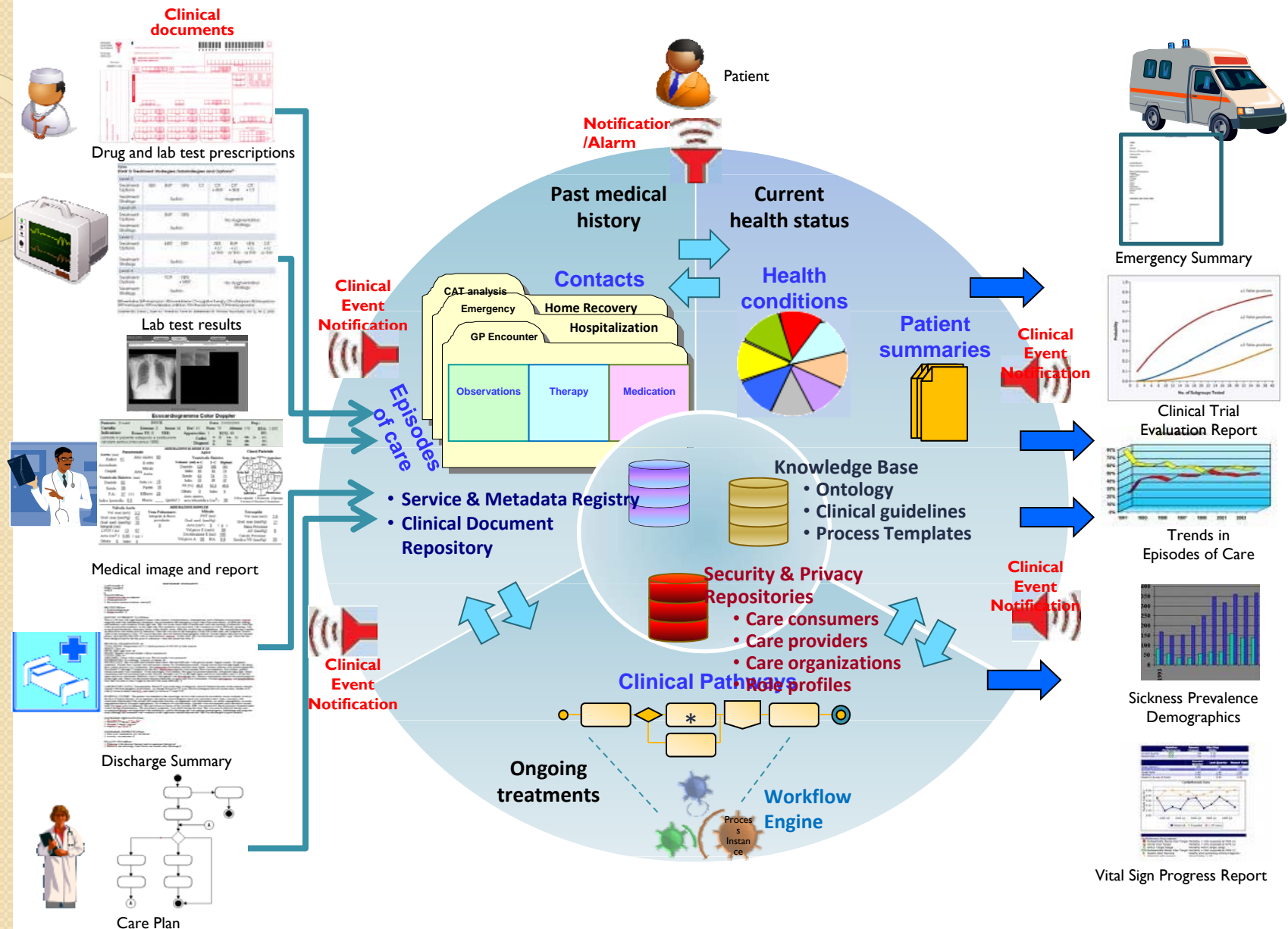


# The Virtual Health Record (VHR)

An internet distributed platform that provides a complete and authoritative representation of the citizen's health:

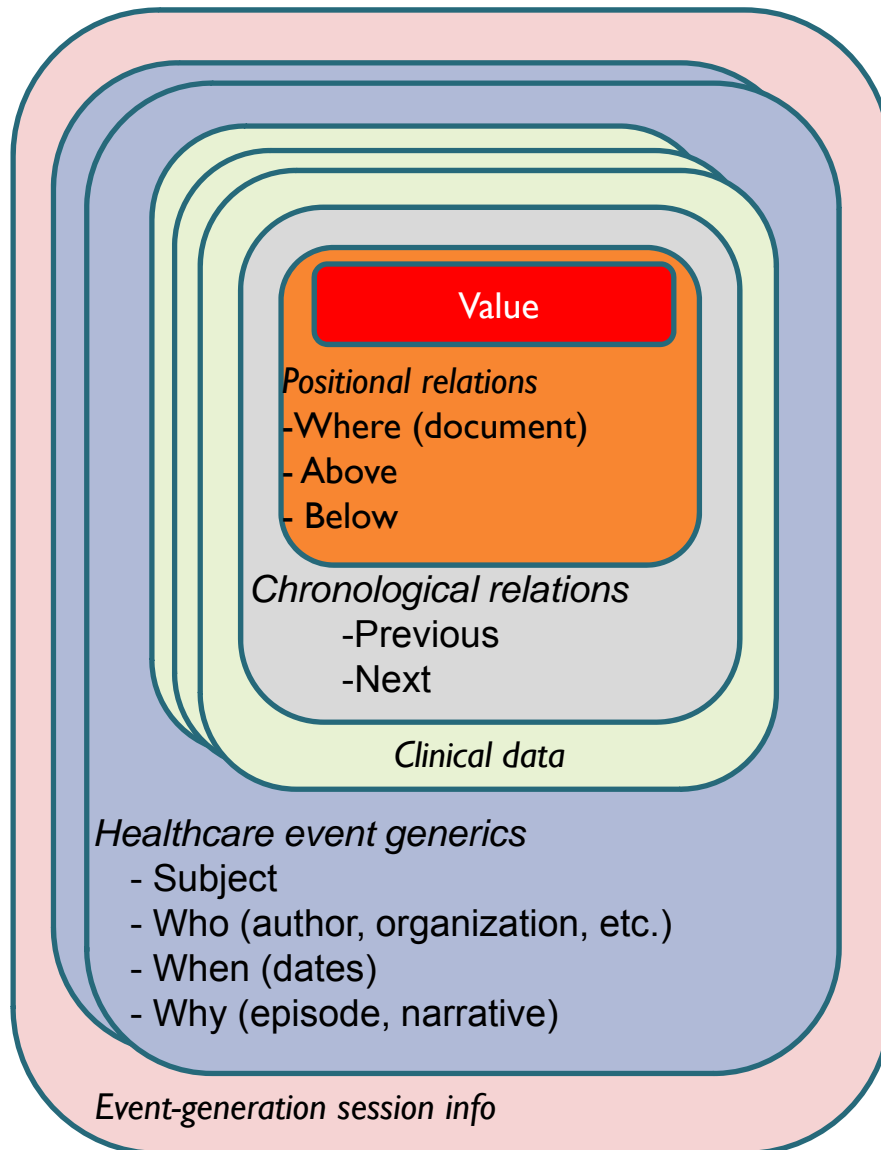
- medical history,
- current health state, and
- on-going treatments.
- VHR supports *the shift from organization-centric to patient-centric model of service delivery* by enabling integration and sharing of patient-related multi-dimensional data in order to promote collaborative, multidisciplinary and cross-organizational healthcare delivery processes.
  - It is highly structured by clinical events and episodes of care,
  - It has a medical guideline-based content
  - It proactively manages care providers and consumers, patient-, caregiver-, as well as condition-specific notifications, and inter-provider communication.

## Virtual Health Record<sup>\*)</sup>



<sup>\*)</sup> L.D.Serbanati, F.Ricci, G.Mercurio, A.Vasileanu, Steps towards a digital health ecosystem, J Biomed Inform, Elsevier, 2011

