ReMINE

High performances prediction, detection and monitoring platform for patient safety risk management

FP7 Contract: 216134

– Deliverable –

D4.3 – RAPS Application ontology (Version 1)

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1 Executive Summary

In this deliverable we describe the background materials and methodology used to develop the RAPS Application Ontology, the latter itself being still work in progress in line with the developments in the course of the ReMINE project. At this stage, the work performed includes:

(1) a representational framework for describing faithfully what is the case in reality in the context of adverse events, consisting of adequate representational units for the relevant entities in reality, and a language for expressing how the entities in reality that are denoted by these units relate to each other;

(2) a classification method and system that allows descriptions of adverse events to be categorized under distinct views; and

(3) a terminology in which terms denote unambiguously (a) entities or relationships in reality, (b) representational units used in the framework, and (c) classes from the classification system.

The work presented here does not – for reasons explained in Deliverable D4.2 – follow the *concept-based* approach in ontology development, but, in contrast, a *realist* agenda which expands considerably the possibilities of the former. The realist agenda is based on the assumptions that (1) reality exists objectively in itself, i.e. independent of the perceptions or beliefs of cognitive beings; (2) reality, including its structure, is accessible to us, and can be discovered through (scientific) research; and (3) the quality of an ontology is at least determined by the accuracy with which its structure mimics the pre-existing structure of reality.

After a short introduction covering the ReMINE project and the role of ontology therein (chapter 2), we describe the methodology used for developing application ontologies in the context of protocol monitoring or guideline execution, and which consists of seven specific steps (chapter 3).

In chapter 4, we cover the principles to be adhered to (ideally) when linking application ontologies of the sort proposed to instance data. We pay specifically attention to the requirements imposed by the dynamic nature of health information technology in the context of adverse events and this in an era where Health IT itself has been found to be a source of adverse events itself [1]! We finish by describing briefly the procedures to be followed to implement a reliable system that satisfies the requirements in a healthcare institution.

We devoted chapter 5 to a motivation for and description of the use of Excel as a temporary ontology authoring environment, thereby highlighting the process of developing application ontologies on the basis of the RAPS taxonomy.

In chapter 6, we focus on a number of aspects of the sort of reasoning that can be offered by our work. A better characterisation will be provided in later versions of this deliverable once the concrete nature of the applications at the ReMINE pilot sites will be more clear.

We end with a short description of future work.

2 Introduction

‘High performances prediction, detection and monitoring platform for patient safety risk management (ReMINE)’ is a European Large Scale Integrating Project (IP) funded by the European Commission under contract 216134 [2]. The statement of work was approved 03 December 2007, and work started Jan 1, 2008. The two main objectives of the ReMINE project are:

(1) to develop a new technological platform that is able to perform semi-automated RAPS (Risks Against Patient Safety) management, and

(2) to propose organisational changes with considerable added value in relevant environments.

The first objective is being achieved by developing the ReMINE system, a RAPS identification and analysis system for the acquisition and mining of relevant multimedia data present in hospitals. This system will then be used to predict, detect and monitor RAPS related events in the collaborating facilities.

Tasks to achieve the second objective include developing adequate clinical risk management processes, establishing a more active role for RAPS managers, and identifying new ways for interactions amongst different health care professionals in a local health care system to solve RASP issues.

An essential component of the ReMINE system is an ontology with associated taxonomy and terminology that will support several functionalities offered by the envisioned technological platform. Table 1 summarises the initial desiderata for this ontology.

Three ReMINE deliverables cover these components. D4.1 describes the domain of adverse events from a cognitive perspective, as perceived by clinicians, adverse event and risk managers, and so forth, i.e. human beings. This description uses the machinery of DOLCE which has been specifically developed – as witnessed by its own title: Descriptive Ontology for Linguistic and Cognitive Engineering – to be able to deal with cognitive issues. The result of the effort described in D4.1 is a taxonomy which provides the "model of use" with which clinicians are familiar.

D4.2 and D4.3 do not look exclusively at the adverse event domain from a cognitive human perspective, but from a perspective that can be understood by machines, including how the domain is cognitively perceived by humans. Indeed, ontologies developed for machine-understanding need to take into account several additional levels of detail that humans can deal with implicitly, but machines can not. The use of Basic Formal Ontology for the work described in these deliverables, in contrast to DOLCE, makes it possible to have a smooth integration with the cognitive perspective by the recognition of three levels of reality in BFO of which the cognitive realm is only one.

Further in line with the state of the art, we make a distinction between a *domain ontology* and an *application ontology*. Whereas the former is intended to be a purpose-independent representation of the portion of reality covered by a domain, the latter is a derivation of the former in light of a specific application.

This deliverable covers the RAPS Application Ontologies, whereas deliverable D4.2 describes the RAPS Domain Ontology.

Table 1. ReMINE desiderata for an ontology for managing risks against patient safety.

A. Domain coverage	A1: adverse events; A2: medical errors; A3: information needs and information seeking behaviour; A4: communication errors.
B. Ontology language requirements	B1: interpretable by software agents responsible for adverse event detection, risk classification, guideline execution and the identification of correlation between data and a DSS engine to allow users to perform simulations and "What if" scenario analysis; B2: usable within the Federated Enterprise Reference Architecture (FERA) framework [3]; B3: OWL compatible.
C. Interoperability requirements	C1: hospital information systems; C2: relevant guidelines; C3: CDC's Public Health Conceptual Data Model [4]; C4: patient safety taxonomies developed by WHO [5-7], DATIX [8] and NRLS [9]

3 Development methodology for application ontologies in the context of guideline execution or protocol monitoring

3.1 Fundamentals

Our approach is based on the ontology development strategy put forward by the OBO-Foundry, an endeavour that has been quite successful in biomedicine [10, 11].

The principles of the Foundry can be summarized, in their current version, as follows [12]:

- First, are syntactic principles to the effect that an ontology must employ one or another common shared syntax, possess a unique identifier space, and have procedures for identifying distinct successive versions.
- Second, are principles involving definitions:
    - textual definitions (and, by degrees, equivalent formal definitions) are to be provided for all terms;
    - terms and definitions must be composed using *the methodology of cross-products* which is the view that where ontologies need to include complex representations these should be built up compositionally out of component representations already defined within other, more basic feeder ontologies if available.
    - ontologies must use relations that are unambiguously defined according to the pattern set forth in the OBO Relation Ontology (RO) [13].
- Third, ontologies are required to be open, have a clearly specified and clearly delineated content, have a plurality of independent users, and be subject to a collaborative development process involving the developers of other ontologies covering neighbouring domains.
- Finally, the *principle of orthogonality* asserts that for each domain there should be convergence upon a single.

The fourth principle, to be practical, requires to make a clean distinction between *reference ontologies* [14] and *application ontologies*.

Reference ontologies are analogous, although in different ways, to both scientific theories and textbooks. Each has its own subject-matter, which consists of the entities in reality addressed by the corresponding domain of science (hence the quasi-synonym *domain ontologies*). Each seeks to maximize descriptive adequacy to this subject-matter by being built out of representations which are correct when viewed in light of our best current scientific understanding and should exhibit the following features [12]:

(1) be a common resource that cannot be bought or sold,

(2) represents a well-demarcated scientific domain;

(3) is subject to constant maintenance by domain experts

(4) is designed to be used in tandem with other, complementary ontologies, and

(5) is independent of format and implementation.

Application ontologies, in contrast, are comparable to engineering artifacts. They are constructed for specific practical purposes such as RAPS management.

Sadly, however, the predominating view, primarily in circles of computer scientists and knowledge engineers, is that ***all*** ontologies are engineering and computer science artifacts which are nothing more than 'just another application' of the developers' computational expertise, and thus as something that is of lesser scientific importance than core computer science issues for example in logic or in systems for ontology mapping [15]. The result has been that many ontologies and the terminologies that can be seen as their predecessors are full of mistakes [16-19] which are not eliminated – although often so argued – through the use of description logics or similar computational devices [20]. As further pointed out in [15], this '*self-limiting approach*' of the computer science approach of ontology design will in the end '*not be able to exploit the full potential of the ontology idea*', and the authors accordingly insist that the ontologies developed for scientific purposes need to be taken much more seriously as first-class citizens by computer scientists and knowledge engineers.

3.2 Steps in realism-based application ontology development

Developing an ontology for guideline execution or protocol monitoring requires to make an analysis of the sort of entities in reality that are referred to in statements describing the protocol or guideline. It does not matter whether these statements are expressed in natural language or in a formal language such as ASBRU [21], the plan specification language used in the ReMINE project.

To accomplish this we must complete, for each *type* of assertion in these statements, the following tasks:

- identify the terms in the assertion that denote portions of reality [22],
- determine the nature of these portions of reality, and more specifically:
    - the level of reality to which they belong [23],
    - whether they are specific or generic entities,
- further subdivide the entities into particulars (including classes), universals, or configurations as defined in any of the BFO-compatible ontologies [11],
- identify the universals of which the particulars are instances, and the classes of which they are members,
- expand the representation, i.e. determine whether other portions of reality that are not explicitly denoted in the statements must be taken into account and if that is the case, apply the previous steps to them as well [24],
- identify the relations which are stated to hold between the particulars in line with the Relation Ontology [13] and other relations used in BFO-compatible ontologies,
- assess whether particulars undergo relevant changes within the timeframe delineated by the protocol or guideline [25].

These steps are based upon

- the distinctions amongst entities as described in Basic Formal Ontology [26],
- the advantages offered by the specific way to keep track of these entities as proposed in Referent Tracking [27], and
- on the needs which the guideline execution or protocol monitoring must serve in the ReMINE system.

To do so, we must further identify whether terms used in the statements denote under all possible scenarios _one_ or _more than one_ particular of a given sort.

In this chapter, we describe the general methodology for developing this kind of application ontologies using as example the following statement from a guideline:

> *The First Aid Doctor (FAD) evaluates vital parameters and possible alterations, acquires possible personal health documentation and asks for diagnostic services*.

3.3 Identification of terms

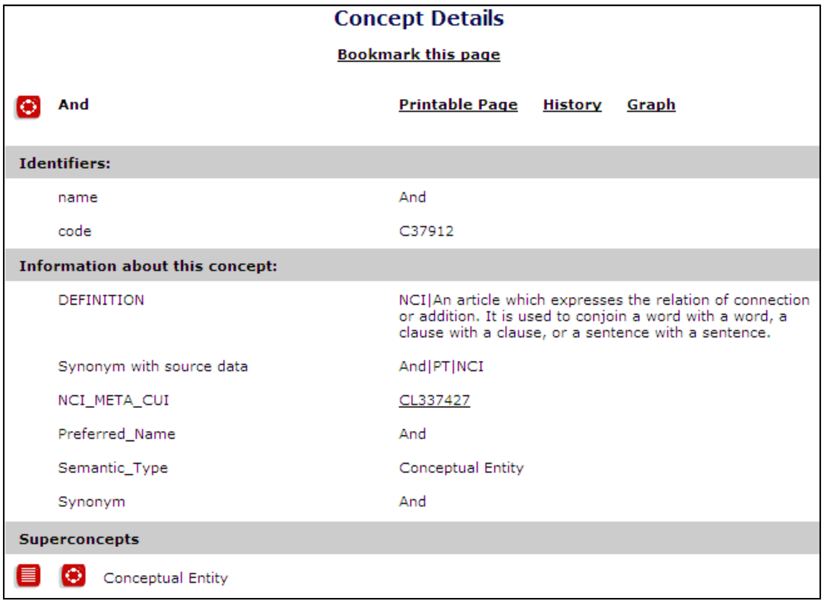
Terms that are trivial (at first glance) to identify are:

First Aid Doctor
FAD
evaluates
vital parameters
alterations
acquires
personal health documentation
asks
diagnostic services

However, at this level, various mistakes can be made.