# A value in VHR

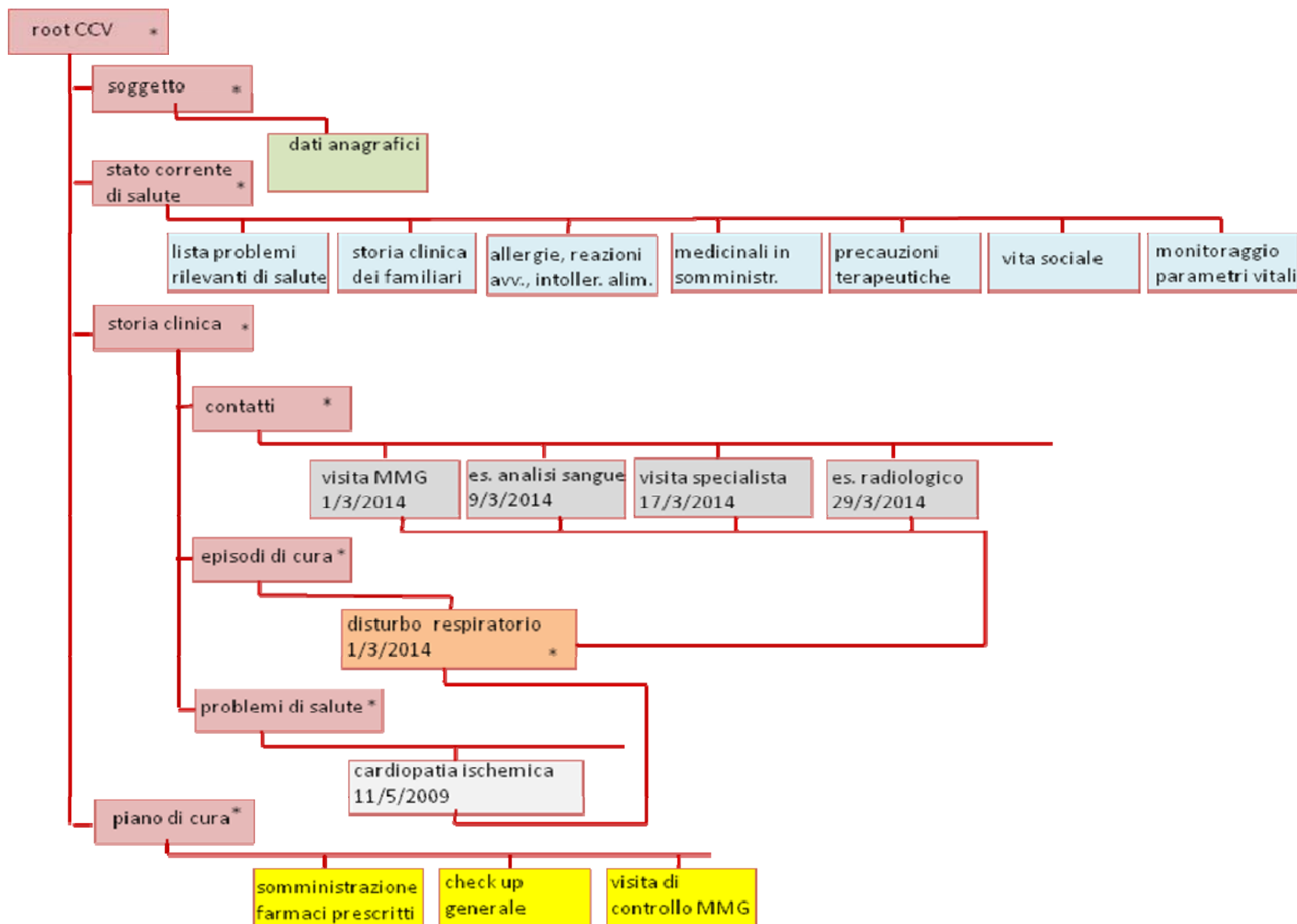


who-where-what-how-why



Context extension

# Data Structures in VHR

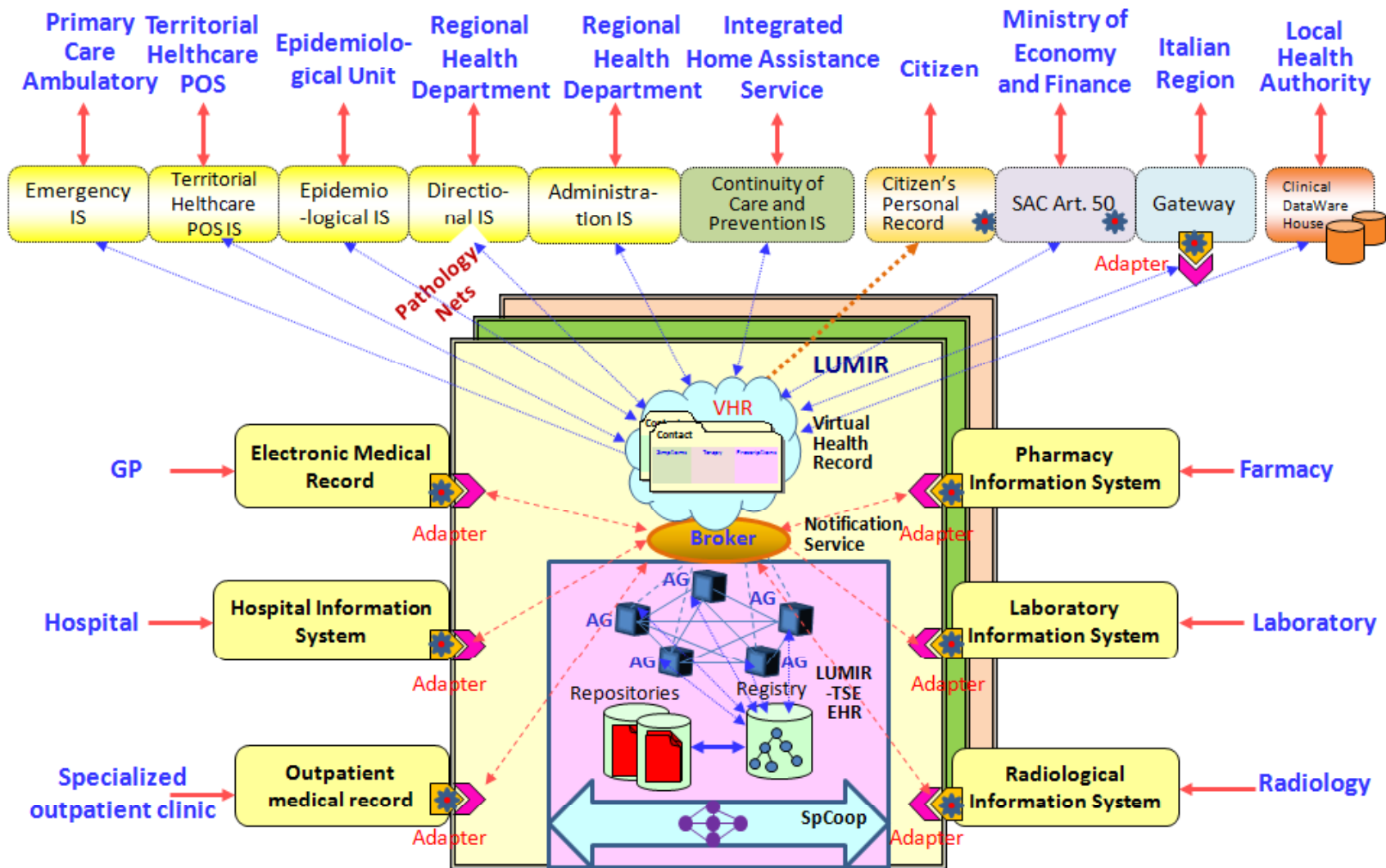




# LUMIR

## (The EHR-S of the Basilicata Region)

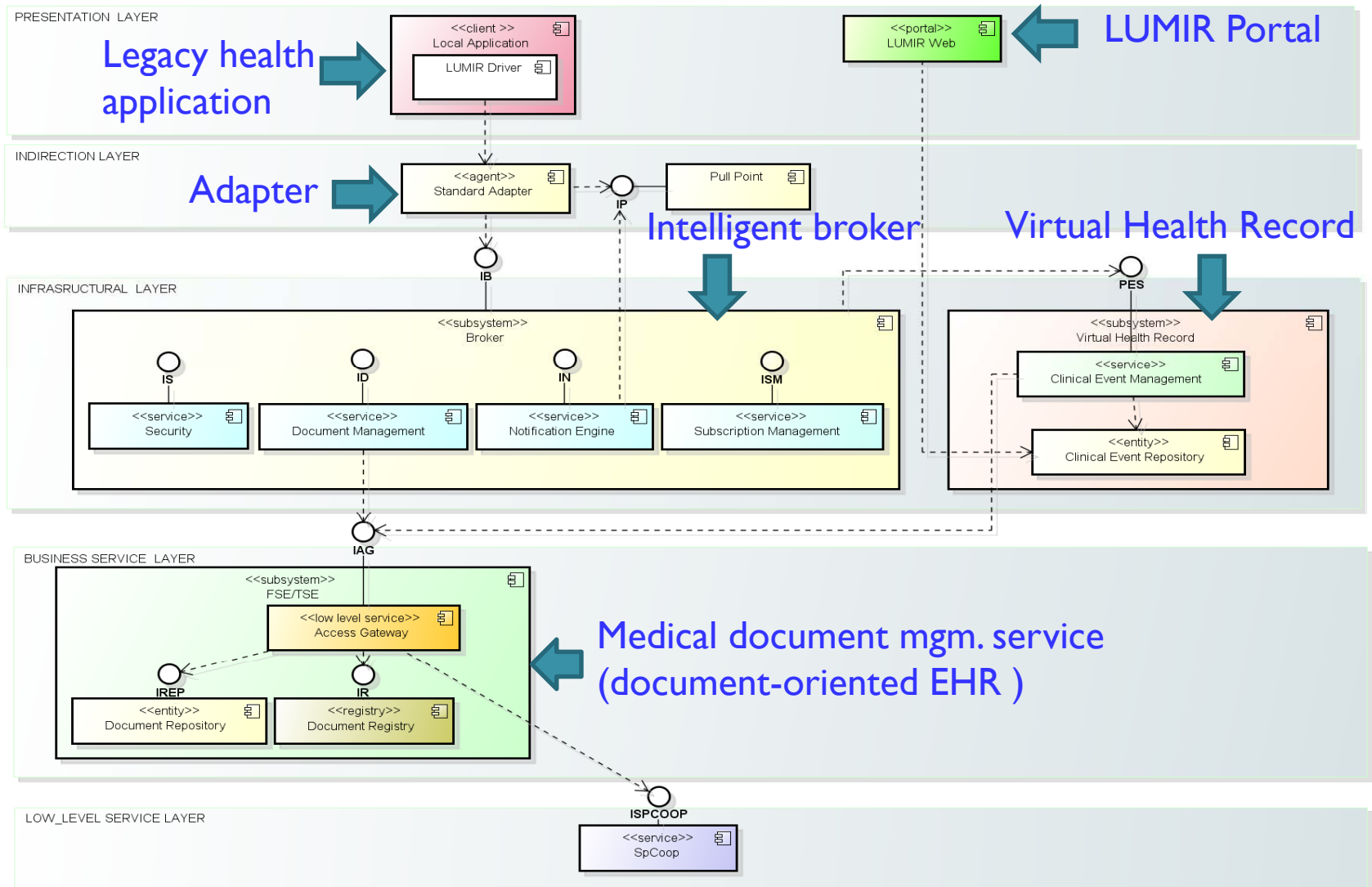
# Interconnecting Health in LUMIR



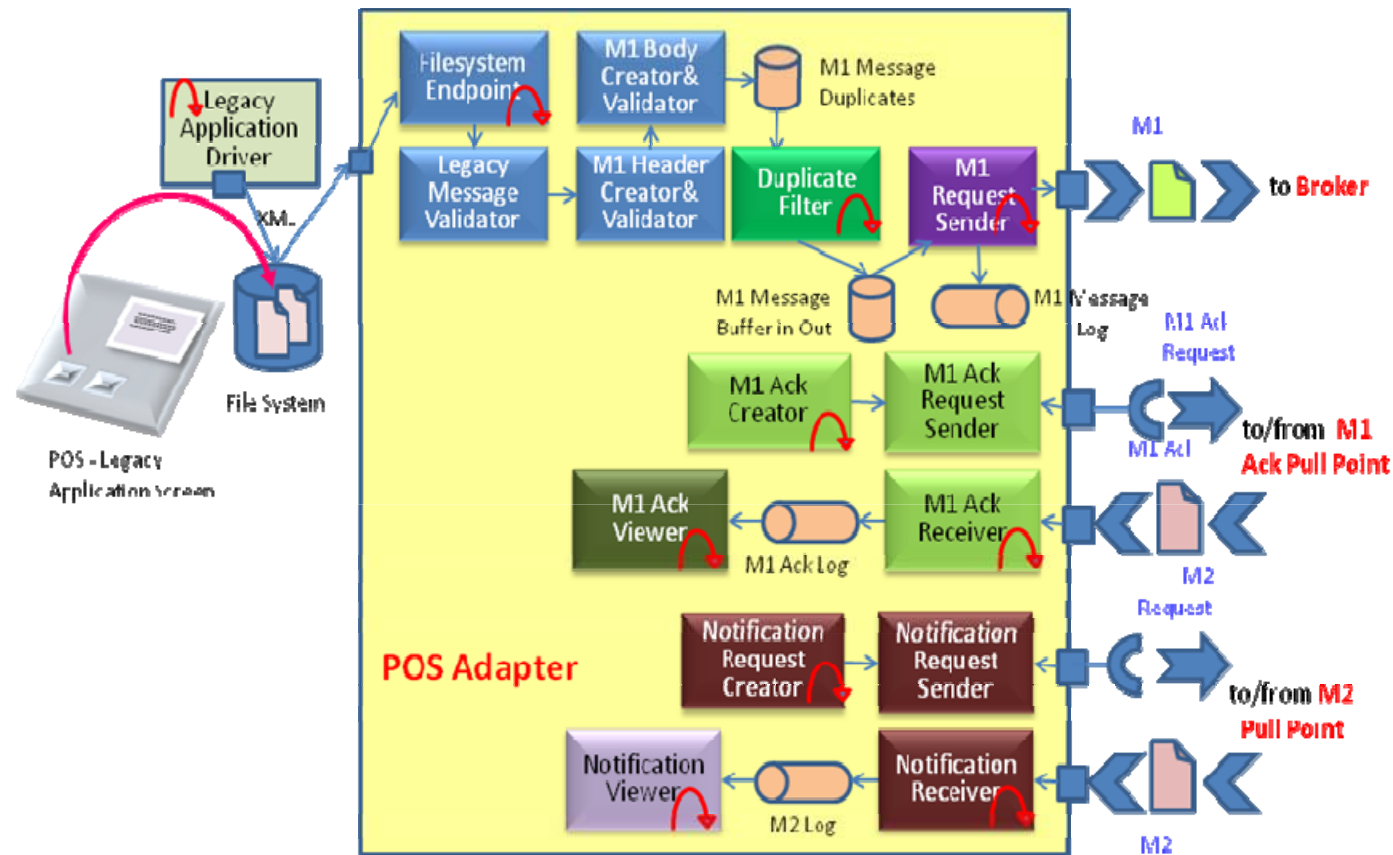