The first one is to pick out words or word combinations that do not denote anything at all, but are mere function words required by the grammar of the language in which the statements are expressed. An example is the word '*and'*, whether or not selected alone as what would be an tenth term in the list above, or keeping it part of what erroneously would be considered to be a larger term, such as '*vital parameters and possible alterations',* what would reduce the list above to only eight terms.

As shown in Figure 1, a mistake of this sort is, for instance, committed in the NCI Thesaurus which is claimed to be a '*semantic model integrating cancer-related clinical and molecular information*' [28], but contains a large amount of terminological and ontological mistakes [16, 29].



Concept Details

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Identifiers:	
name	And
code	C37912
Information about this concept:	
DEFINITION	NCI|An article which expresses the relation of connection or addition. It is used to conjoin a word with a word, a clause with a clause, or a sentence with a sentence.
Synonym with source data	And|PT|NCI
NCI_META_CUI	CL337427
Preferred_Name	And
Semantic_Type	Conceptual Entity
Synonym	And
Superconcepts	
Conceptual Entity	

Figure 1: Entry 'and' from the NCI thesaurus, retrieved from http://nciterms.nci.nih.gov/NCIBrowser/ Dec 6th, 2008.

A second pitfall to avoid is selecting phrases that are not terms but rather *statements in disguise*. Examples here are '*possible alterations'* and '*possible personal health documentation*'. Clearly, there are no such things in reality as possible alterations or possible personal health documentations, in the sense that there would be some entity in front of a number of clinicians that one would be able to point to and say: 'look, there is a possible alteration'. What is meant here is *that it is possible that alterations are present*, and *that the patient might (not) have personal health documentation*. Of course, one should not ignore that the word 'possible' is used in a statement of a given sort: its use expresses that various configurations may be encountered in which the entities denoted by the terms stand in different relations to each other.

3.4 Delineate relevant portions of reality

In contrast to traditional terminology approaches, the *realist* orientation in ontology is based on the view that terms in ontologies are to be aligned not on concepts but rather on entities in reality [30]. Central to this view are three assumptions [23].

The first is that reality exists objectively in itself, i.e. independent of the perceptions or beliefs of cognitive beings. Thus not only do a wide variety of entities exist in reality (human beings, diseases, treatments...), but also how these entities relate to each other (that human beings are citizens of countries, that diseases are in human beings, that human beings can be cured from diseases through treatment, and so forth) is not a matter of agreements made by scientists or database modellers but rather of objective fact.

The second assumption is that reality, including its structure, is accessible to us and can be discovered: it is scientific research that allows human beings to find out what entities exist and what relationships obtain between them.

The third assumption is that an important aspect of the quality of an ontology is determined by the degree to which the structure according to which the terms are organized mimics the pre-existing structure of reality.

In the context of information systems, including the sort of RAPS management system that is built in the ReMINE project, it means that an important aspect of the quality of an information system is determined by the degree to which (1) its individual representational units correspond to entities in reality, and (2) the structure according to which these units are organized mimics the corresponding structure of reality.

3.4.1. Levels of reality

The above assumptions form the basis for distinguishing between three levels of reality which have a role to play wherever ontologies are used as artifacts for annotation and tagging, and wherever automated or semi-automated reasoning is required to be able to deal with an overload of information, parts of which can be expected to be wrong.

The three levels are [23]:

(1) Level 1: the (first-order) reality 'in the field': the patients that are diseased and the doctors that treat them, the events that are monitored, the users of the information system, and so forth;

(2) Level 2: the beliefs and cognitive representations of this reality embodied in observations and interpretations on the part of observers, data collectors, analysts and others;

(3) Level 3: the publicly accessible concretizations of such cognitive representations in representational artifacts of various sorts such as statements (whether spoken or written), pictures, health records, and so forth.

A second important distinction to be made at this point is that in each level of reality, there are entities which are *generic* as opposed to those which are *specific*. Specific entities are those which carry identity such as the ReMINE project, each of the persons that participate in it, and so forth.

Generic entities can be characterised as being the types to which specific entities belong to. Thus ReMINE is a type of project, its participants are specific entities some of which are of the type organisation while others are of the type human being. Both the notions of specific entity and generic entity will be elaborated on further down in order to arrive at a more detailed description of what exist in reality.

3.4.2. Application to the example

In this step, we have to identify for each of the terms that resulted from step (1) (see section 3.3) what is (or might be) referred to by them. Note that to most terms both a specific and generic interpretation can be given depending on the context in which they are used. Within the description of a protocol, generic terms tend to prevail: so even if it is stated that '*The First Aid Doctor (FAD) evaluates …*', not a specific doctor is meant, rather any doctor which can be qualified as a first aid doctor. When monitoring activities for their adherence to a protocol, most terms need to be interpreted as denoting specific entities: at that time it should be assessed whether the specific doctor who is or intends to evaluate the patient, is indeed a first aid doctor.

Table 2 lists the entities denoted by the terms identified in the example sentence. We assigned for further reference (for the purposes of this document only) to these entities a local identifier composed of a number preceded by a marker suggesting the type of entity involved. These markers are:

(1) 'S' for specific entity

(2) 'G' for generic entity

We also indicate by 'L1', 'L2' or 'L3' what level of reality is involved. Some terms might involve more than one level of reality. Note that the descriptions provided in Table 2 are ***not*** definitions.

Table 2: plausible denotations for the terms identified in step (1) of the application ontology development methodology.

Term		Specific interpretation		Generic interpretation	
First Aid Doctor	L1	**S-1**	a specific medical doctor providing first aid services in the Ospedale Niguarda Cà Granda	**G-2**	any medical doctor providing first aid services in the Ospedale Niguarda Cà Granda
FAD	L1		same as above		same as above
evaluates	L1	**S-3**	a patient evaluation carried out by **S-1**	**G-4**	the evaluation procedures carried out by a medical doctor in the Ospedale Niguarda Cà Granda when realization his role as first aid doctor
vital parameters	L1	**S-5**	a collection of the vital signs of that specific patient	**G-6**	the vital signs of a person
alterations	L1	**S-7**	a collection out of **S-5** of those vital parameters which are abnormal	**G-8**	the abnormal vital signs of a person
	L2	**S-9**	collection of beliefs on the side of **S-1** about which vital signs in **S-5** are abnormal	**G-17**	collection of beliefs on the side of **S-1** about what vital signs are abnormal
	L3	**S-10**	collection of statements in some protocol or guideline issued by the Ospedale Niguarda Cà Granda about what vital parameters are to be considered abnormal.	**G-11**	collection of statements in state of the art documents indicating what vital parameters are abnormal
acquires	L1	**S-12**	the process carried out by **S-1** to obtain **S-13**	**G-18**	acquiring personal health documentation
personal health documentation	L3	**S-13**	collection of statements on some form(s) concerning the personal health of the patient evaluated by **S-1**	**G-14**	statements in or on some medium about the personal health of a patient
asks	L1	**S-15**	the process carried out by **S-1** to have the patient undergo instances of **S-16**	**G-19**	ordering diagnostic services
diagnostic services	L1			**G-16**	process carried out with the goal to assess the health status of a person

The various interpretations that can be given to the term '*alterations'* demonstrate the importance of analyzing terms at various levels of reality: these analyses provide further ground to develop guideline execution and protocol monitoring algorithms of higher sophistication which take the many differences concerning, in this case '*alterations in vital parameters'*, into account.

Under the specific reading, **S-7** is the collection of those vital parameters for the patient being evaluated by **S-1** which are objectively – i.e. from the god's-eye perspective [25] – abnormal, irrespective of what **S-1** may believe, or what is considered to be correct according to the state of the art.

S-9, in contrast, as a level-2 entity, does not comprise vital parameters at all, but beliefs on the side of **S-1**, more precisely beliefs about which parameters in **S-5** are abnormal. Note that if **S-1**'s beliefs would be correct, **S-7**, a level-1 entity, would still not be equal to **S-9**. But clearly, in that specific case, the collection of vital parameters *about which* **S-1** correctly believes that they are abnormal is equal to **S-7**.

Figure 2, in contrast, depicts another configuration. Also displayed as distinct entity is **S-10**, a level-3 entity which is, although in a more lose sense, similar to **S-9** about all or some vital signs in **S-5**. The partially overlapping squares symbolize the disagreements between the normative view of **S-10** and the clinical view of **S-1** about which vital parameters out of **S-5** are abnormal, in addition to what is objectively abnormal (**S-7**).

Representing these differences in an application ontology, and keeping track of the various views when the ontology is actually used in an application – e.g. by registering for each vital parameter of a specific patient whether it is abnormal under which views – has several advantages as it might contribute to determine – at least when additional outcome parameters are collected – whether, for instance:

(1) a specific clinician adheres to the guidelines

(2) patients assessed by a specific clinician have better outcomes irrespective of whether he adheres to the guidelines

(3) the guidelines need to be updated (based on empirical evidence),

(4) …

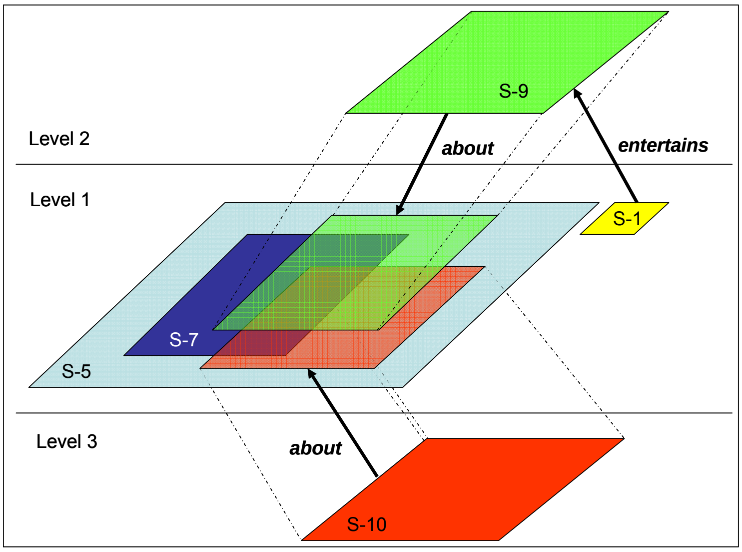

Figure 2: relationships between the three levels of reality

The generic readings of the term '*alterations'* add further complexity to the situation. **S-10** and **G-11**, for instance, are both normative, yet can be distinct. The author(s) of **S-10** might have had good reasons to deviate from what is considered to be the state of the art [31, 32]. But whether they differ or not, they might both be wrong, i.e. when applying the rules to the patient under scrutiny does not result in the vital parameters which are in **S-7**.

Clearly, the generic readings that we have provided in Table 2 are not the only plausible ones. In fact, several distinct levels of generality can be applied. In the context of **G-2**, i.e. any medical doctor providing first aid services in the Ospedale Niguarda Cà Granda, we could have proposed a variety of other, more or less, generic entities, depending on what the authors of the sentence under scrutiny had in mind when using the phrase '*First Aid Doctor*', such as:

(1) any medical doctor *of the First Aid Department* (if there exists such department) in the Ospedale Niguarda Cà Granda

(2) any medical doctor *specialized* in providing first aid services in the Ospedale Niguarda Cà Granda (whether or not from that department),

(3) any medical doctor *capable of* providing first aid services in the Ospedale Niguarda Cà Granda (whether or not specialized in delivering such services),

(4) any of the above, whether or not in the Ospedale Niguarda Cà Granda,

(5) … .

3.5 Identify particulars, universals and configurations

On closer inspection of Table 2, it becomes clear that some specific entities carry a generic flavour too. As an example, **S-5**, characterised as '*a collection of the vital signs of that specific patient*', goes hand in hand with the notion of '*a vital sign of that specific patient*'. This calls for a more fine-grained analysis of the notions just sketched.

3.5.1. A taxonomy for portions of reality

Reality consists of a huge – if not infinite – combination of portions of reality. By '*portion of reality*' is meant any individual entity or configuration of entities standing in some relation to each other.

A '*configuration'* is a portion of reality which is not an entity in its own right. Whereas a specific person, his or her activities, the social network he belongs to, the clinician examining that person, and that examination itself are each individual entities, the configuration that the activities of this person are being analysed by a doctor, or his or her being part of that social network, is not. Another example of a configuration is the being of a medical device in a clinical examination room. Both that device and the room are entities, but the fact that that device is in that room, is not. If that device would not be in the room, but, for instance be placed by a nurse outside the room for decontamination purposes, still the very same entities (the device and the room) would be involved, but there would be another configuration.

By '*entity'* is meant anything that exists or has existed in the past, whatever its nature.

In Basic Formal Ontology (BFO) [33], an explicit distinction made between specific entities called '*particulars'* from generic entities called '*universals'*. Particulars are specific and unique entities, unique in the sense that they each occupy specific regions of space and time, and that nothing other than a specific particular can be that particular. Examples are concrete persons such as George W. Bush Jr. and George W. Bush's heart. Some particulars, such as each of four clips in a surgical suture, may exactly look the same, but they are still distinct particulars. One can be removed, while the other three remain in place. For particulars of specific interest, such as persons and hospitals, proper names are used to mark the importance of their individual identity. For other particulars, such as ambulances or pieces of complex equipment, serial numbers are used for unique identification purposes.

3.5.1.1 Upper ontology universals in Basic Formal Ontology

Universals, in contrast to particulars, are such that they are (1) generic and (2) expressed in language by means of general terms such as '*person*', '*clip*', and '*device*', and (3) represent structures or characteristics in reality which are exemplified in an open-ended collection of particulars in arbitrarily disconnected regions of space and time.

A first important distinction in Basic Formal Ontology (BFO) is the one between continuants and occurrents. This central dichotomy between objects and processes concerns two distinct modes of existence in time [33]. BFO endorses first of all a view according to which there are entities in the world that endure through time: entities which persist self-identically even while undergoing changes of various sorts. Such continuant or endurant entities come in several kinds. Examples are: the Ospedale Niguarda Cà Granda, its First Aid department, its First Aid doctors, but also the size of the hospital, the skills of the department head, his body mass, and so forth. The department head, for instance, is the same person today as he was yesterday and will be tomorrow. This means that if we segment the region of space occupied by a continuant, then we segment the continuant also. Continuants are not, however, bound with respect to time. This means that however we segment the interval of time during which a continuant exists, we find this continuant itself in every segment.

BFO endorses in addition a view according to which the world contains occurrents, more familiarly referred to as processes, events, activities, changes. Occurrents include: the Ospedale Niguarda Cà Granda's functioning, the breathing of the First Aid Department head, the coughing of patients seen in that department, but also the spreading of an epidemic through a population and the chemical synthesis of proteins. Occurrents have, in addition to their spatial dimensions also a fourth, temporal dimension, and they are, in contradistinction to continuants, bound with respect to time. This means that if we segment the interval of time during which an occurrent occurs then we segment the occurrent also. Occurrents occur in time and they unfold themselves through a period of time in such a way that they can be divided into temporal parts or phases.

Not all entities are segmentable in this way. This is because there are beginnings and endings and other boundaries in the realm of occurrents, which are instantaneous: they are analogous to the edges and surfaces of objects in the realm of continuants. Just as the latter can exist only as the boundaries of three-dimensional spatially extended objects, so the former can exist only as the boundaries of temporally extended processes. Typically, the beginning and ending of an occurrent, as well as everything that takes place between these two points, are parts of the occurrent itself. The beginning and ceasing to exist of a continuant, in contrast, are not parts of the continuant itself, but rather parts of that occurrent which is its life or history.

In addition to the orthogonal continuant and process categories, BFO draws distinctions between *dependent* and *independent* entities. Processes depend for their existence on their participants. The act of swallowing cannot exist without some esophagus; nor can the process of peristaltic contraction proceed without the muscle layers of the esophageal wall [14]. Such processes are all dependent on some continuant entity, which in an organism is an anatomical structure or a portion of some body substance. BFO also draws distinctions between dependent and independent continuants. The lumen of the esophagus or its surfaces cannot exist without some esophagus also existing. Role is likewise a dependent continuant, rather than a process. The role of a first aid doctor endures while the doctor works in the department even if it is not always realized, for instance while he is eating.

Figure 3 depicts BFO’s upper ontology schematically while Figure 4 and Figure 5 provide more detail on the continuant and occurrent portions of reality respectively.

CONTINUANT = endure through time		OCCURRENT = occur in time	SPATIO-TEMPORAL
INDEPENDENT	DEPENDENT		
Object: Living thing, Rock	Attribute: Quality, Role	Event, Process	Spatial Region, Temporal Interval

Figure 3: Basic Formal Ontology’s partitioning of reality

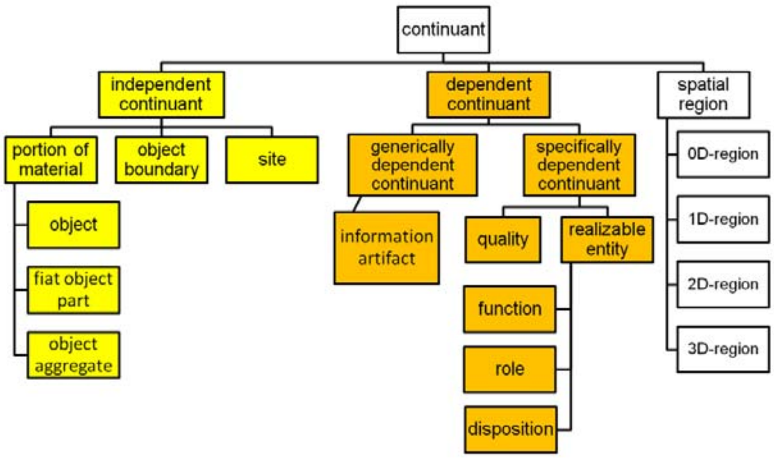

Figure 4: BFO’s continuant ontology

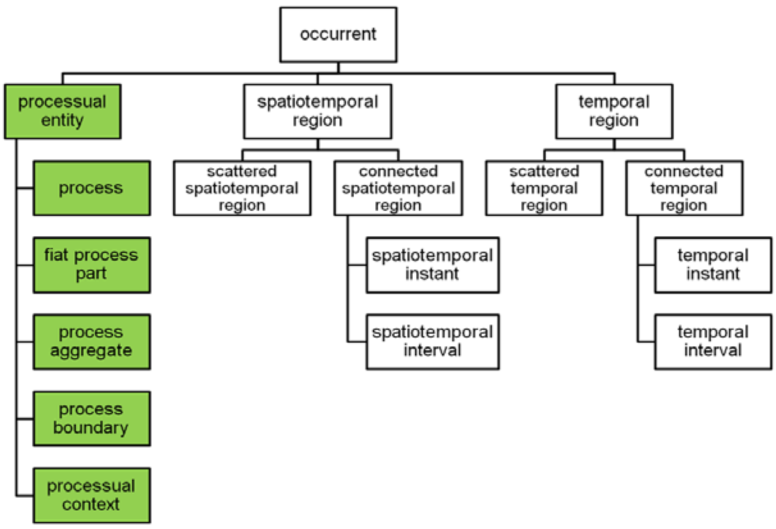

Figure 5: BFO’s occurrent ontology

3.5.1.2 Classes as collections of particulars

A collection of particulars (of molecules in John's body, of pieces of equipment in a certain operating theatre, of operations performed in this theatre over a given period of months) is a Level 1 particular comprehending other particulars as its members [34]. Note that we can use the very same general terms to refer both to universals and to collections of particulars as in 'HIV is an infectious retrovirus' versus 'HIV is spreading very rapidly through Asia'.

These collections come in various flavours.

A *class* is a collection of all and only the particulars to which a given general term applies, examples of such terms being:

- '*vital sign*',
- '*heart rate*',
- '*vital sign of John Doe*',
- '*heart rate measured at noon*',

Note that there is only one '*heart rate of John Doe measured at noon*' and thus that in this case there is no collection involved. We indeed mean here John Doe's heart rate, and not a measurement of his heart rate. '*Measurement of John Doe's heart rate at noon'* and even '*measurement of John Doe's heart rate at noon on Dec 5, 2008*' are again generic terms since there can be many such measurements performed at the same time using distinct methods.

Where the general term in question refers to a universal, then the corresponding class, called the *extension of the universal* (at a given time), comprehends all and only those particulars which as a matter of fact instantiate the corresponding universal (at that time) [23]. Of the examples given above, only '*heart rate*' denotes a universal. '*Vital sign*' would easily be mistaken to denote a universal, but, as we will argue below, does not.

A *defined class* is a subset of the extension of a universal defined as being such that the members of this class exhibit an additional property (taken in the most general sense which includes being in some specific configuration) which is (a) not shared by all instances of the universal, and, (b) also (can be) exhibited by particulars which are not instances of that universal. Of the examples given above, '*heart rate measured at noon*' denotes a defined class: the class is constituted by the heart rate of any organism which has a heart. '*Vital sign of John Doe*' does not, since '*vital sign*' does not denote a universal.

A *compositional* (or *composite*, or *ad hoc*) class is an ad hoc collection of particulars such that some particulars are instances of a universal which is not instantiated by other particulars of that class. '*Vital sign*' is an example of a term that denotes particulars in such class. This is because, in line with the definition proposed in the disease part of the RAPS Domain Ontology [35, 36], all vital signs are signs, and the latter are '*bodily features of a patient that are observed in a physical examination and are hypothesized by the clinician to be of clinical significance'*. Some bodily features are continuants, such as skin rashes and pimples, other bodily features are processes such as muscle jerks, tremors, coughs, and so forth. Nothing which is a continuant can be a process or the other way round. In addition, nothing which is a continuant can become at a later stage in its history a process or vice versa. Thus any collection of bodily features may include particulars that are instances of a universal which is not instantiated by other particulars of that class, and therefore the terms 'bodily feature', 'sign' and 'vital sign' denote members of a composite class.