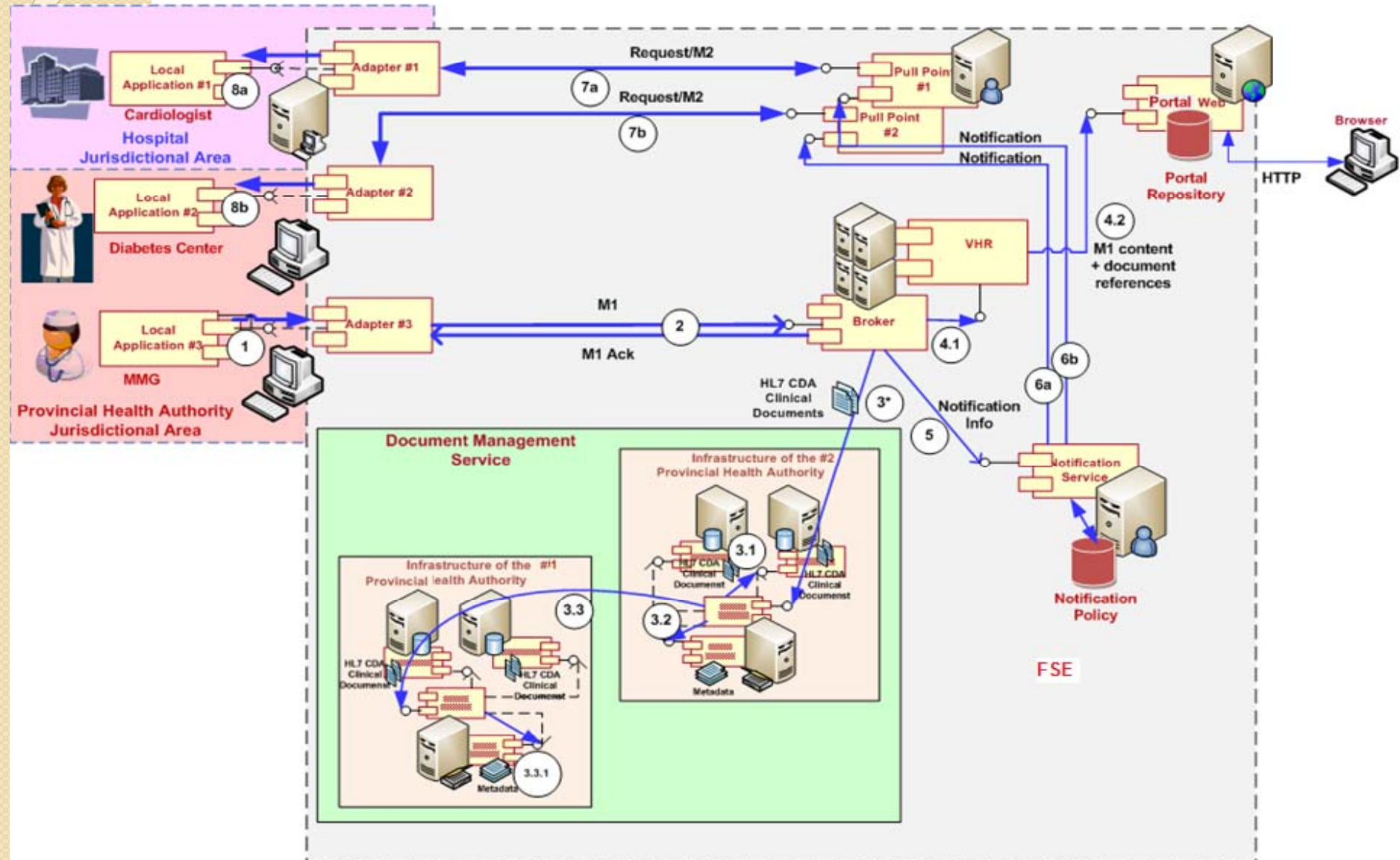
# LUMIR Layered Architecture



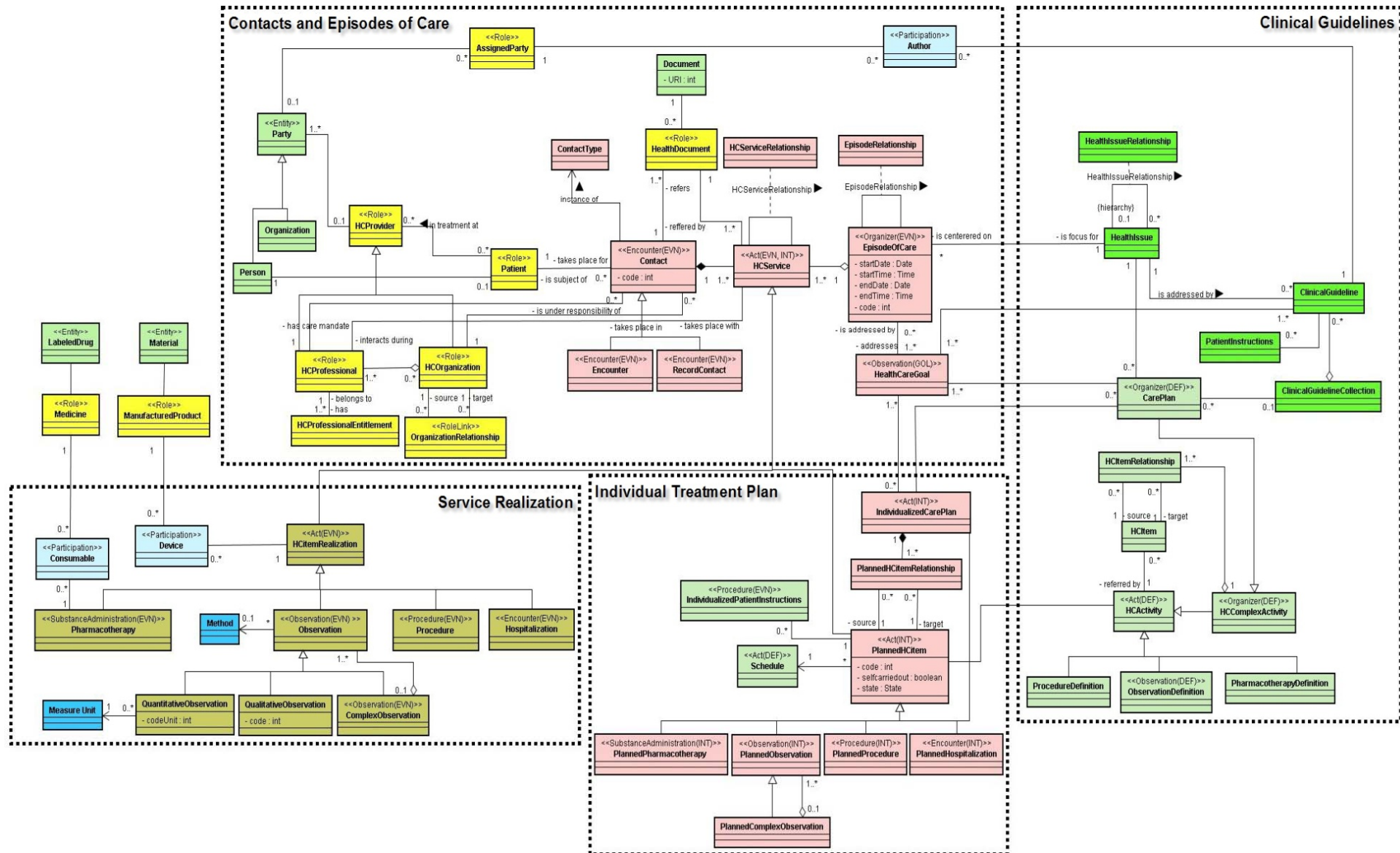
# Adapter Component



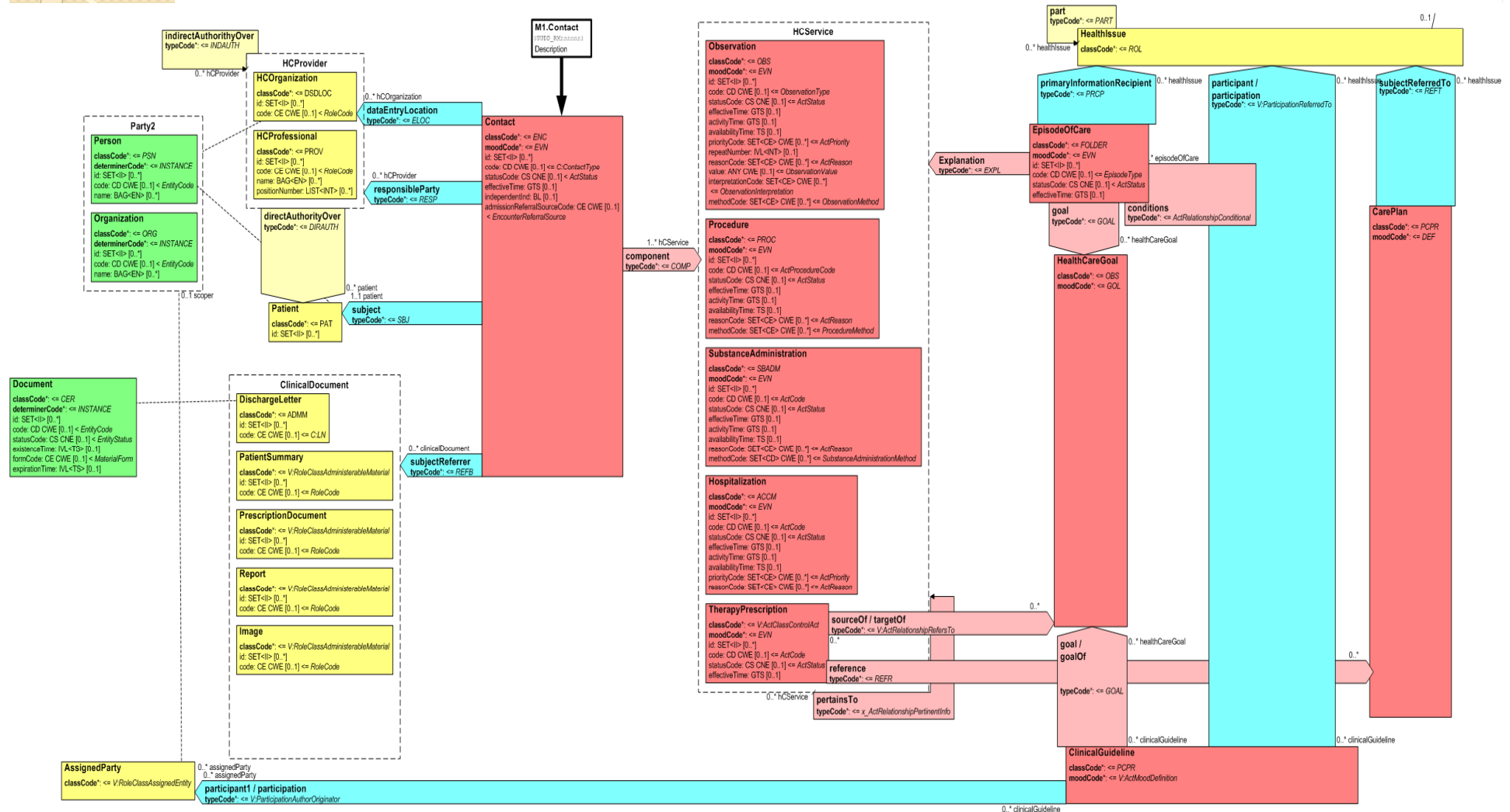
# Interaction Scenario in LUMIR



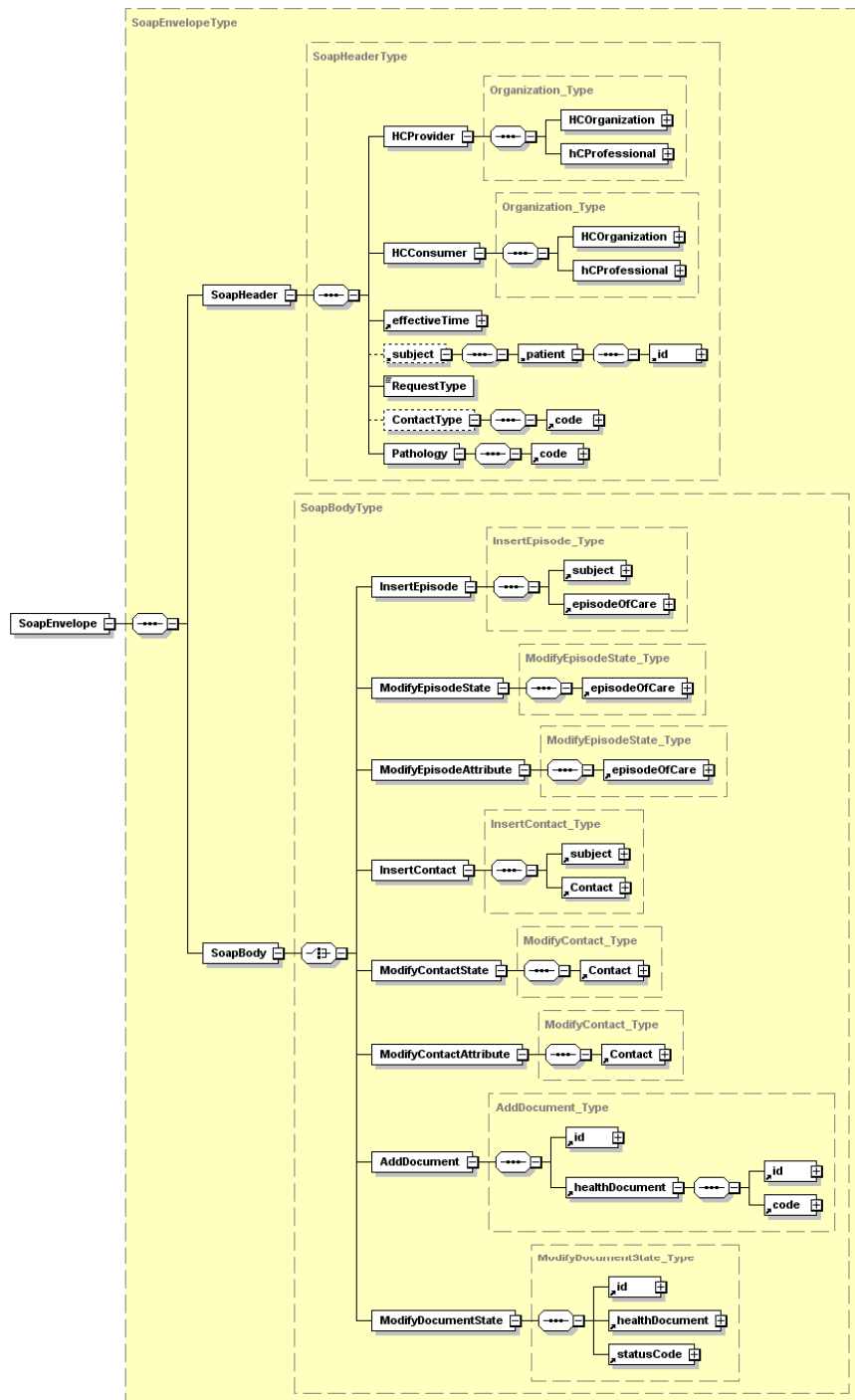
# HL7 Domain Analysis Model (DAM) for the LuMiR Healthcare Domain