Figure 6 provides another example of how 'bodily features' should be partitioned in terms of the various sorts of classes:

- *extensions*: rashes, tremors, edemas, fevers, orthostatic tremors
- *defined classes*: infectious fevers, infectious rashes, allergic rashes
- *composite classes*: bodily features, signs of infectious disease, signs of Graves' disease

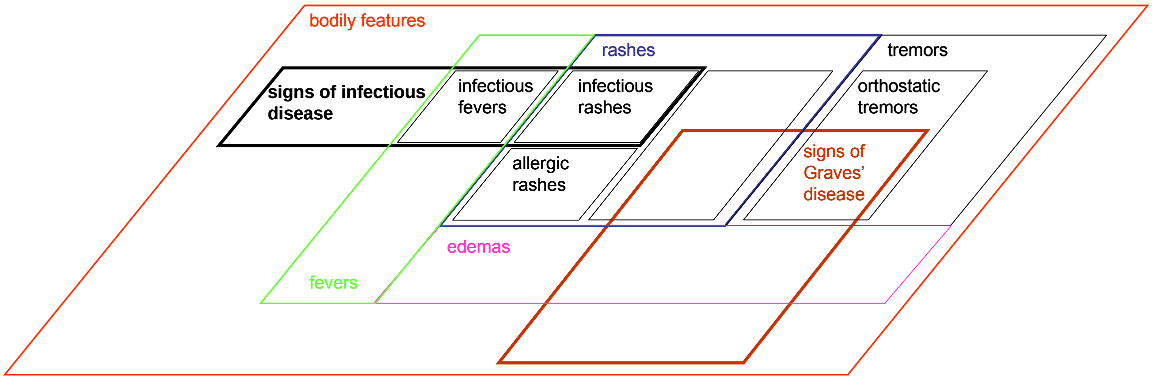

Figure 6: a partitioning of bodily features

3.5.2. Application to the example

In order to identify a first – i.e. before applying the sort of expansion as discussed in section 3.7 – set of particulars, universals, and classes involved in the sentence '*The First Aid Doctor (FAD) evaluates vital parameters and possible alterations, acquires possible personal health documentation and asks for diagnostic services'*, we rephrase this sentence in a specific and generic form and then analyse them each separately.

Note that for building a RAPS application ontology, always the RAPS Domain Ontology [35] should be used to identify the classes and universals that are applicable. If in the Domain Ontology no applicable representational unit (RU) can be found at the required level of detail, a RU should be added to the application ontology being developed. At a later stage, it should be discussed with the Domain Ontology authors whether the additional RUs should become part of the Domain Ontology.

3.5.2.1 Specific reformulation

'*This First Aid Doctor (FAD) evaluates at that time this collection of vital parameters of that patient and possible alterations thereof, acquires possible personal health documentation of that patient and asks for this set of diagnostic services'*.

When interpreting this sentence, the reader should picture a specific event as if it really happened. We added 'at that time' because processes, as discussed in section 3.5.1.1 p15, are bound by time. An evaluation carried out by the same doctor on the same patient at another time, even when he follows exactly the same procedure, is a distinct evaluation. The particulars then involved are shown in Table 3. We use the following markers:

(3) 'I' for singular particular (at the relevant level of granularity and ontological zooming [37]. When examining a patient, the relevant level is an individual human being, and not a collection of molecules in some specific arrangement).

(4) 'E' for extension

(5) 'DC' for defined class

(6) 'CC' for composite class

When a DC or E is involved, we also specify the corresponding universal taken from the RAPS Domain Ontology, where available.

Table 3: Particulars denoted in the specific interpretation of the sentence under scrutiny

Term		Particulars		Corresponding universals
This First Aid Doctor	L1	**I-1**	that specific medical doctor providing first aid services in the Ospedale Niguarda Cà Granda	**HUMAN BEING**
	L1	**I-11**	**I-1**'s medical doctor role	**MEDICAL DOCTOR ROLE**
FAD			same as above	
evaluates	L1	**I-2**	that specific patient evaluation carried out by **I-1** at that time	**PROCESS**
vital parameters	L1	**CC-3**	the collection of the vital signs of that specific patient at that time	-
alterations	L1	**CC-4**	the collection out of **CC-3** of those vital parameters which are abnormal	-
	L2	**DC-5**	the collection of beliefs, at that time, on the side of **I-1** about which vital signs in **CC-3** are abnormal	**BELIEF**
	L3	**DC-6**	the collection of statements in some protocol or guideline issued by the Ospedale Niguarda Cà Granda about what vital parameters are to be considered abnormal.	**INFORMATION ARTIFACT**
acquires	L1	**I-7**	the process carried out by **I-1** to obtain **DC-8**	**PROCESS**
personal health documentation	L3	**DC-8**	the collection of statements on some form(s) concerning the personal health of the patient evaluated by **I-1**	**INFORMATION ARTIFACT**
asks diagnostic services	L1	**I-9**	the process carried out by **I-1** to have the patient undergo diagnostic services	**PROCESS**

3.5.2.2 *Generic reformulation*

'A First Aid Doctor (FAD) in the Ospedale Niguarda Cà Granda evaluates vital parameters and possible alterations, acquires possible personal health documentation and asks for diagnostic services'.

Table 4: Particulars denoted in the generic interpretations of the sentence under scrutiny

Term		Particulars		Corresponding Universals
First Aid Doctor	L1	**DC-10**	the collection of medical doctors providing first aid services in the Ospedale Niguarda Cà Granda	**HUMAN BEING** **MEDICAL DOCTOR ROLE**
FAD			same as above	
evaluates vital parameters	L3	**DC-11**	directives about the evaluation procedures to be carried out by a doctor from **DC-10** when realizing his role as first aid doctor	**INFORMATION ARTIFACT**
vital parameters	L1	**CC-12**	the collection of vital signs of a human being	-
alterations	L1	**CC-13**	the abnormal vital signs of a person	-
	L2	**DC-14**	collection of beliefs on the side of a doctor from **DC-10** about what vital signs are abnormal	**BELIEF**
	L3	**DC-15**	collection of statements in state of the art documents indicating what vital parameters are abnormal	**INFORMATION ARTIFACT**
acquires personal health documentation	L3	**DC-16**	directives about acquiring personal health documentation of the sort required to be done by a doctor from **DC-10**	**INFORMATION ARTIFACT**
personal health documentation	L3	**DC-17**	statements in or on some medium about the personal health of a patient	**INFORMATION ARTIFACT**
asks diagnostic services	L3	**DC-18**	directives about ordering diagnostic services in the Ospedale Niguarda Cà Granda	**INFORMATION ARTIFACT**

Note that there is a deviation here from the path originally walked in section 3.4.2 p12. Whereas earlier the generic interpretation of the term '*acquires*' in the original sentence was taken to be '*acquiring personal health documentation*', and of '*asks*' in a similar way '*ordering diagnostic services*', we can not hold that – in an attempt to identify the portions of reality that are denoted by these terms – there really ***is*** a collection of such activities that are or have been carried out. It might very well be that no such activity ever existed. In that case, these terms, taken literally, would denote nothing at all, in the same way as the terms '*unicorn'*, '*leprechaun'*, '*God'*, and also '*prevented abortion*', and '*absent nipple*' do not denote anything existing.

It is in the treatment of terms like these, that the realism-based approach to building ontologies differs substantially from the concept-based approach [23, 30]. Adepts of the latter would see no problem in defining the 'concepts' *unicorn*, *leprechaun*, and so forth in the same way as they would define the 'concepts' *human being* or *process*. They make the mistake that it is not because the term '*human being*' denotes existing entities, as well as the terms '*human beings who believe in leprechauns*', '*human beings who believe in God*', and '*human beings with absent nipples*', that any term used within such denoting term, denotes also! By introducing such 'concepts', the ontologies that result from it are not able to make the difference between entities in reality and fantasies.

Although we could safely assume that in the *Ospedale Niguarda Cà Granda* activities of that kind have been carried out, we preferred, for the sake of the example, not to do so, but rather interpret the terms as denoting *directives*. This situation is similar to formulations of plans and recipes. An experienced chef may very well invent a new recipe, write it down on paper and finish the recipe with '*and now the Veal Grand Boldano is ready*' before he ever cooked the thing. Thus at that point in time, the term 'Veal Grand Boldano' does not denote food: the recipe (or plan or directives) to make Veal Grand Boldano exists, but not (yet) such a plate. In the case of a protocol, the directives as stated in the protocol may exist before any realization of them.

3.6 Specifying instantiation and class membership

3.6.1. Fundamental relations

In this step, it needs for each particular to be determined of what classes they are *members*, and what universals they *instantiate*. For the sake of intelligibility we use here for the specification of these relations a semi-formal syntax, which can, however, be translated in a simple way into standard logical notation. We use variables of the following sorts:

- CL, CL_1, … to range over classes of any sort;
- C, C_1, ... to range over continuant classes;
- P, P_1, ... to range over process classes;
- i, i_1, … to range over particulars of any sort;
- c, c_1, ... to range over continuant particulars;
- p, p_1, ... to range over process particulars;
- t, t_1, ... to range over instants or periods of time.

With respect to instantiation, the Relation Ontology upon which we build further distinguishes two kinds of instance-level relations: those (applying to continuants) whose representations must involve a temporal index, and those (applying to processes) which do not, a distinction which is still perfectly consistent with the fact that processes themselves occur in time, and that processes may be built out of successive subprocesses instantiating distinct classes [13]:

– *c* **instance_of** *C* **at** *t* - a primitive relation between a continuant and a universal which it instantiates at a specific time;

– *p* **instance_of** *P* - a primitive relation between a process and a universal which it instantiates holding independently of time.

The relationship between a particular (processual entity or continuant) and a class is that of *membership* (not to be confused with the sort of membership of which we talk in the context of clubs or boards of directors, reason for which we will use the term **class_member_of**):

- *i* **class_member_of** *CL* **at** *t* – a primitive relation between a particular and a class of which it is a member at a specific time.

On the basis of these *primitive* relations, three additional *defined* relations can be introduced [38]:

- CL_1 **subclass_of** CL_2 **at** t = [def]: for all i, t, if *i* **class_member_of** CL_1 **at** *t* then *i* **class_member_of** CL_2 **at** *t*
- CL **extension_of** C **at** t = [def]: for all c, t, if *c* **instance_of** C **at** t then c **class_member_of** CL **at** t
- CL **extension_of** P **at** t = [def]: for all p, t, if *p* **instance_of** P then p **class_member_of** CL **at** t

Figure 7 provides an example of these relations using the particular **I-1** and the defined class **DC-10** as described in Table 3 and Table 4.

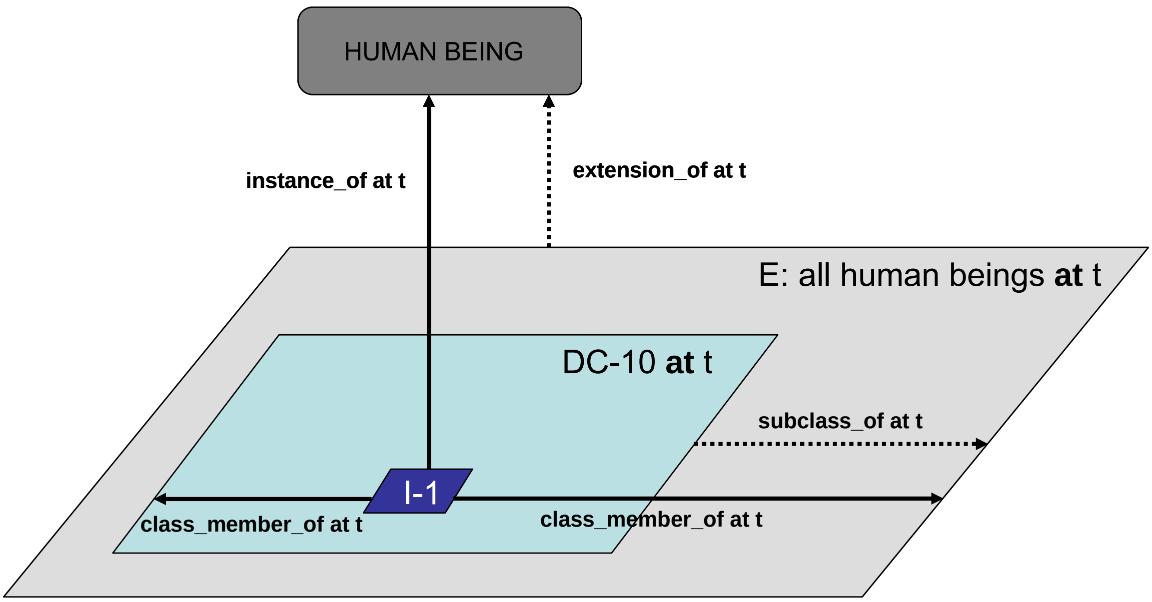

Figure 7: fundamental relationships between particulars, classes and universals

The importance of the time stamps becomes clear when looking at Figure 8[1]. Any instance of the universal HUMAN BEING is an independent continuant which changes over time through the process of AGING. So there exist the universal CHILD and the universal ADULT. The relationship between the latter universals and HUMAN BEING is the universal-level relation *is_a*, as defined in [13]:

- *C is_a* C_1 = [def] for all *c*, *t*, if *c* **instance_of** *C* **at** *t* then *c* **instance_of** C_1 **at** *t*.

  thus, for example:

  if **I**-1 **instance_of** child **at** t_1 then **I**-1 **instance_of** human being **at** t_1

  if **I**-1 **instance_of** adult **at** t_2 then **I**-1 **instance_of** human being **at** t_2

[1] For an explanation of the transformation relation, see section 3.9

- *P is_a P*$_1$ = [def] for all *p*, if *p* **instance_of** *P* then *p* **instance_of** *P*$_1$.

Note that we have now a set of fundamental relations which is larger than what is available in OWL. The latter has only a variant of our sub_class_of relation which unfortunately ignores time.

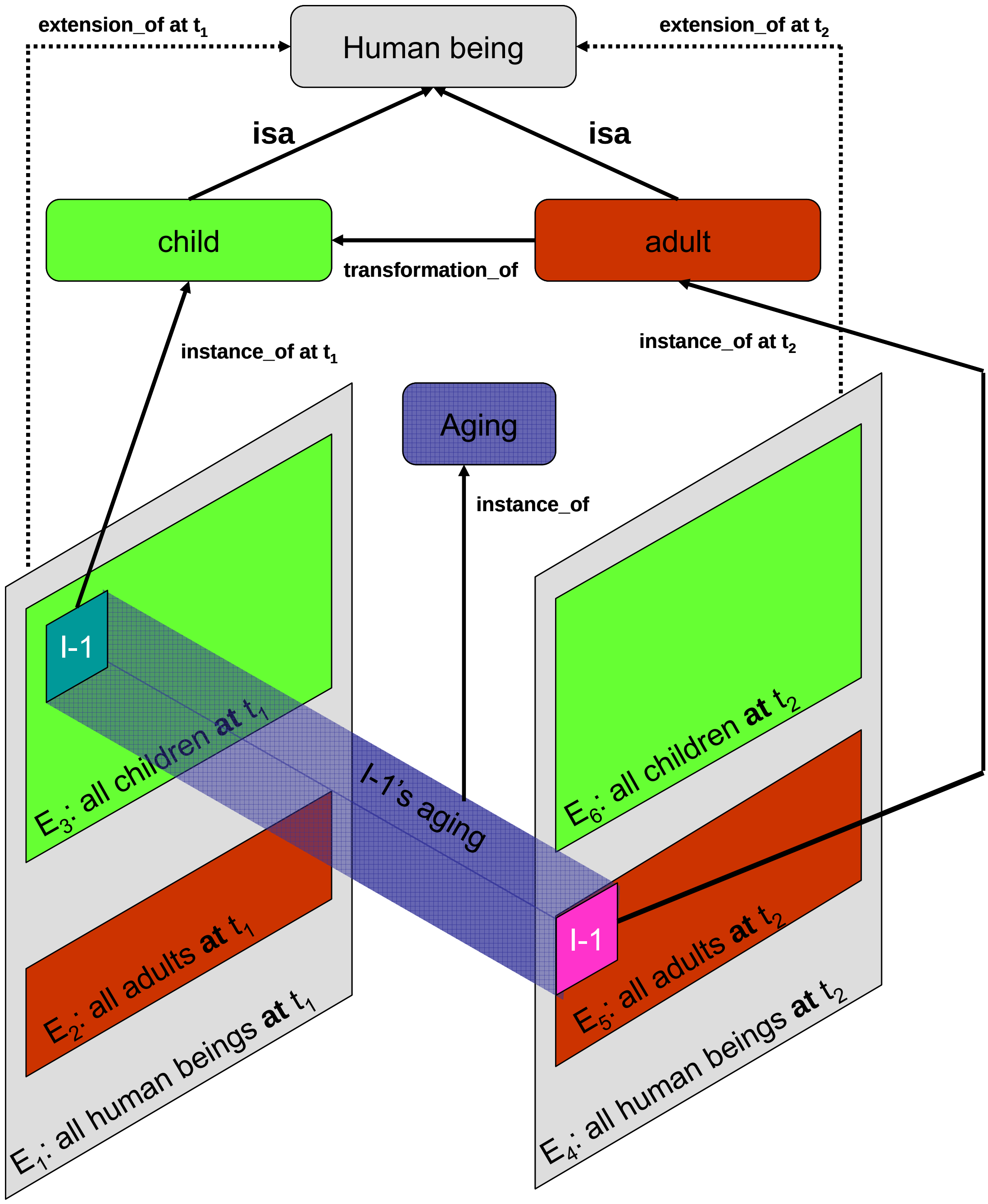

Figure 8: Change of a continuant over time

3.6.2. Application to the example

Table 5 lists the relations that obtain between the entities that we identified thus far. For relations that require a time stamp, we will just write '**at** *t*', not differentiating between any specific time periods.

Table 5: Relations between specific and generic interpretations of terms in the example sentence

Term	Specific		Generic		Relations			
This First Aid Doctor	L1	**I-1**	L1	**DC-10**	*I-1* *I-1*	**instance_of** **class_member_of**	**HUMAN BEING** *DC-10*	**at** *t* **at** *t*
	L1	**I-11**			*I-11*	**instance_of**	**MEDICAL DOCTOR ROLE**	**at** *t*
evaluates	L1	**I-2**	L3	**DC-11**	*I-2* *DC-11*	**instance_of** **instance_of**	**PROCESS** **INFORMATION ARTIFACT**	 **at** *t*
vital parameters	L1	**CC-3**	L1	**CC-12**	*CC-3*	**subclass_of**	*CC-12*	**at** *t*
alterations	L1	**CC-4**	L1	**CC-13**	*CC-4* *CC-13*	**subclass_of** **subclass_of**	*CC-3* *CC-12*	**at** *t* **at** *t*
	L2	**DC-5**	L2	**DC-14**	*DC-5*	**subclass_of**	*DC-14*	**at** *t*
	L3	**DC-6**	L3	**DC-15**	*DC-6* *DC-15*	**instance_of** **instance_of**	**INFORMATION ARTIFACT** **INFORMATION ARTIFACT**	**at** *t* **at** *t*
acquires	L1	**I-7**	L3	**DC-16**	*I-7* *DC-16*	**instance_of** **instance_of**	**PROCESS** **INFORMATION ARTIFACT**	 **at** *t*
personal health documentation	L3	**DC-8**	L3	**DC-17**	*DC-8* *DC-17*	**instance_of** **instance_of**	**INFORMATION ARTIFACT** **INFORMATION ARTIFACT**	**at** *t* **at** *t*
asks diagnostic services	L1	**I-9**	L3	**DC-18**	*I-9* *DC-18*	**instance_of** **instance_of**	**PROCESS** **INFORMATION ARTIFACT**	 **at** *t*

3.7 Expansion of the representation

The next step is to determine whether other portions of reality that are not explicitly denoted in the statements must be taken into account and if that is the case, apply the previous steps to them as well [24]. The procedure to do so is:

- for all representational units it must explicitly be stated what upper-level universals represented in BFO are instantiated by the entities represented through these units (the main reason being the need to identify whether the entities are dependent or independent as this determines the next action to be taken);
- for each dependent entity – thus all dependent continuants and all processual entities (see section 3.5.1.1) – we must include in the representation representational units for those entities on which the dependent entities depend, which is for processes, all continuants that participate in it;
- for each independent entity, we must identify whether the class of which it is a member is the extension of the universal of which it is an instance, and if not:
  - (2a) in case the class is a defined class, add representations for the particulars and universals so that necessary and sufficient conditions for class membership can be given;
  - (2b) in case the class is a composite class, identify all relevant universals that are involved and decompose the class in defined classes;
- repeat all steps for each entity so discovered through steps (1), (2) and (3) until no new representational units are required.

3.7.1. Application to the example

Table 6 lists the elements that result from the expansion process following the procedure sketched above. Elements that were already present before are depicted in grey background although in some cases the description was made more precise. Thus, as an example, where we wrote before for **CC-3**: '*the collection of the vital signs of that specific patient at that time*', we replaced it with '*the collection of the vital signs of **I-1001** at that time*' since we introduced in this step a representational unit for that patient, namely ***I-1001***.