# Domain Message Information Model (D-MIM) of the Contact concept



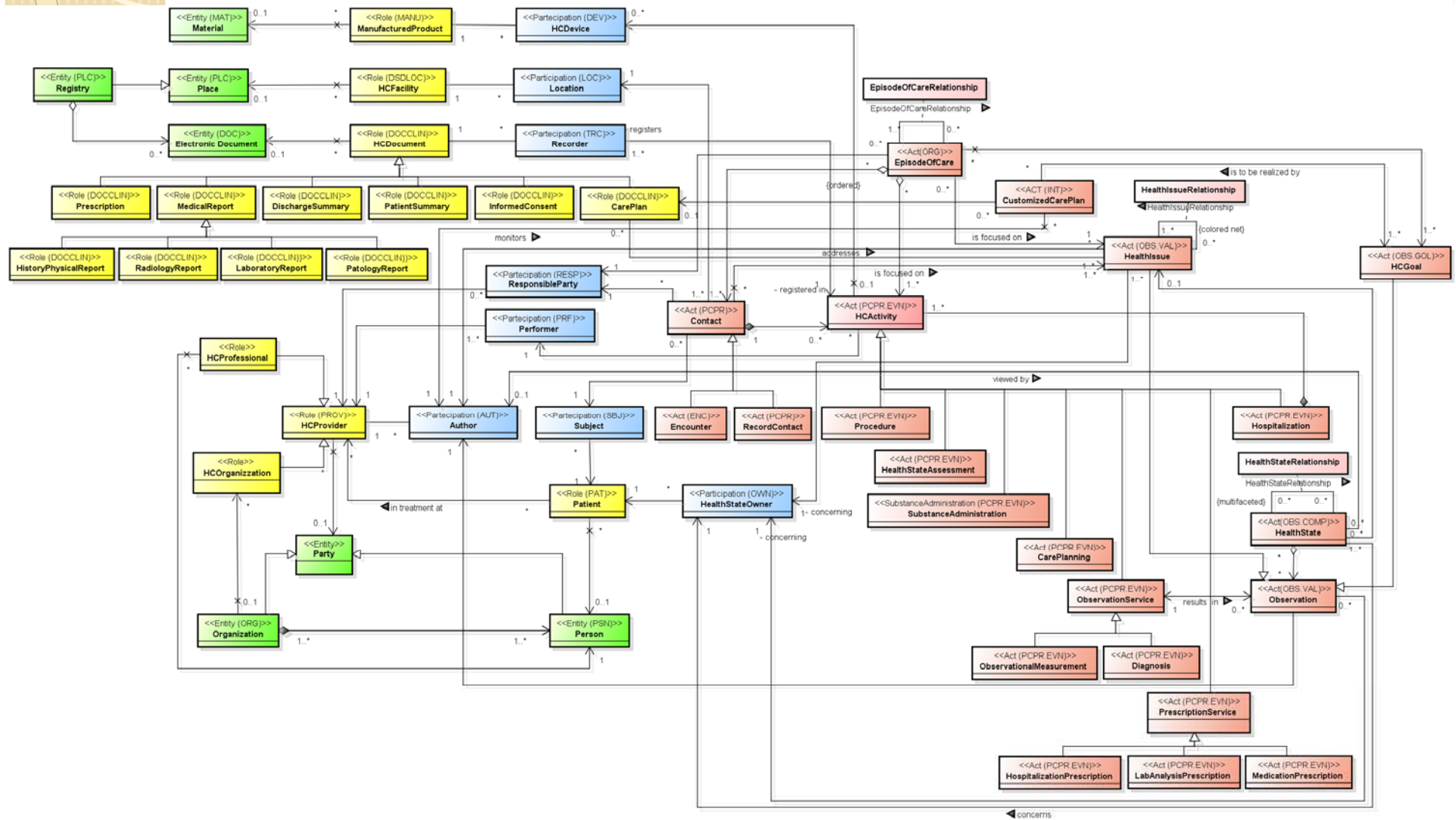
# HL7 generated message

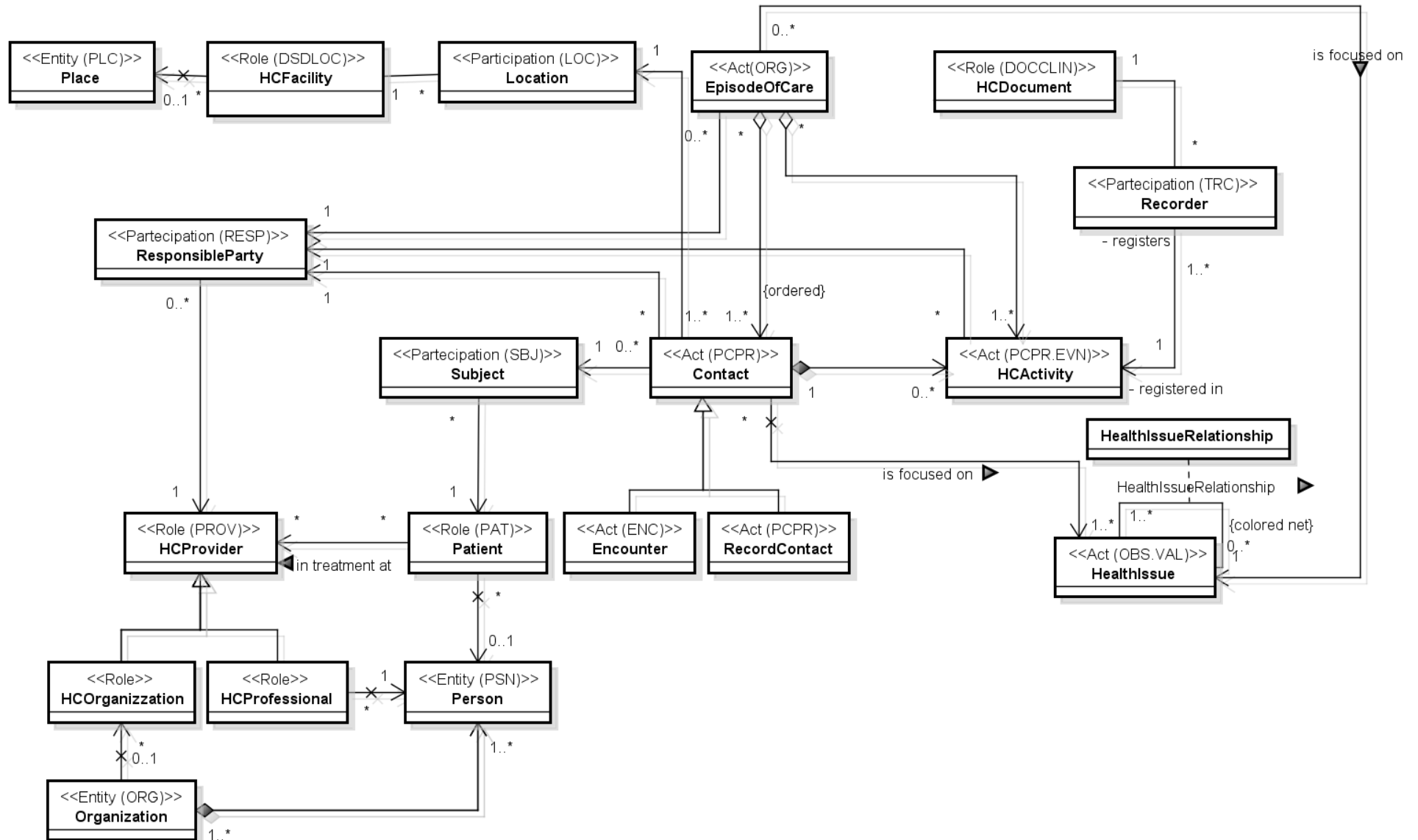




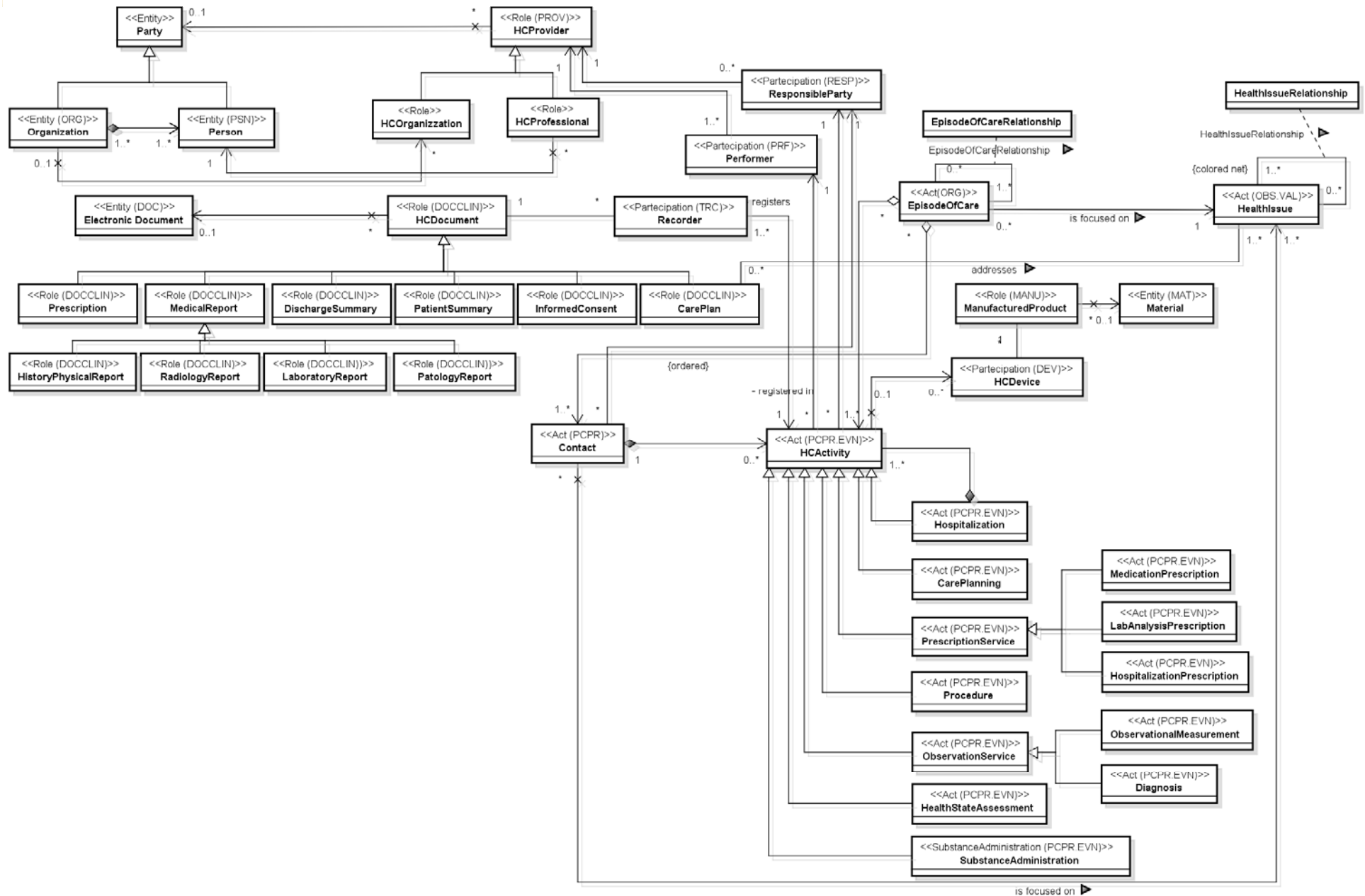
# **SMART EHR-S**

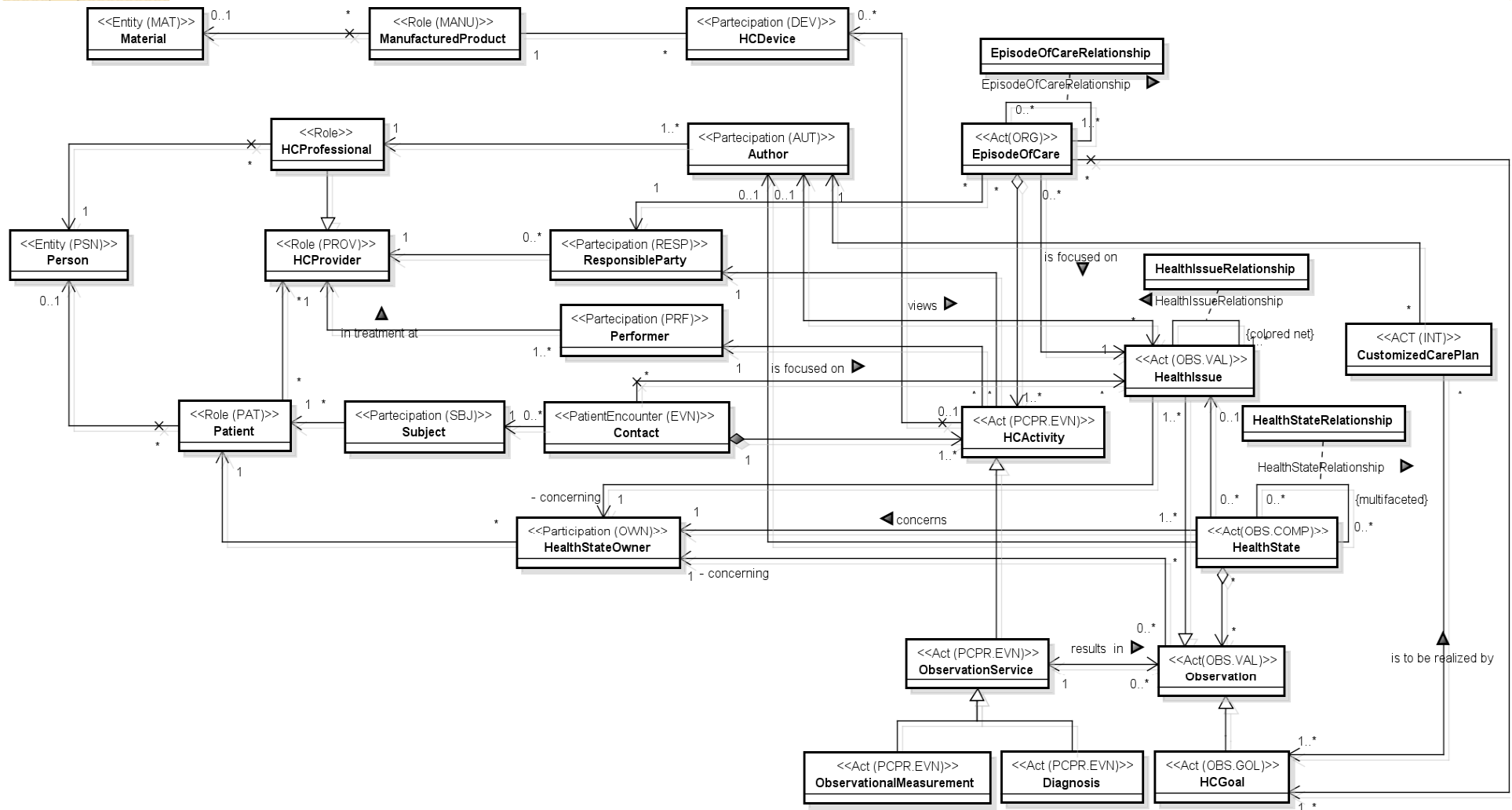