Table 6: Expansion of the representation

Term		Particulars		Corresponding universal	Place in BFO (or supertype)
This First Aid Doctor (FAD)	L1	**I-1**	that specific medical doctor providing first aid services in the Ospedale Niguarda Cà Granda	HUMAN BEING	INDEPENDENT CONTINUANT
	L1	**I-1001**	the human being that undergoes **I-2**	HUMAN BEING	INDEPENDENT CONTINUANT
	L1	**I-1002**	the role played by **I-1001**	EMERGENCY PATIENT ROLE	ROLE
	L1	**I-1003**	the Ospedale Niguarda Cà Granda	HEALTHCARE FACILITY	OBJECT AGGREGATE
	L1	**I-11**	**I-1**'s medical doctor role	MEDICAL DOCTOR ROLE	ROLE
First Aid Doctor (FAD)	L1	**DC-10**	the collection of medical doctors providing first aid services in **I-1003**	HUMAN BEING	INDEPENDENT CONTINUANT
evaluates	L1	**I-2**	that specific patient evaluation carried out by **I-1** at that time	PATIENT EVALUATION	PROCESS
vital parameters	L1	**CC-3**	the collection of the vital signs of **I-1001** at that time	-	
	L1	**DC-3001**	the collection of bodily features[2] of **I-1001** that are continuants	CONTINUANT BODILY FEATURE	CONTINUANT
	L1	**DC-3002**	the collection of bodily features of **I-1001** that are processes	PROCESSUAL BODILY FEATURE	PROCESS
	L1	**DC-3003**	the collection out of **DC-3001** of bodily features that participated in **I-2** (perhaps not all features were observed)	CONTINUANT BODILY FEATURE	CONTINUANT
	L1	**DC-3004**	the collection out of **DC-3002** of bodily features that participated in **I-2** (perhaps not all features were observed)[3]	PROCESSUAL BODILY FEATURE	PROCESS
	L1	**CC-12**	the collection of vital signs of a human being	-	
	L1	**DC-1201**	the collection of continuant bodily features of a human being which are vital signs, i.e. have been observed through some patient evaluation	CONTINUANT BODILY FEATURE	CONTINUANT
	L1	**DC-1202**	the collection of processual bodily features of a human being which are vital signs, i.e. have been observed through some patient evaluation	PROCESSUAL BODILY FEATURE	PROCESS
evaluates vital parameters	L3	**DC-11**	directives about the patient evaluation procedures to be carried out by a doctor from **DC-10** when realizing his role as first aid doctor	INFORMATION ARTIFACT	GENERICALLY DEPENDENT CONTINUANT
	L1	**I-1101**	information bearer on which **DC-11** depend (e.g. the book containing the directives)	CONTINUANT	CONTINUANT
alterations	L1	**CC-4**	the collection out of **CC-3** of those vital parameters which are abnormal	-	
	L1	**DC-4001**	the collection out of **DC-3001** of those vital parameters which are abnormal	CLINICALLY ABNORMAL CONTINUANT BODILY FEATURE	CONTINUANT BODILY FEATURE
	L1	**DC-4002**	the collection out of **DC-3002** of those vital parameters which are abnormal	CLINICALLY ABNORMAL PROCESSUAL BODILY FEATURE	PROCESSUAL BODILY FEATURE
	L1	**DC-4003**	the collection of bodily features which are	CLINICALLY ABNORMAL	CONTINUANT

[2] 'signs' are defined in the RAPS Domain Ontology as bodily features that are observed
[3] CC-3 is thus the union of DC-3003 and DC-3004

Term		Particulars		Corresponding universal	Place in BFO (or supertype)
			members of both **DC-3003** and **DC-4001**	CONTINUANT BODILY FEATURE	BODILY FEATURE
	L1	**DC-4004**	the collection of bodily features which are members of both **DC-3004** and **DC-4002**[4]	CLINICALLY ABNORMAL PROCESSUAL BODILY FEATURE	PROCESSUAL BODILY FEATURE
	L1	**CC-13**	the abnormal vital signs of a person	-	
	L1	**DC-1301**	the collection of abnormal continuant bodily features of a human being which are vital signs, i.e. have been observed through some patient evaluation	CLINICALLY ABNORMAL CONTINUANT BODILY FEATURE	CONTINUANT BODILY FEATURE
	L1	**DC-1302**	the collection of abnormal processual bodily features of a human being which are vital signs, i.e. have been observed through some patient evaluation	CLINICALLY ABNORMAL PROCESSUAL BODILY FEATURE	PROCESSUAL BODILY FEATURE
	L2	**DC-5**	the collection of beliefs, at that time, on the side of **I-1** about which vital signs in **CC-3** are abnormal	BELIEF	SPECIFICALLY DEPENDENT CONTINUANT
	L3	**DC-6**	the collection of statements in some protocol or guideline in use in **I-1003** about what vital parameters are to be considered abnormal.	INFORMATION ARTIFACT	GENERICALLY DEPENDENT CONTINUANT
	L1	**I-6001**	information bearer on which **DC-6** depend (e.g. the book containing the protocol or guideline)	CONTINUANT	CONTINUANT
	L2	**DC-14**	collection of beliefs on the side of a doctor from **DC-10** about what vital signs are abnormal	BELIEF	SPECIFICALLY DEPENDENT CONTINUANT
	L3	**DC-15**	collection of statements in state of the art documents indicating what vital parameters are abnormal	INFORMATION ARTIFACT	GENERICALLY DEPENDENT CONTINUANT
	L1	**I-1501**	information bearer on which **DC-15** depend (e.g. the book containing the statements)	CONTINUANT	CONTINUANT
acquires	L1	**I-7**	the process carried out by **I-1** to obtain **DC-8**	PROCESS	PROCESS
personal health documentation	L3	**DC-8**	the collection of statements on some form(s) reflecting **DC-8002.**	CLINICAL HISTORY REPRESENTATION	INFORMATION ARTIFACT
	L1	**DC-8001**	**I-1001**'s clinical history	PROCESSUAL BODILY FEATURE[5]	PROCESS
	L1	**DC-8002**	collection of those members from **DC-8001** about which there are statements in **DC-8**	PROCESSUAL BODILY FEATURE	PROCESS
asks diagnostic services	L1	**I-9**	the process carried out by **I-1** to have the patient undergo diagnostic services	ORDER FOR SERVICE	PROCESS
	L3	**DC-18**	directives about ordering diagnostic services in **I-1003**	INFORMATION ARTIFACT	GENERICALLY DEPENDENT CONTINUANT
	L1	**I-1801**	information bearer on which **DC-18** depend (e.g. the book containing the directives)	CONTINUANT	CONTINUANT

3.8 Identifying additional relations

Realism-based ontologies, as explained in deliverable D4.2 [35], use many more relations. The goal of this step in the development process is to identify the *ontological* relations which are necessary to support the computations required for the application. In order to maintain forward compatibility with other realism-based ontologies, we build further on the Relation Ontology [13].

We expand here also the temporal aspects of the representation such that it can take full advantage of the European Norm EN12381:2005: Time Standards for Healthcare-Specific Problems as shown in Figure 9 and Figure 10.

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[4] CC-4 is the union of DC-4003 and DC-4004
[5] a clinical history is a collection of processes as defined in the RAPS Domain Ontology. Thus a tumour (an independent continuant) is not part of the clinical history, but the coming into existence of that tumour, or the manifestation of it, is part.

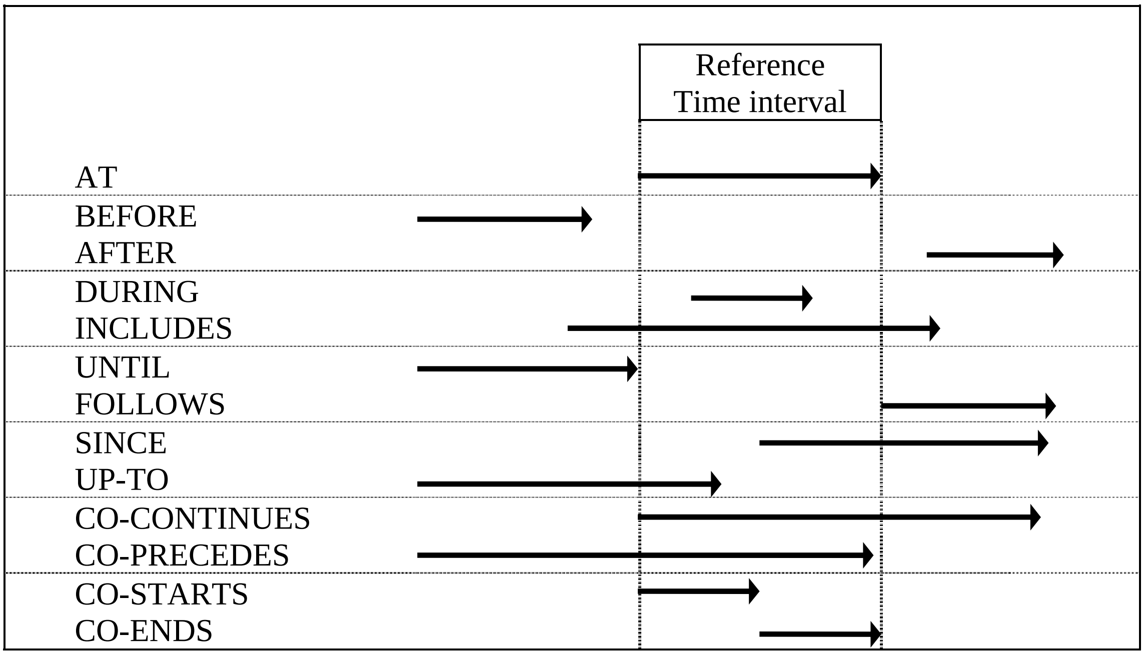

Figure 9: Semantics of the allowed set of temporal comparators when an episode is temporally related to a time-interval.

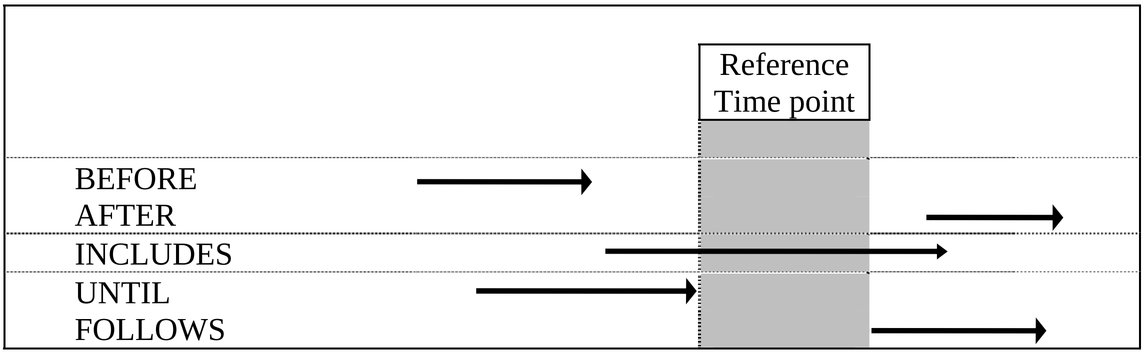

Figure 10: Semantics of the allowed set of temporal comparators when an episode is temporally related to a time-point.

Table 7 lists a few instance-level relations that turned out to be required for our purposes, while Table 8 contains the application of these relations to the entities identified during the previous steps. These tables are not complete, but function merely as examples of the procedure. When it is decided within the ReMINE consortium that the First Aid scenario will be the topic of a demo-application, these tables will be completed.

All the relationships are presented as *assertions* about the instances (including temporal instances), although for some of them it might have been possible – at least at first sight – to arrive to them by means of *inferences*. It might seem obvious, for instance, to infer that I-1 is an instance of human being when it is known that the role medical doctor inheres in I-1. But that is only possible if the former is a necessary condition for the latter. It would not be a necessary condition if, for instance, robots would also qualify as medical doctors. Whether or not conditions are necessary (and/or sufficient) for certain relationships to hold, is a matter that must be discussed (1) in the broader realism-based ontology community for universals and (2) in user-groups of specific applications for defined and composite classes.

Furthermore, we marked relationships that very likely hold, but not for sure, by placing a question mark in front of the name of the relation in Table 8.

Issues like these will cause in the future new versions of D4.3 and D4.2 to be harmonized such that everything which is universally the case in the domain will move from D4.3 to D4.3.