## **(The EHR-S of the Sicily Region)**





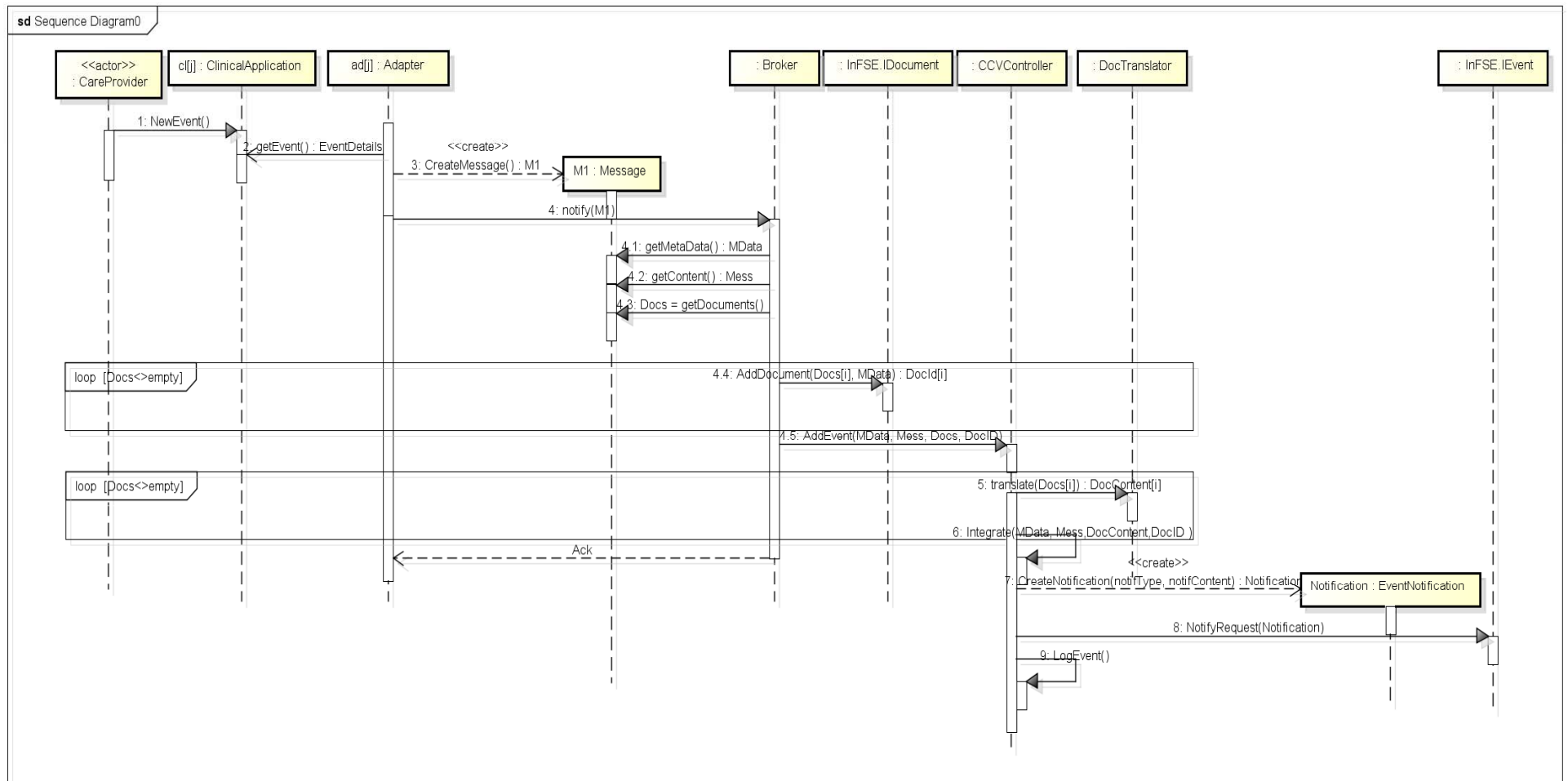




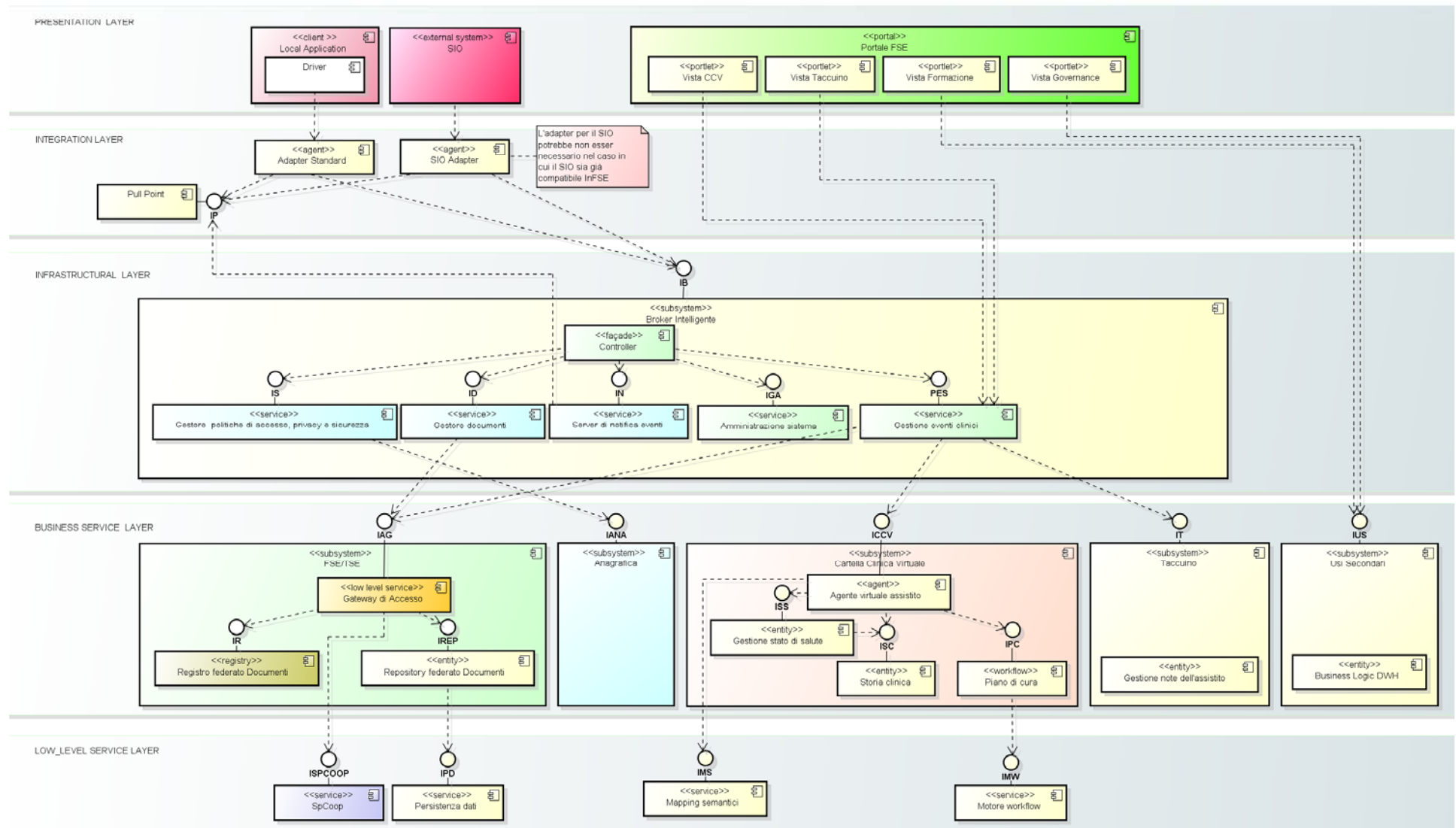


# Scenario: New Clinical Event

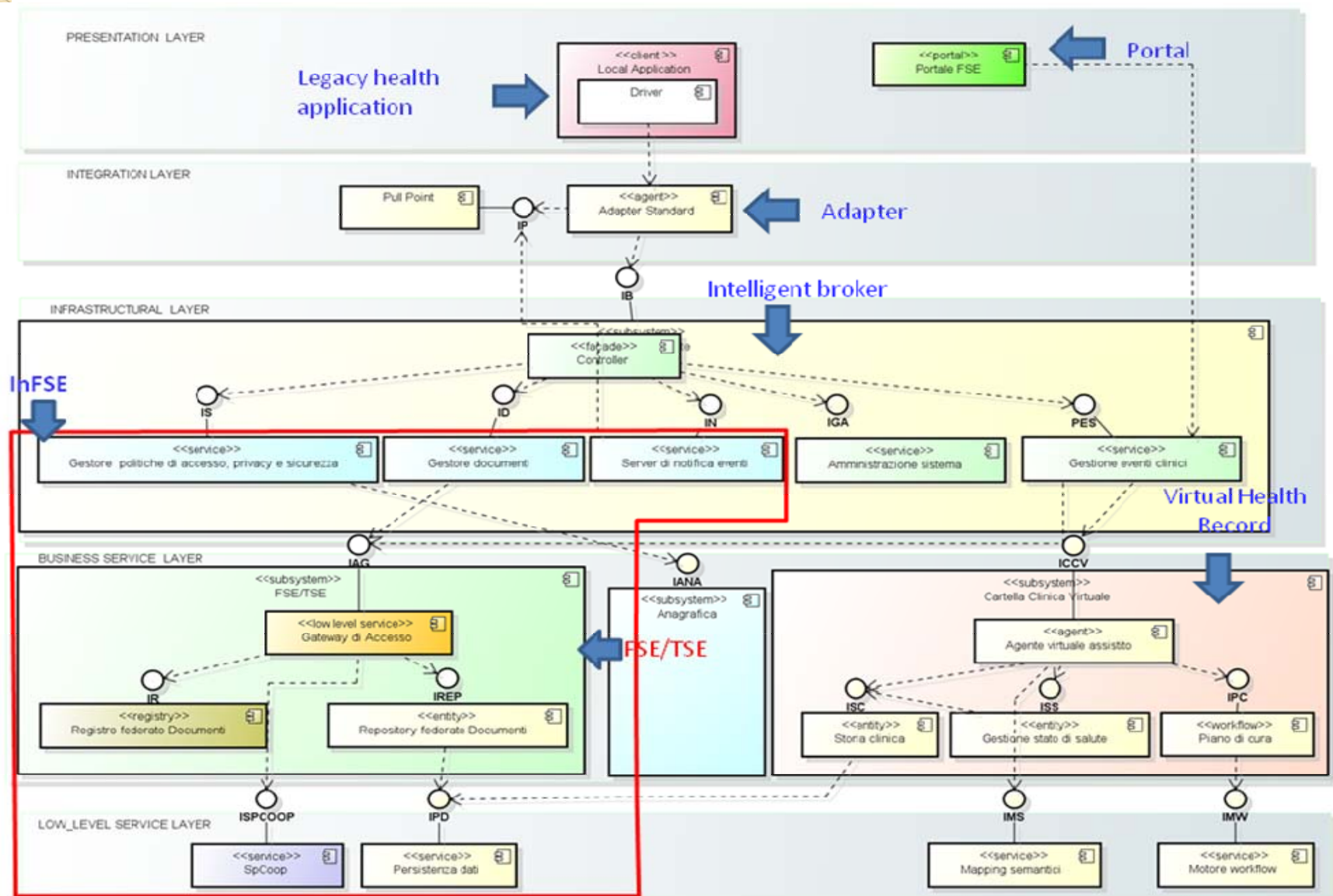
## Supplying EHR with documents and discrete data



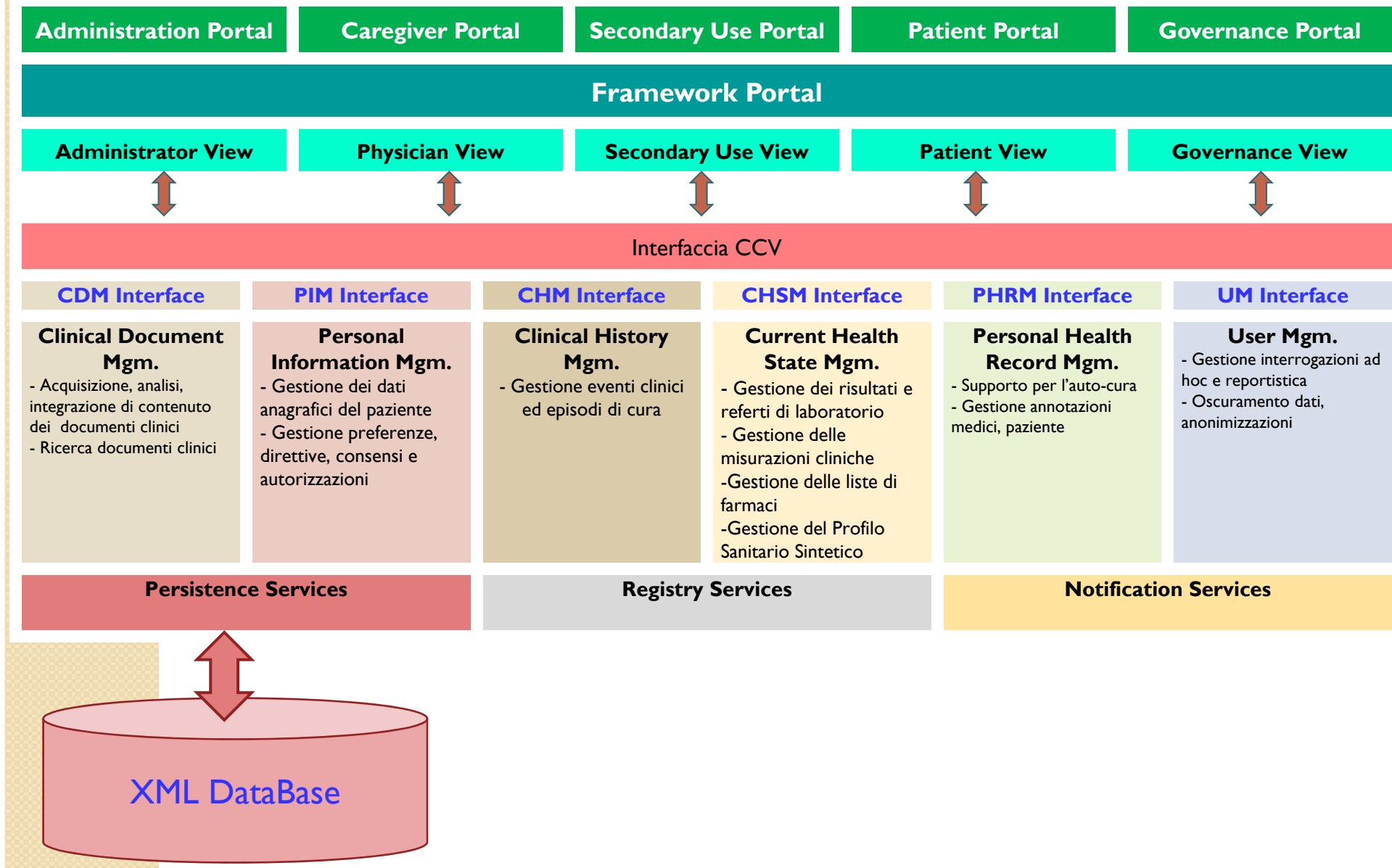
# Smart EHR Component Architecture



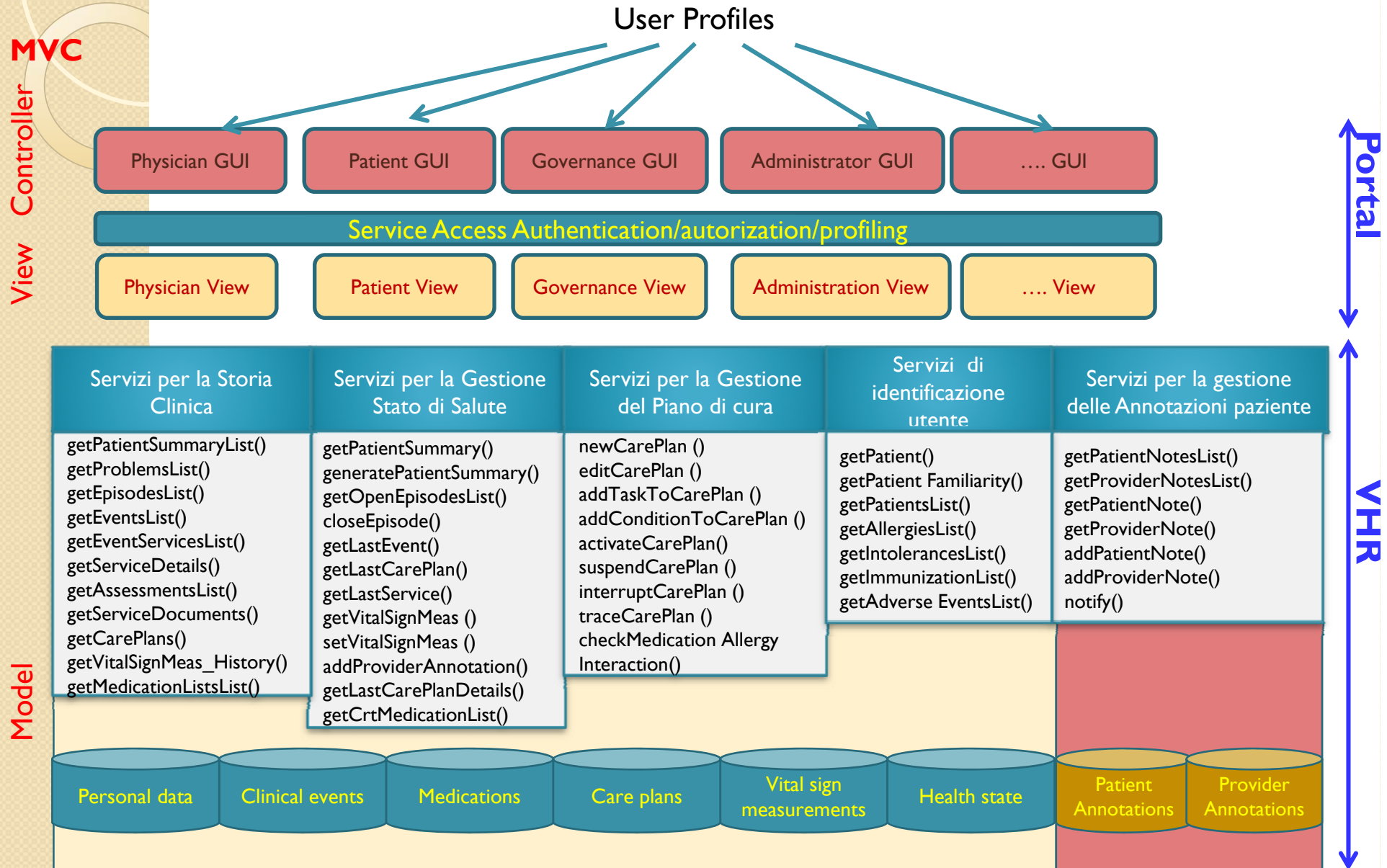
# Smart EHR Architecture with Reusing



# Smart EHR Layered Architecture

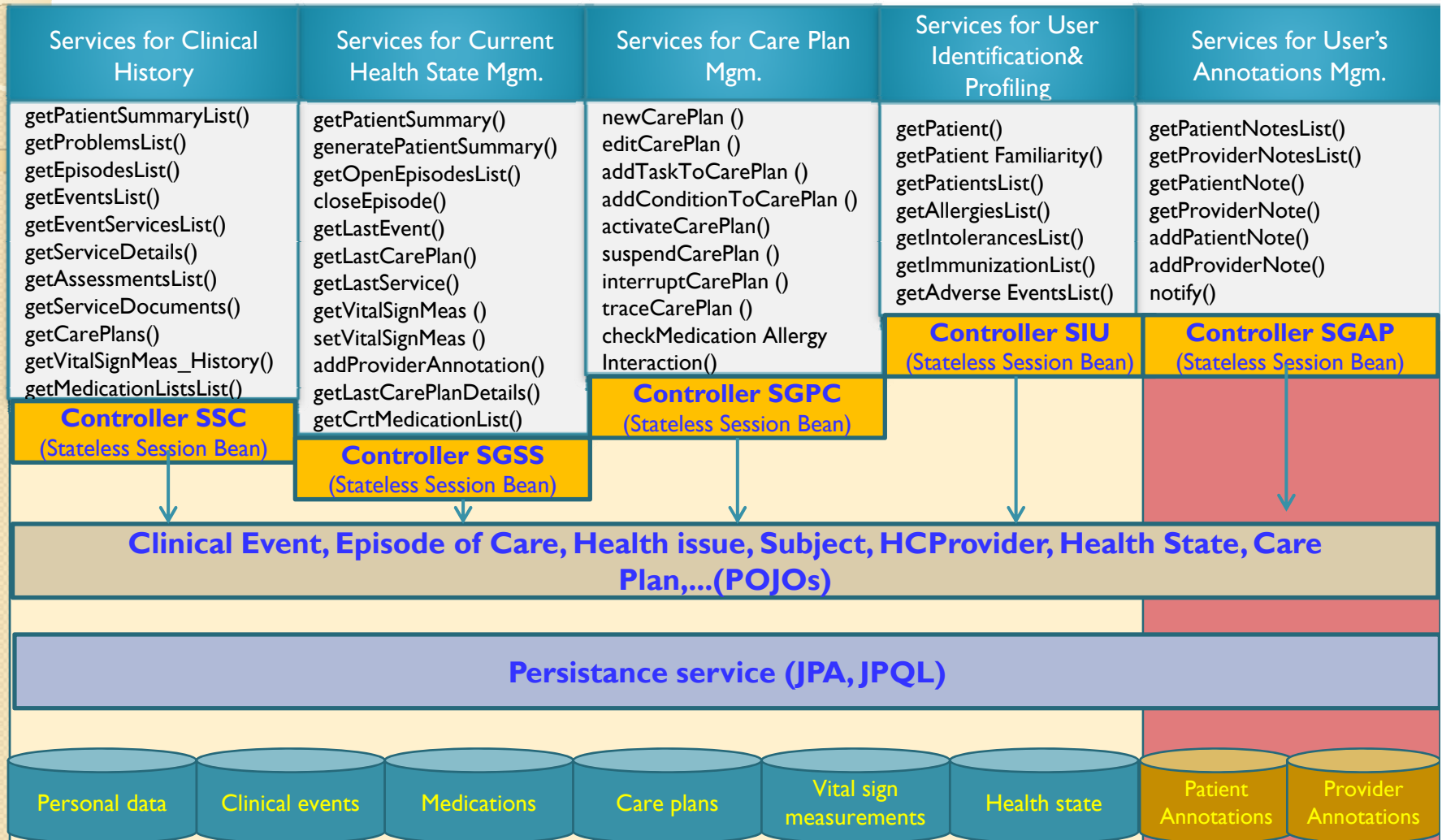


# VHR Service Architecture



# VHR: Service-Based Architecture

Data Service Domain Applic.  
layer layer layer





# Context Awareness

# Ambient Intelligence

- ICT is giving us the ability to present information anywhere and anytime. Despite this ability, there is often a large gap, in fact a *cognitive distance*, between physical spaces and virtual information (computing) spaces.
- **Ambient Intelligence** is about how this cognitive distance can be reduced, i.e. how to create an environment that is sensitive, adaptive and responsive to the presence of people, in order to create the desired atmosphere and functionality.
- This environment should be aware of human presence, needs, and personalities, and capable of intelligent interactions with humans.
- Ambient Intelligence is not only Intelligent User Interface, and Ubiquitous Communications and Computing, but also **Context Awareness**.
- A technological challenge for ambient Intelligence: Internet of Things with **smart objects**.

# The Context Definition

- Context in computing = a setting in which an event occurs.
- *“Context is any information that can be used to characterize the situation of any entity (person, place or object) that is considered relevant to the interaction between a user and an application, including the user and applications themselves.” \*)*
- *Our definition of Context in e-health.*

Context is a collection of information that represents the situation of an entity in its environment or setting. It is used by other entities (stakeholders and/or applications) to reshape their interpretation of the state or behavior of the entity.

\*) Dey, A.K., Abowd, G.D., Towards a Better Understanding of Context and Context-Awareness, <https://smartech.gatech.edu/bitstream/handle/1853/3389/99-22.pdf>, 1999.

# Context-awareness Evolution

Context Awareness  
in Virtual World



Avatar's context

Person's Context  
Awareness



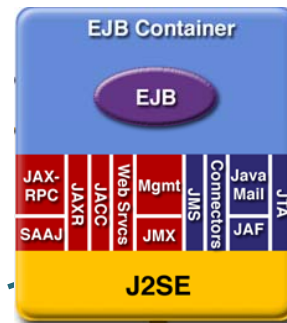
Person context

End User's  
Context  
Awareness



User's context

Application  
Context  
Awareness



Context of software  
components

Context Aware  
Mobility



Mobile Assets

End Use Contextual  
Information

Device context

Minimize Cognitive Distances between Real and Virtual!

# Strengthening the Context Concept

- When new domains, scenarios and applications are considered, other categories of information should be added to the Context concept semantics.
- Evolution of the context concept provides us with a ever richer semantics that requires increasingly complex models to support context-aware applications.
- Primary context (according to Dey and Abowd, 1999): location, identity, time, and activity.
- For healthcare applications we extend the context concept, with four **information dimensions** of the secondary context: **environmental**, **clinical**, **social**, and **BDI emotional**.
- An agent-based architecture to deal with this extended context is proposed .



## Multi-Agent System (MAS)

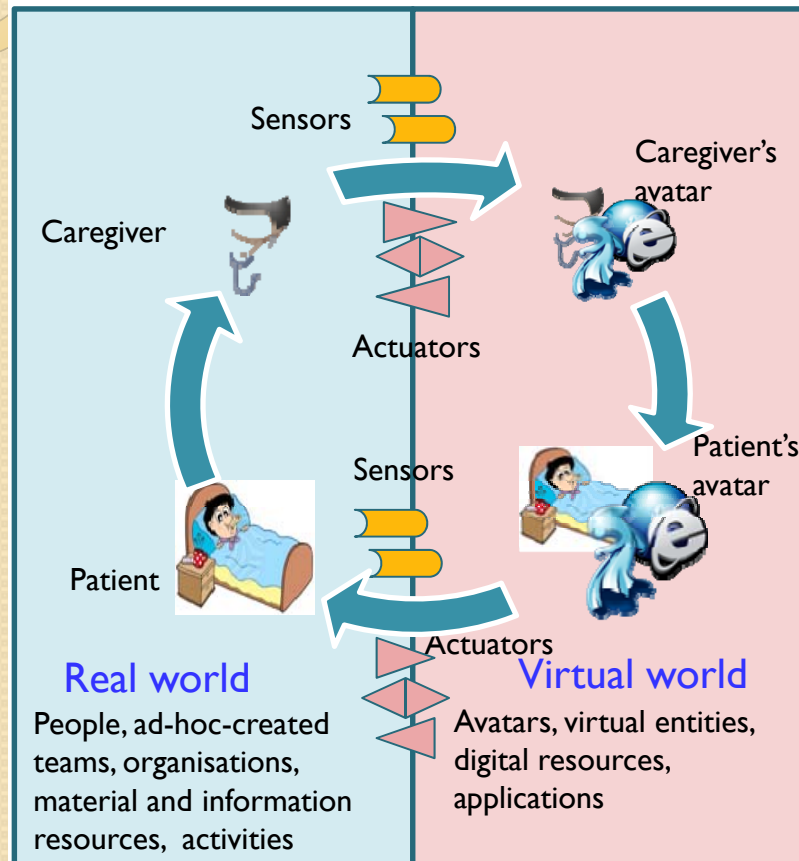
- The MAS paradigm could be used to model, design and implement software platforms that integrate software applications in healthcare systems.
- MASs are a more natural way to represent many situations that often occur in medical settings, such as:
  - absence of a comprehensive control system,
  - limited or insufficient resources for a care provider to solve a given problem, and
  - geographical distribution of the needed information and knowledge.
- On the other hand, in health systems we can identify many recurrent features common to MASs:
  - delegation of responsibility,
  - re-allocation of tasks,
  - need to consider a large variety of user concerns and problems,
  - planning the collaborative work ,
  - think and work in open spaces, etc.

# E-support for Healthcare Processes

Due to sensors and actuators, information flows from Real to Virtual and from Virtual to Real (**R2V2R**)

**E-health objective:**

People should seamlessly interact with technology in healthcare scenarios.



*Sub-objectives of the Virtual World:*

**R**  $\Rightarrow$  **V** -awareness of human presence, personalities and needs;

**V**  $\Rightarrow$  **R** -be able to intelligently interact with humans.

The virtual world consists in digital ecosystems populated by context-aware systems.

# Our approach to R2V2R paradigm

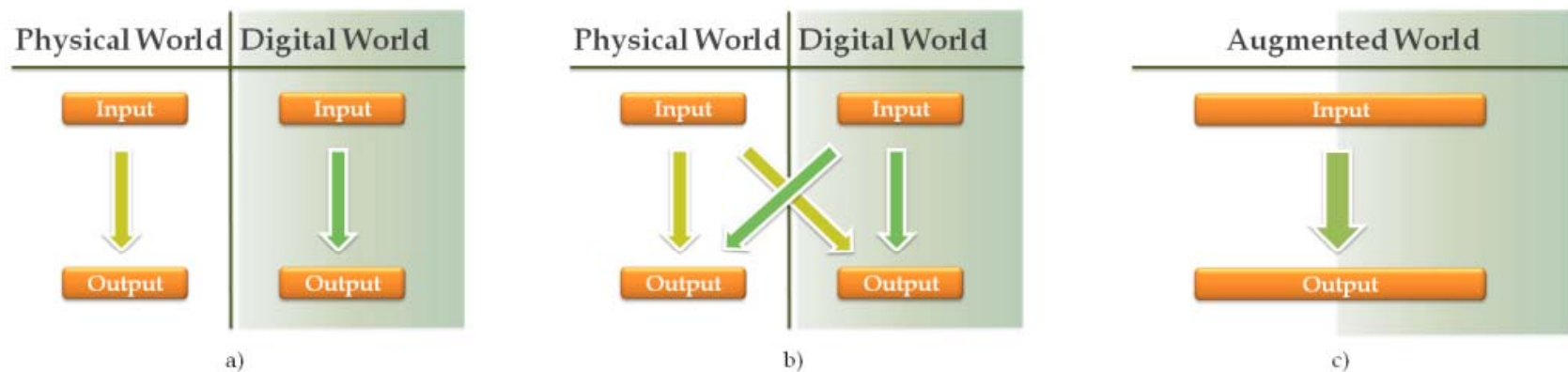
**R → V** awareness of human presence, personalities and needs.

- In a regional health information organization (RHIO) all stakeholders in the real world (care providers, health organizations, patients and their relatives) and other knowledge sources are represented as **virtual entities (VE)** in the virtual world. Each VE provides services that exhibit the most relevant properties and behaviour of its corresponding stakeholder.

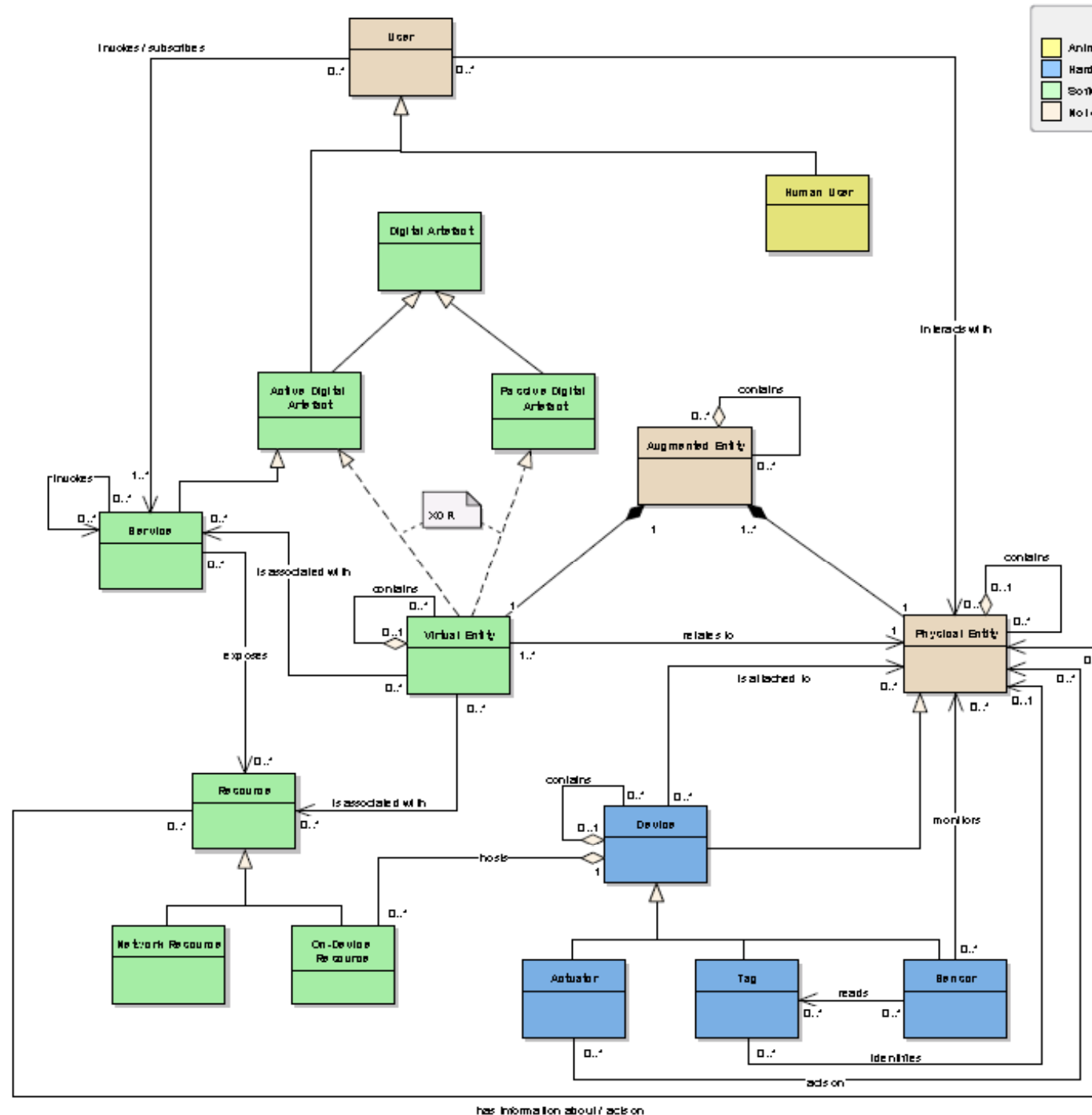
**V → R** be able to intelligently interact with humans.