Table 7: Additional instance-level relationships and their definitions

Relation	Comments
role_of(c,c1, t.c.[6] t)	a defined relation between a role c and a continuant c1. c role_of c1 at t iff: c inheres_in c1 at t and c instance_of Role at t
has_participant(p, c, t.c. t)	a primitive relation between a process, a continuant, and a time at which the continuant participates in some way in the process.
has_agent(p, c, t.c. t)	a primitive relation between a process, a continuant, and a time at which the continuant participates causally active in the process.
located_in(c,c1, t.c. t)	located_in(c, c1,t) ↔ part_of(regionFn(c, t) , regionFn(c1, t))
…	

Table 8: Application of relationships in the extended representation

Rel-1	Relation	Rel-2	Comment
I-1	class_member_of at t1	**DC-10**	the specific first aid doctor is a member of the class of the first aid doctors of the Ospedale Niguarda Cà Granda
I-11	role_of at t2	**I-1**	he has the role of medical doctor
I-1	instance_of at t3	**HUMAN BEING**	he is a human being
t1	during	**t2**	the time period during which he is an Ospedale first aid doctor is part of the time period during which he is a medical doctor
t2	during	**t3**	the time period during which he is a medical doctor is part of the time period during which he is a human being
I-1001	instance_of at t4	**HUMAN BEING**	the patient
I-1002	role_of at t5	**I-1001**	his role as emergency patient
t5	during	**t4**	he can only have this role while being a human being (and not, for instance, while being a dead body or a gastrula)
I-2	instance_of	**PATIENT EVALUATION**	the evaluation of the vital parameters
I-2	has_agent at t6	**I-1**	the doctor 'does' the evaluation
I-2	has_participant at t6	**I-1001**	the patient 'undergoes' the evaluation.
t6	during	**t1**	the evaluation happens while the doctor is member of the first aid doctors
t6	during	**t5**	the evaluation happens while the subject is a patient
I-1003	instance_of at t7	**HEALTHCARE FACILITY**	the Ospedale Niguarda Cà Granda
I-1001	located_in at t8	**I-1003**	the patient is in the Ospedale Niguarda Cà Granda
t5	co-continues	**t8**	being an emergency patient starts when located at the first aid department in the hospital, but can take longer, for instance when transported to another facility for certain tests
t6	during	**t8**	the evaluation is done while the patient is in the hospital
I-1	? located_in at t6	**I-1003**	the first aid doctor is probably in the hospital (unless he performs his evaluation using telemedicine services)
…			

[6] we use 't.c.' here as placeholder for any of the applicable temporal comparators

3.9 Assessment of relevant changes within continuants

Continuants undergo various changes during their existence. For instance, when at some point in time an entity is an instance of ADULT, then at an earlier point in time that very same entity must have been an instance of CHILD (see Figure 8). The opposite is not true: not all children grow up to adults. Thus there is universal-level relation transformation_of which holds between continuant universals and which in [13] is defined as:

- C transformation_of C_1 = [def] C and C_1 for all *c*, *t*, if *c* **instance_of** *C* **at** *t*, then there is some t_1 such that *c* **instance_of** C_1 **at** *t*, and t_1 earlier *t*, and there is no t_2 such that *c* **instance_of** *C* **at** t_2 and *c* **instance_of** C_1 **at** t_2.

  thus, for example:

  ADULT transformation_of CHILD.

The example sentence on which we worked thus far does not contain any references to particulars which undergo *relevant* changes of this sort. Of course there are changes: the collection of vital signs of the patient increases while the evaluation is carried out, the report reflecting the clinical history of the patient becomes more complete while the first aid doctor is interviewing the patient and writing down his findings, and so forth.

A relevant change might be encountered when a continuant bodily feature becomes clinically abnormal and this change is detected when performing a second evaluation. However, situations like this can only be captured while linking instance data to the ontology (as part of the application in which the ontology is used), and not *in* the ontology itself.

4 Linking RAPS application ontologies to instance data: a case for Referent Tracking

Today, information is primarily maintained in information systems which consist of data repositories that contain data in either unstructured form (such as free text or digital multi-media objects) or structured form, the latter being such that numerical information is expressed by means of numbers, and non-numerical information by means of codes or terms associated with what is commonly called '*concepts',* taken from different sorts of terminologies (such as vocabularies, nomenclatures, concept systems, and so forth) as they are offered in terminology servers. Since data in structured form are better suited to provide software agents with a deep understanding of what the data represent, considerable efforts are spent to turn unstructured data into structured data, at least partially. However, whether data are captured in structured form when entered, or rendered as such afterwards using text and image analytics software which add codes corresponding to concepts, current information systems exhibit at least two major shortcomings as far as concept-based coding is concerned: (1) formal impreciseness about *what* is tagged, and (2) incompatibility of distinct tagging systems.

Mainstream information systems do not offer a mechanism to unambiguously determine in each individual case what entity in reality a concept from a terminology server is used to relate to. As a consequence, information systems thus conceived work with instances of data, but algorithms working on such data have no clue what the data are about, i.e. about what specific entity in reality each specific data-element contains the information.

If, for example, a driving license number is used in an information system, it is often not formally clear whether the number is used to denote the driving license of a person or that person itself.

As a further example, if in an information system the gender of a person is stated to be '*unknown'*, then it is often not formally clear whether this means either

- that the person does have a gender which is one of the scientifically known gender types such as female, male, mosaic, etc., but that information of the precise gender of that person is not available in that information system, or
- that the gender of that person is known to be of a type which scientifically has not yet been determined.

Another example is that if at a certain time the gender of a specific person is registered in some information system as '*male'*, and at a later time as '*female'*, then there is, under existing data storage paradigms, no way to derive from this change whether the change in the information system reflects

- a change in reality, for instance, because the person underwent transgender surgery,
- a change in what became known about reality: the person's gender might because of a congenital disorder not have been determinable at the time of birth, but only later after several investigations, or
- that there was no change in reality or what we know about it, but that at the time of the first entry a simple mistake was made.

One can even imagine a fourth possibility, namely that the meaning of the word '*female'* would have been changed. The latter might seem to be too far fetched – in fact, this did never happen for the words '*male'* and '*female'* – but there are several examples in the past that come close. The title '*Chief Executive Officer*', for instance, was introduced in Europe in the late eighties, replacing titles such as '*Director General*' or '*Managing Director*'. A change in title, in those days, for sure did not entail a change in position or power of the person to whom the new title was attributed.

4.1 The need for meta-coding

In line with the theory of granular partitions [39] we argue that complex representations should be composed in modular fashion of sub-representations built out of representational units that are assumed to correspond to portions of reality (POR). Some characteristics of the units in a representation are:

- each such unit is assumed by the authors of the representation to be veridical, i.e. to conform to some relevant POR as conceived on the best understanding (which may, of course, rest on errors). Thus if in a data repository a representational unit standing proxy for a specific person is associated with the name 'George Bush', then, under the realist paradigm, we assume that a person with this name exists or has existed (that on the basis of the name only it cannot be determined which specific person is meant, does not make the unit non-veridical);
- several units may correspond to the same POR by presenting different though still veridical views or perspectives, for instance at different levels of granularity (one thing may be described both as being brown and as reflecting light of a certain wavelength, or one event as an event of administering and of consuming drugs);
- what units are included in a representation depends on the purposes which the representation is designed to serve.

The real world is subject to constant change, and so also is our knowledge thereof. To keep track of these two sets of changes, any representation concerning a relationship between entities should be associated with at least the following pieces of information:

- an index for the time period during which the relationship obtains,
- an index for the time at which the representation is made, i.e. the time at which the relationship is (believed to be) known,
- an index for the time that piece of information is made available in the system, and
- an identifier standing proxy for the author of the representation.

Keeping track of these various types of information makes it possible not only to track reality faithfully from the perspective of an individual clinician or patient, but also to preserve the knowledge about what was known by whom and at what time after information which was residing originally in distinct systems becomes merged. It also allows to assess whether information is disclosed in a timely fashion.

Referent Tracking (RT) has been designed to do exactly that! RT is a paradigm for information management that is distinct from other approaches in that each data element has to point to a portion of reality in a number of predefined ways (Figure 11). It has been introduced in the context of Electronic Health Record keeping [40], but its applicability is wider than that, examples being digital rights management [41], corporate memories [42], and achieving semantic interoperability amongst intelligence and national security agencies [43].

4.2 Reality and data about reality

RT uses distinct data types for the various sorts of portions of reality as described in section 3.5 p14 and shown in Figure 11. Thus it makes explicitly the distinction between two sorts of particulars: those that are '*information bearers*', and those that are not; the latter called '*non-referring particulars*'. Whereas non-referring particulars belong exclusively to the first level of reality – they are pure first-order entities – information bearers play a role in both levels 1 and 3.

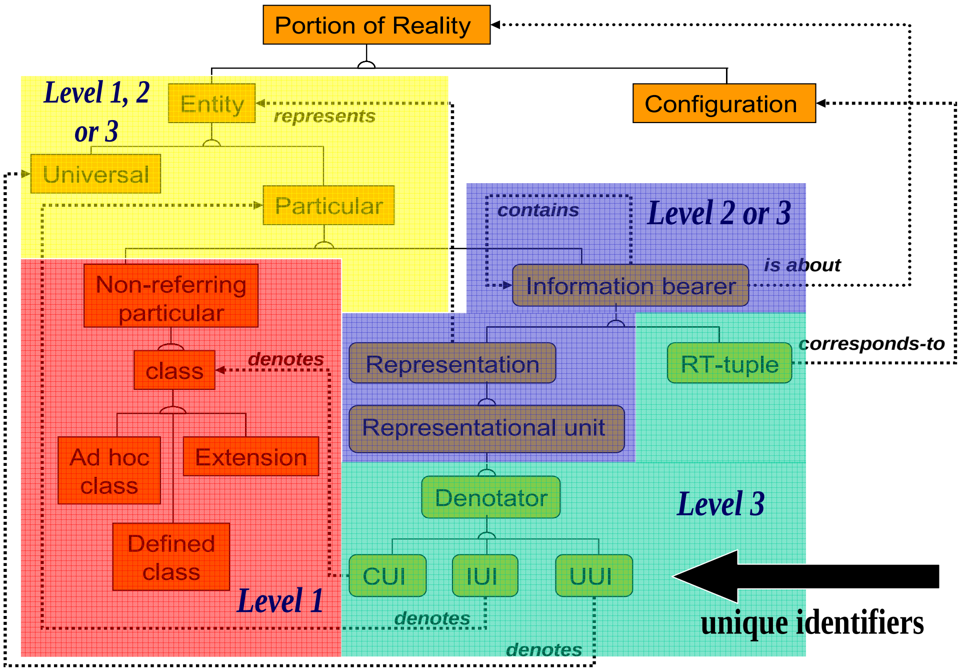

Figure 11: A taxonomy of portions of reality

Examples of information bearers are a piece of paper containing a text about a person's medical history, and a digital object, such as an image of a person in an information system. Information bearers are ***about*** something else, while non-referring particulars are not about something else. Information bearers can be about not only non-referring particulars, an example being the hospital badge of a doctor which is about its working status in that hospital, but also about other information bearers, an example being a textual description of a specific person's badge, stating, for instance, that the name of the doctor is almost not readable. A copy of such a badge can be at the same time about both the card and the rights enjoyed by the badge holder.