- Caregivers and patients are represented as **avatars**, i.e. highly proactive, specialized VEs acting on behalf of its owner (the corresponding individual in the real world). An avatar may also act as an Assistant for its owner: it can propose her/him actions to do.

# Internet of Things (IoT)



Visual representation of the IoT paradigm: the evolution from the current context, where the digital and the physical environment are uncoupled (a), to one where they can interact (b) and, finally, to one where an augmented world seamlessly merges the physical and digital environments (c).



# The IoT Domain Model

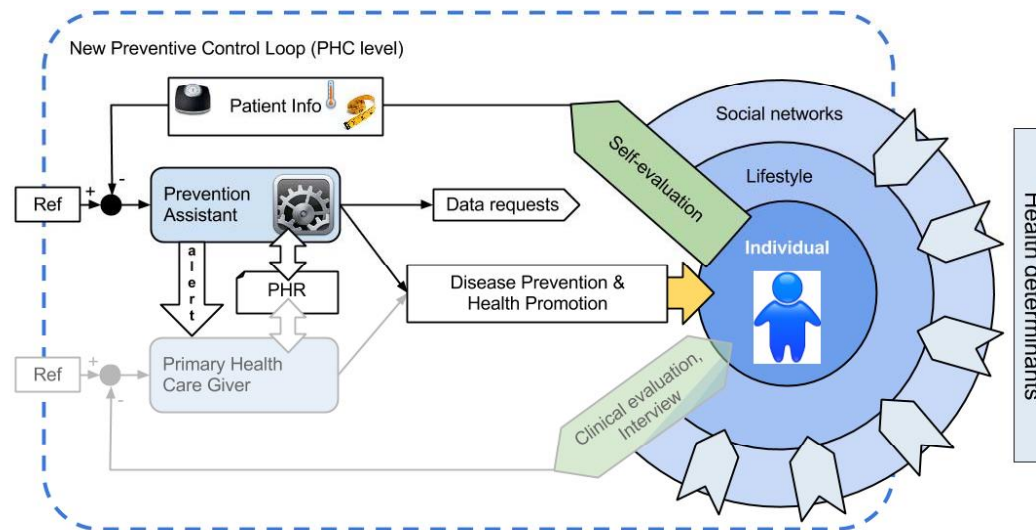


# Patient Empowerment

*Patient empowerment* represents a major trend in the healthcare worldwide militating for the patients to become conscious and responsible of their health and try to manage it in a more independent way.

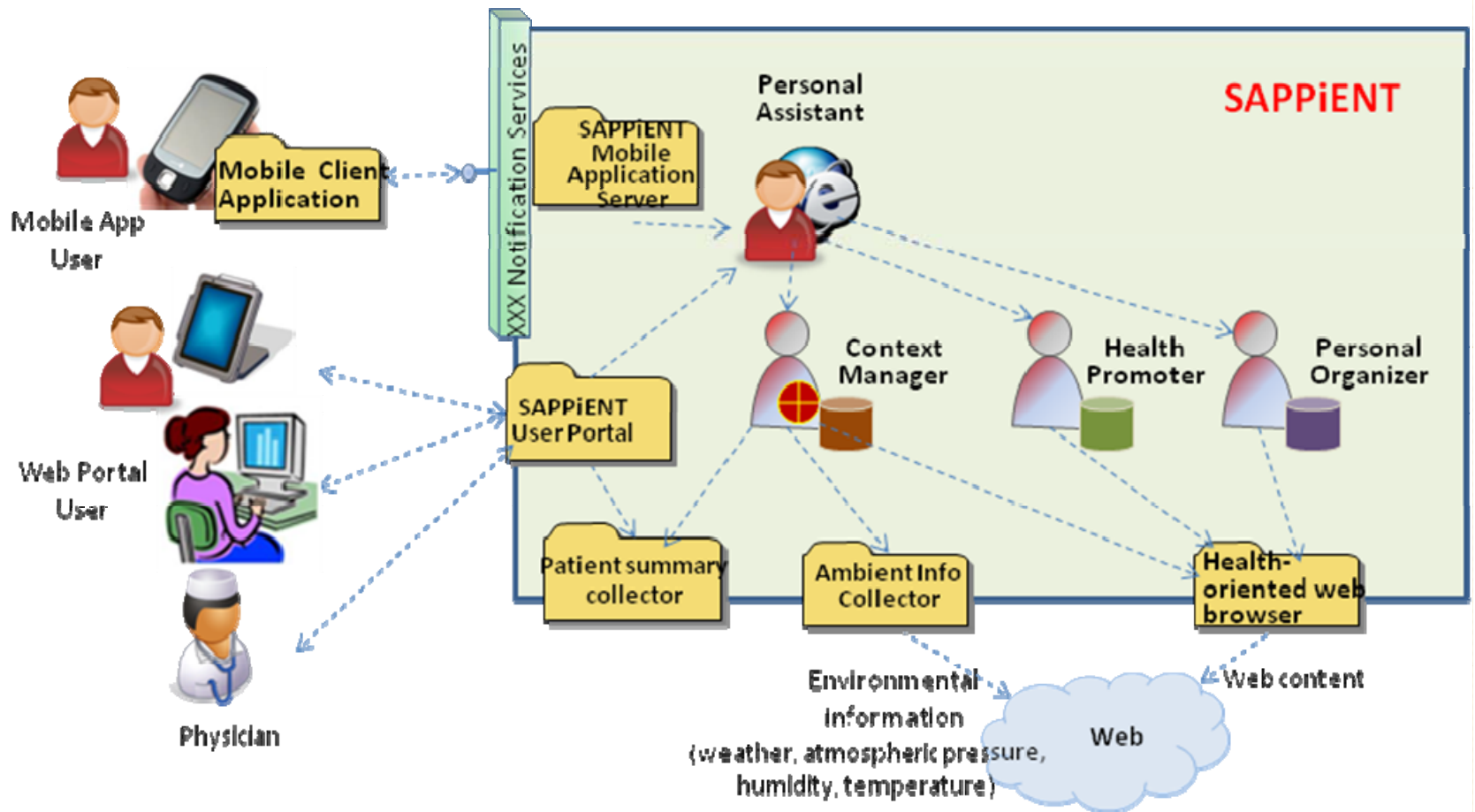
# Patient Empowerment: The SAPPiENT Project

- **The project goal:** To provide the citizen/patient with an IT product that enables her/him to extend the management of daily activities to include also health-oriented actions, with the aid of a Personal Assistant, a virtual expert in health and social assistance.



- The project's end-product is conceptually an extended personal health record (PHR), which integrates prevention oriented services. Basically, a *personal health record* (PHR) is a collection of health-related information that is documented and maintained by the individual it pertains to.
- The main idea of the envisioned improvement is closing an additional control loop around the patient.

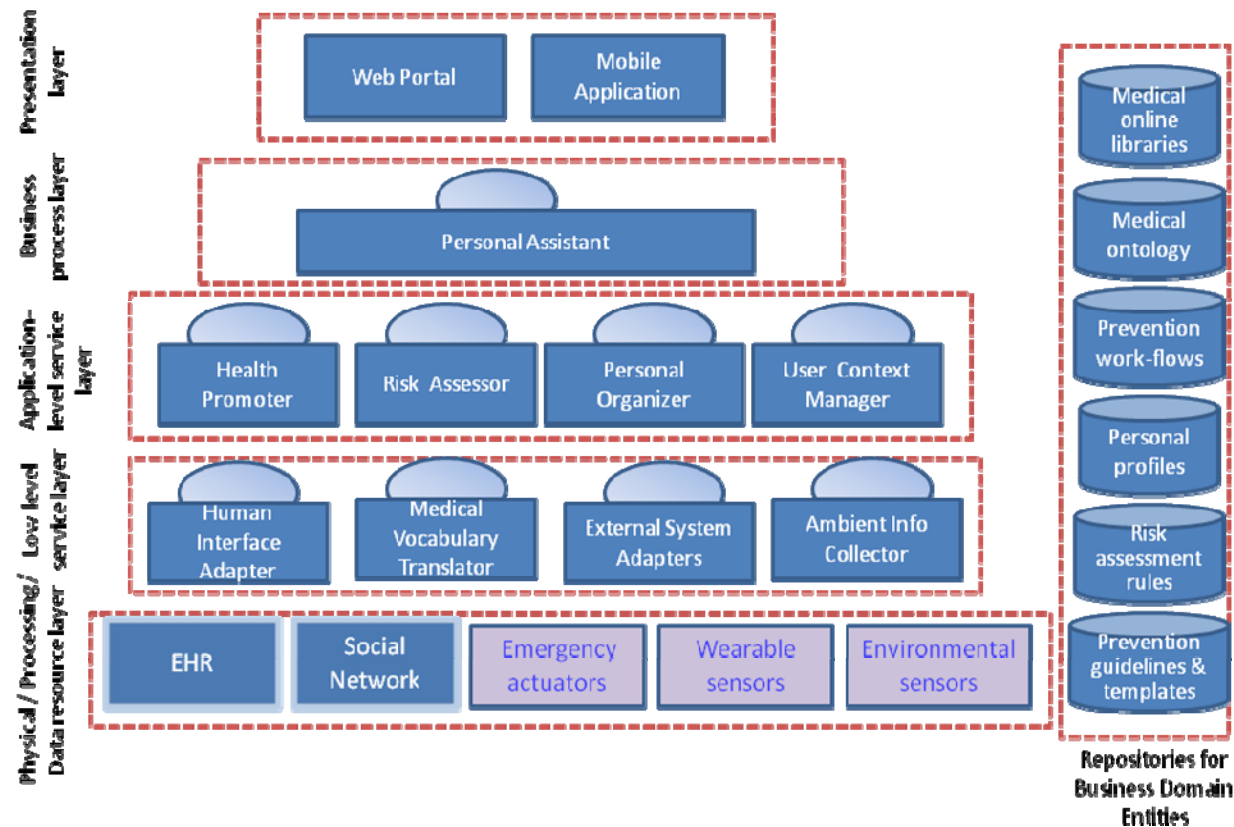
# SAPPiENT and Its Environment



# The SAPPiENT Architecture

To access the platform services two client application types are considered:

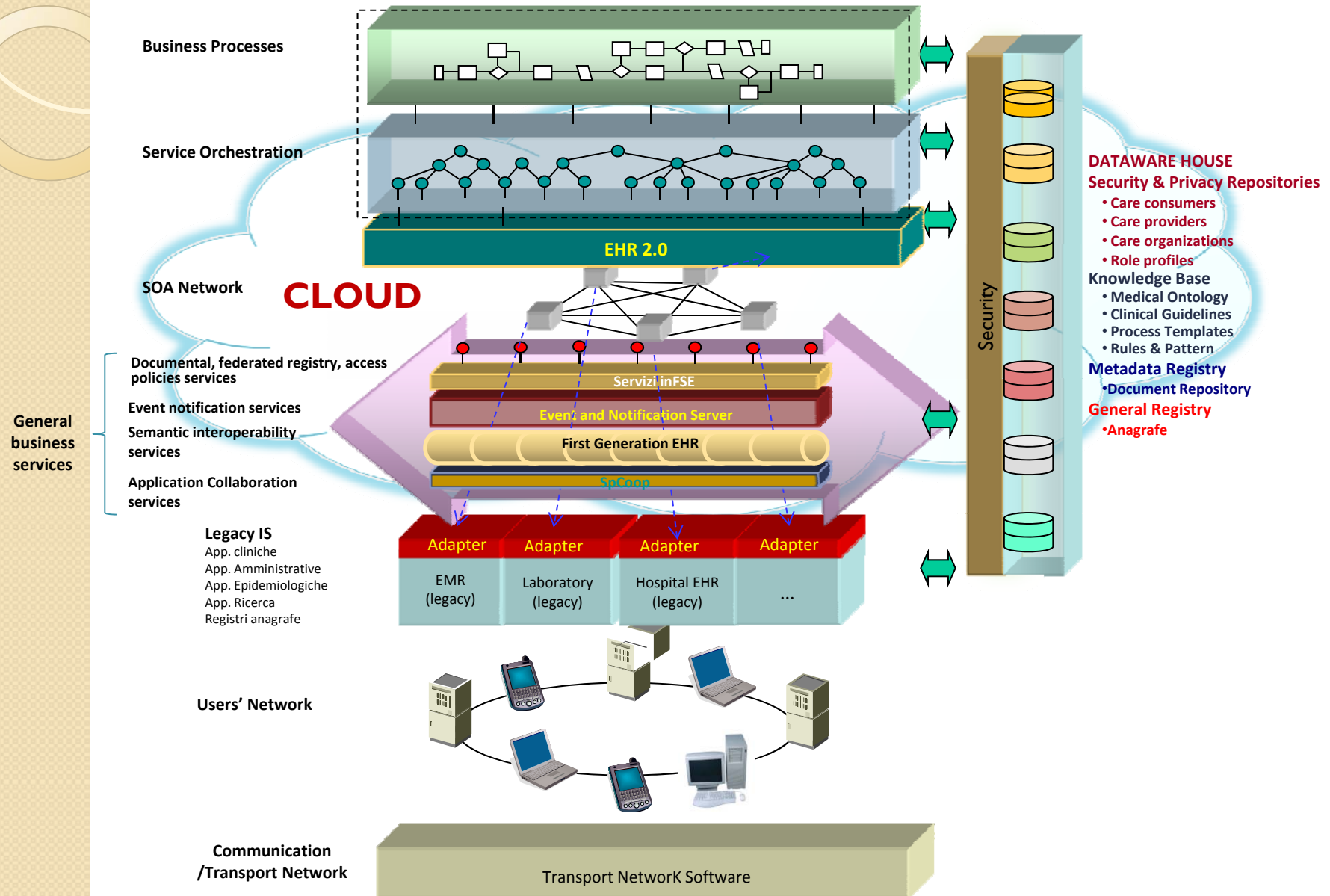
- *Browser-based client application.*
- *Mobile application.*



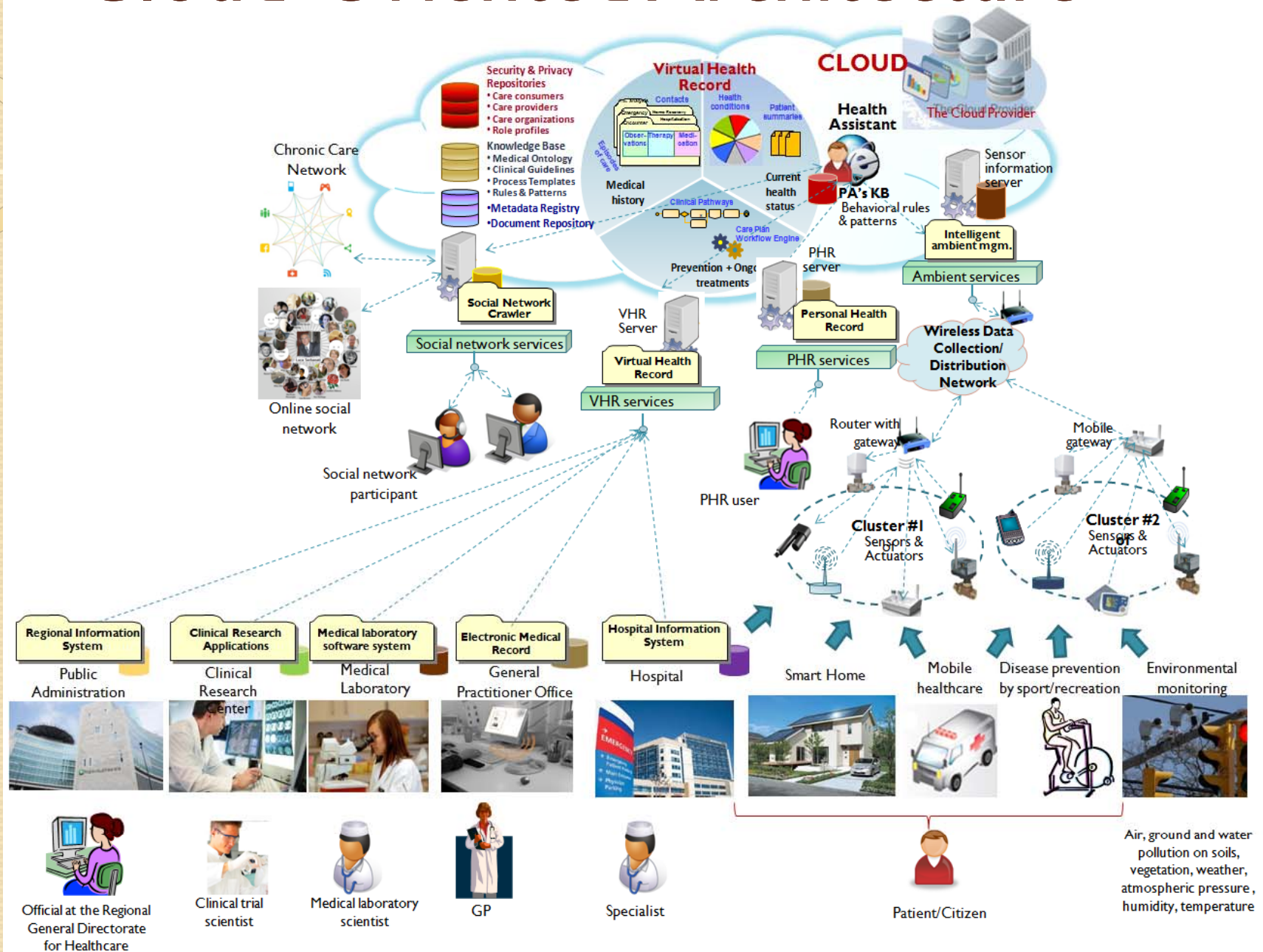


# Porting VHR in Cloud

# Porting EHR in Cloud



# Cloud-Oriented Architecture



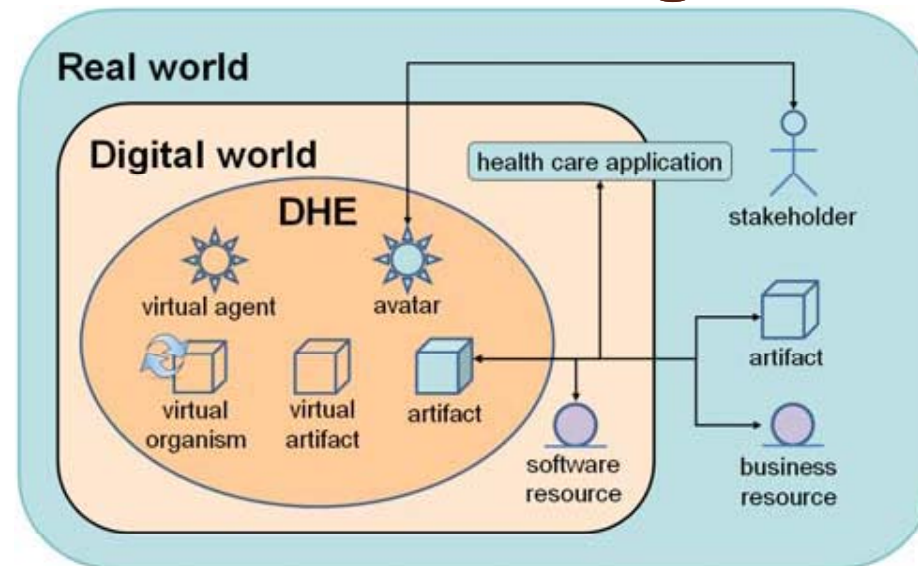


# Digital Health Ecosystem

# Ecosystem

- A *natural ecosystem* is a biological community of interacting organisms plus their physical environment.
- Correspondingly, a health ecosystem can be defined as a network consisting of a multitude of health service suppliers and consumers, and healthcare organizations, all of them supported by IT.
- *Digital ecosystems* are:
  - pervasive digital environments, populated by digital components, which evolves and adapts to local conditions with the evolution of the components.
  - dynamic and synergetic complex of Digital Communities consisting of interconnected, interrelated and interdependent Digital Species situated in a Digital Environment, that interact as a functional unit and are linked together through actions, information and transaction flows.
- *Digital business ecosystem* is a self-organising digital infrastructure aimed at creating a digital environment for networked organisations that supports the cooperation, the knowledge sharing, the development of open and adaptive technologies and evolutionary business models.
- *Digital health ecosystem* (DHE) is an IT infrastructure designed to work in synergy with the health ecosystem by mainly supporting health activities in the real world.

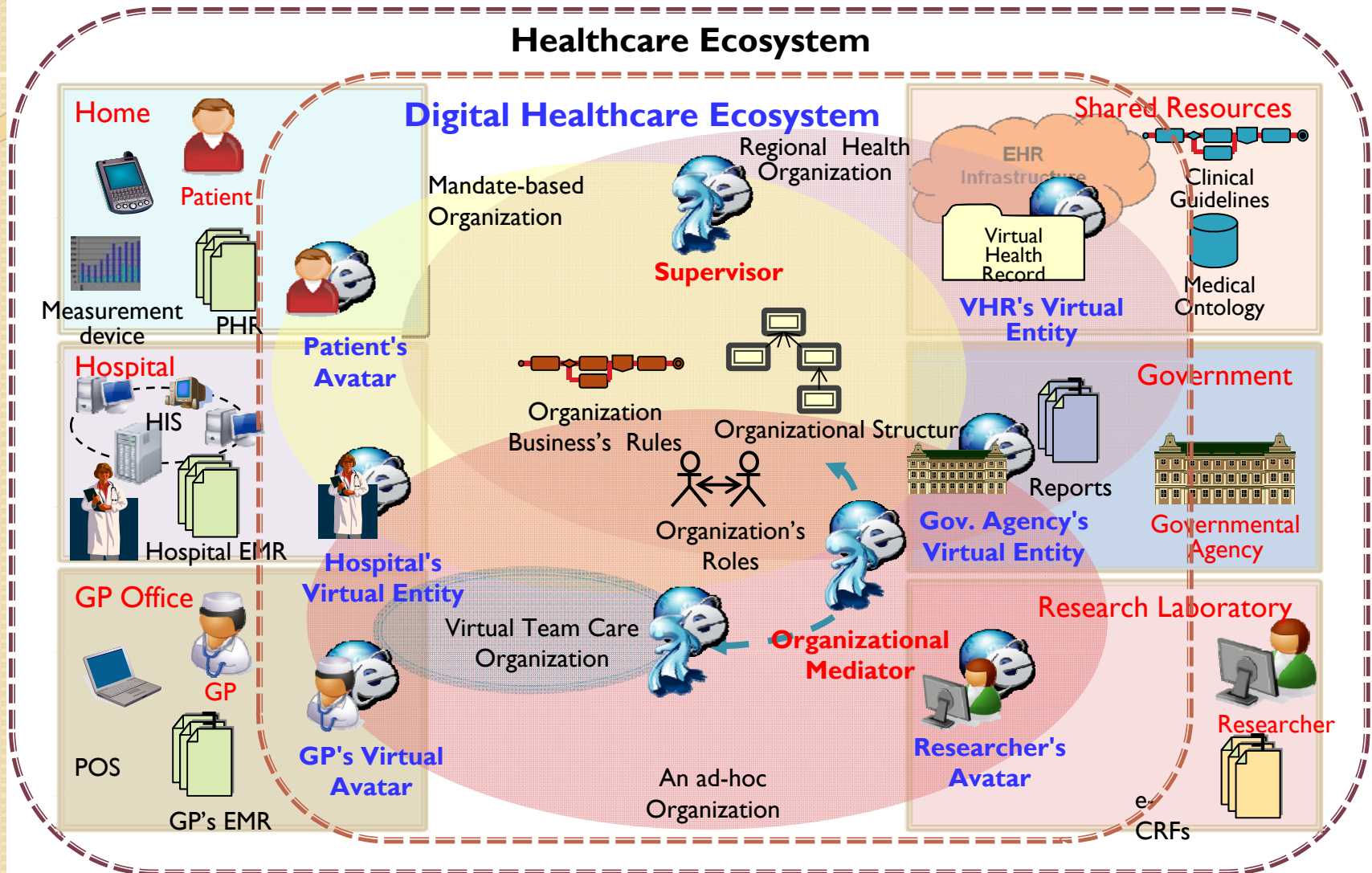
# Entities inhabiting the DHE \*)



- They are partitioned in two groups.:
  - entities that map a real entity into the virtual world
    - avatar - proactive agent working towards the goals of the stakeholder
  - purely virtual entities without any real counterpart:
    - passive virtual artifacts
    - proactive virtual agents, such as those that will perform monitoring and maintenance tasks in DHE.
- Avatar is a proactive agent working towards the goals of the stakeholder it represents, but also following additional objectives related to the virtual environment in which it lives.

\*) V. Rentea, F.L. Ricci, L.D. Serbanati, A. Vasilateanu, *Supporting Adaptability in Agent-Based Digital Healthcare Ecosystems*, COGNITIVE 2011, The Third IARIA Conf., Rome, Sept. 2011.

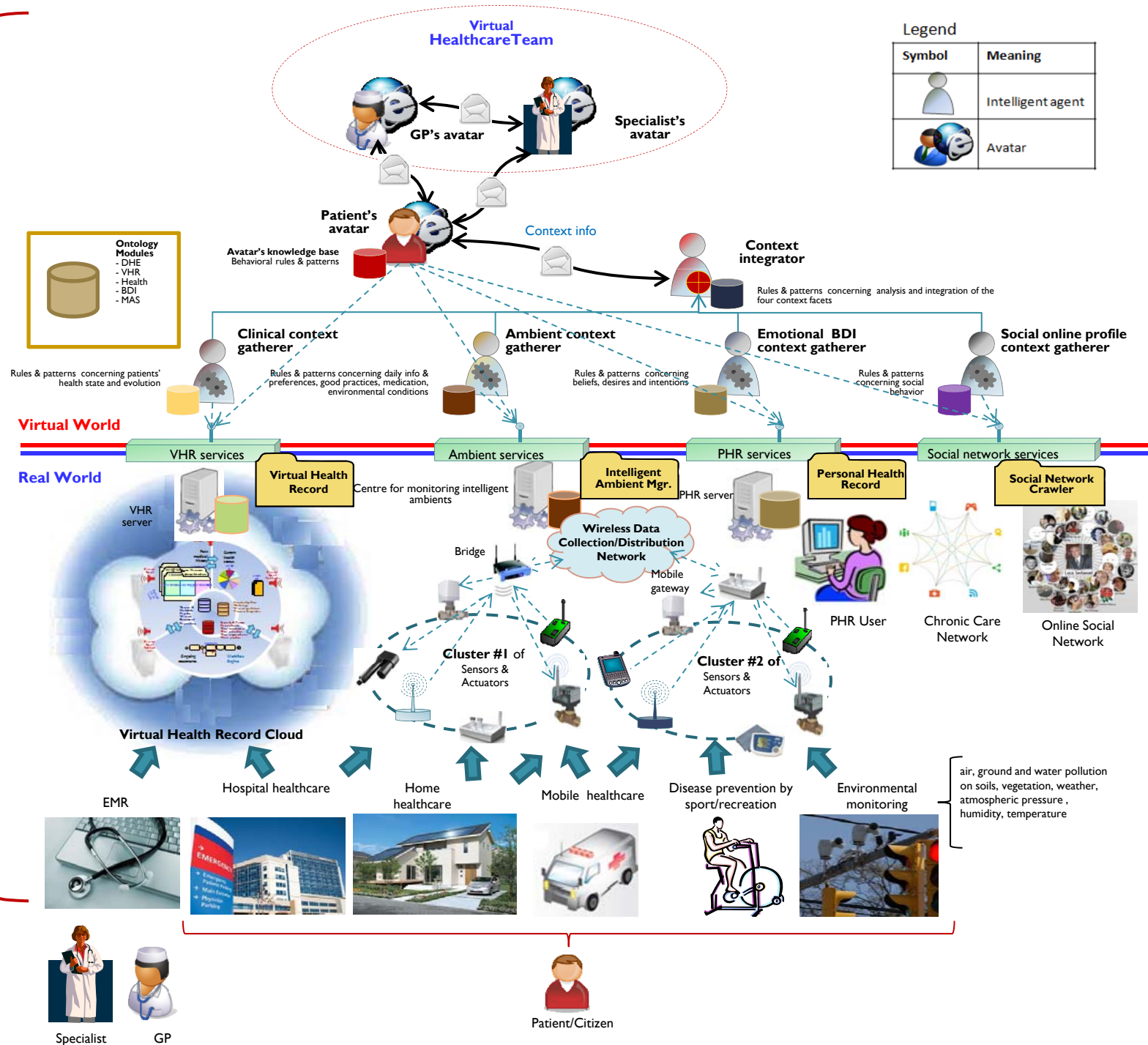
# The health ecosystem and its digital ecosystem<sup>\*)</sup>



<sup>\*)</sup> L.D.Serbanati, F.Ricci, G.Mercurio, A.Vasilateanu, Steps towards a digital health ecosystem, J Biomed Inform, Elsevier, 2011

# Smart Health Architecture

Digital Health Ecosystem





THANK YOU!