Configurations are referred to by means of a data type called a '*RT-tuple*', whereas entities are represented by means of a data type called '*representation*'. Both data types come in several forms depending on the nature of the portion of reality they carry information about.

4.2.1. Assignment of denotators as unique identifiers

A denotator is a representational unit which denotes directly an entity in its entirety without providing a description. An example of a denotator is the string '*Ospedale Niguarda Cà Granda*' in the sentence '*Ospedale Niguarda Cà Granda is a referral centre for all childhood and adult pathologies*'. The sentence itself is an information bearer according to our terminology. Because many representations are built out of constituent sub-representations as their parts, in the way in which paragraphs are built out of sentences and sentences out of words, RT uses the data type called '*representational unit*' to represent such smallest part. Examples are: icons, names, simple word forms, or the sorts of alphanumeric identifiers found in digital records. Note that many images are not composite representations since they are not built out of smallest representational units in the way in which molecules are built out of atoms (Pixels are not representational units in the sense defined.) [23].

RT distinguishes explicitly and formally between three types of denotators, referred to respectively as '*IUI*', '*UUI*' and '*CUI*'.

An IUI – abbreviation for '*Instance Unique Identifier*' – is a denotator in the form of a persistent, globally unique and singular identifier which denotes (or is believed to denote) a particular and which is managed in a referent tracking system. A UUI – for '*Universal Unique Identifier*' is a denotator which denotes a universal within the context of a realism-based ontology. A CUI – abbreviation for '*Concept Unique Identifier*' – is a denotator for entities of a type that is commonly and ambiguously called a '*concept'* [30], but which in BFO corresponds with 'class' or any of its subtypes.

4.2.2. RT-tuples

Configurations are not assigned a denotator because they are not entities in their own right. They are described by RT-tuples. RT-tuples, although all corresponding to portions of reality, come in various flavors depending on the sort of information they contain. RT-tuples are stored in a *RT-system*, which, as shown in Figure 12, can form the bridge between databases in the hospital and the ontologies used.

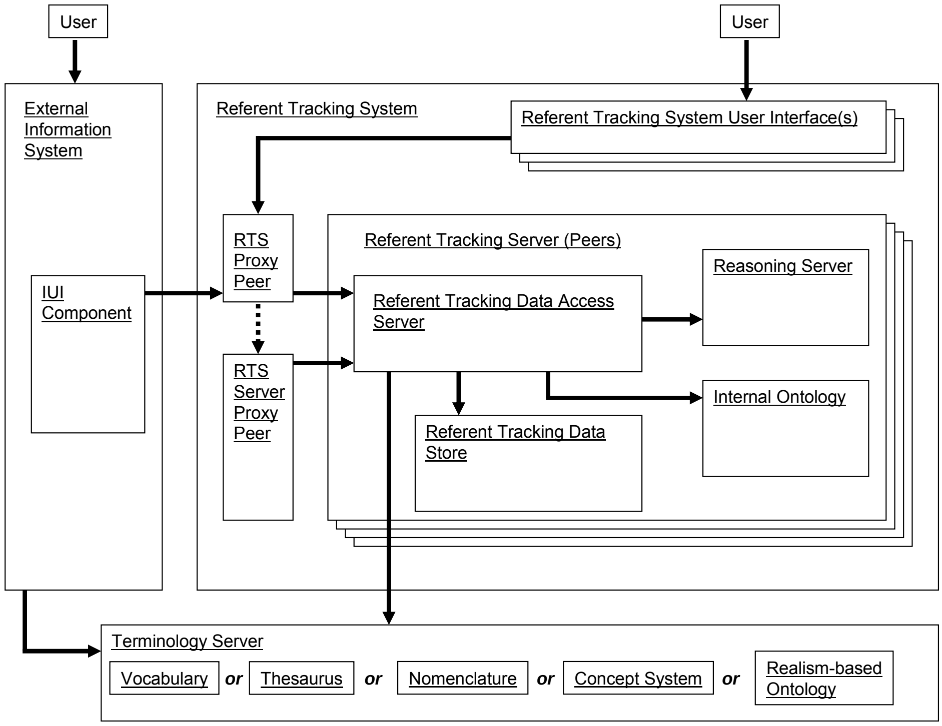

Figure 12: Architecture for keeping track of instances

4.2.2.1 A-tuples

A-tuples correspond to the assignment by some agent of an IUI to a particular. For the typical case, that particular is a pure first-order entity such as a specific person or a specific building about which information is to be stored in the RT system. However, by storing tuples, the RT system itself acts as an agent that assigns IUIs to the tuples itself. Indeed, for each insertion of an A-tuple, there is a corresponding insertion of a D-tuple that contains information about the corresponding A-tuple. To prevent infinite regress, the assignment of these IUIs does not involve the generation of an additional A-tuple, but is implemented through the use of these tuple-IUIs as an internal annotation to the tuple itself.

Three factors can be distinguished as structural elements involved in such an assignment act: (1) the generation of the relevant alphanumeric string, (2) its attachment to the relevant object, and (3) the publication of this attachment [40].

A-tuples are of the form $< IUI_p, IUI_a, t_{ap} >$ where IUI_p is the IUI of the particular in question, IUI_a is the IUI of the author of the assignment act, and t_{ap} is a time-stamp indicating when the assignment was made.

4.2.2.2 D-tuples

In light of the need or desire to resolve mistakes [44], RT includes the use of D-tuples, which are to be created whenever (1) a tuple other than a D-tuple is added to the RTS Data Store, in which case it includes meta-data about by whom and at what time the corresponding tuple was deposited or (2) a tuple, including D-tuples, is declared invalid in the system, in which case it includes additional info concerning the type of mistake committed and the reason therefore.

D-tuples are of the form < IUI_d, IUI_T, t_d, E, C, S >, where:

- IUI_T is the IUI of the tuple about which the D-tuple contains information.
- IUI_d: is the IUI of the entity annotating IUI_T by means of this D-tuple,
- E is either the symbol 'I' (for insertion) or any of the error type symbols as discussed further,
- C is a symbol for the applicable reason for change as discussed further,
- t_d is the time the tuple denoted by IUI_T is inserted or 'retired', and
- S is a list of IUIs denoting the tuples, if any, that replace the retired one.

4.2.2.3 PtoP-tuples

Descriptions which express configurations amongst particulars have the form of *PtoP* – particular to particular – tuples. Here again a number of structural elements can be distinguished:

1. an authorized user observes one or more objects which have already been assigned IUIs in the referent tracking system (RTS) in hand,
2. the user recognizes or apprehends that these objects stand in a certain relation, which is represented in some realism-based ontology,
3. the user asserts that this relation holds and publishes this assertion by entering corresponding data which are then published in the referent tracking data store.

This relationship data will then take the form of an ordered sextuple <IUI_a, t_a, r, IUI_o, P, t_r>, where

a. IUI_a is the IUI of the author asserting that the relationship referred to by r holds between the particulars referred to by the IUIs listed in P;
b. t_a is a time-stamp indicating when the assertion was made;
c. r is the denotator in IUI_o of the relationship obtaining between the particulars referred to in P;
d. IUI_o is the IUI of the ontology from which r is taken;
e. P is an ordered list of IUIs referring to the particulars between which r obtains; and
f. t_r is a time-stamp representing the time at which the relationship was observed to obtain.

P contains as many IUIs as are required by the arity of the relation r. In most cases, P will be an ordered pair which is such that r obtains between the particulars represented by its first and second IUIs when taken in this order.

4.2.2.4 PtoU-tuples

Another type of information that can be provided about a particular concerns what universal within an ontology it instantiates. Here, too, time is relevant, since a particular, through development, growth or other changes, may cease to instantiate one universal and start to instantiate another: thus a particular patient about which an information system might contain information, changed from *foetus* to *newborn*, and from *child* to *adult*. Descriptions of this type (which we will refer to as *PtoU*-tuples – for: particular to universal) are represented by ordered tuples of the form

$<IUI_a, t_a, inst, IUI_o, IUI_p, UUI, t_r>$, where

(1) IUI_a is the IUI of the author asserting that IUI_p is an instance (inst) of UUI;

(2) t_a is a time-stamp indicating when the assertion was made;

(3) inst is the denotator in IUI_o of the relationship of instantiation;

(4) IUI_o is the IUI of the realism-based ontology from which inst and UUI are taken;

(5) IUI_p is the IUI referring to the particular whose inst relationship with the universal denoted by UUI is asserted;

(6) UUI is the denotator of the universal in IUI_o with which IUI_p enjoys the inst relationship; and

(7) t_r is a time-stamp representing the time at which the relationship was observed to obtain.

Note that it is specified from which ontology inst and UUI are taken (and precisely which inst relationship in those cases where an ontology contains several variants). Such specifications not only ensure that the corresponding definitions can be accessed automatically, but also facilitate reasoning across ontologies that are interoperable with the ontology specified.

4.2.2.5 PtoC-tuples

Whereas for PtoU-tuples their denotators of relationships and universals are taken from realism-based ontologies rather than from other knowledge repositories in terminology servers, PtoC-tuples do allow CUIs to be used instead of UUIs. Of course, the relationship to be used is not to be some variant of 'inst' since the standard definitions in use for '*concept'* (such as '*unit of knowledge*' or '*unit of thought*') disallow most particulars from being declared as instances of concepts. PtoC-tuples (for particular to concept code) have the form $<IUI_a, t_a, IUI_c, IUI_p, CUI, t_r>$, where:

1. IUI_a is the IUI of the author asserting that terms associated to *CUI* may be used to describe IUI_p;
2. t_a is a time-stamp indicating when the assertion was made;
3. IUI_c is the IUI of the concept-based system from which *CUI* is taken;
4. IUI_p is the IUI referring to the particular which the author associates with *CUI*;
5. *CUI* is the CUI in the concept-system referred to by IUI_c which the author associates with IUI_p; and
6. t_r is a time-stamp representing a time at which the author considers the association appropriate.

Such tuples are to be interpreted as providing a facility equivalent to a simple index of terms in a work of scientific literature.

4.2.2.6 PtoU(-) – tuples

Since the RT paradigm requires that only entities that exist or have existed are to be assigned an IUI, a capability is provided that deals with what is called 'negative findings' or 'negative observations' as captured in expressions such as: 'no medical history', 'cancer ruled out', 'absence of imminent danger', and 'abortion prevented'. Such statements seem at first sight to present a problem for the referent tracking paradigm, since they imply that there are no entities in reality to which appropriate unique identifiers could be assigned. We therefore defined the relationship '*p* lacks *u* with respect to *r* at time *t*' such that there obtains a relation between the particular *p* and the universal *u* at time *t*, which is such that *p* stands to no instance of *u* in the relationship *r* at *t* [45, 46].

This ontological relation can be expressed by means of a 'PtoU(-) tuple' which is a lacks-counterpart of the PtoU-tuple and has the form $<IUI_a, t_a, r, IUI_o, IUI_p, UUI, t_r>$, expressing that the particular referred to by IUI_a asserts at time t_a that the relation *r* of ontology IUI_o does not obtain at time t_r between the particular referred to by IUI_p and any of the instances of the universal *UUI* at time t_r.

4.2.2.7 PtoN-tuples

Important particulars such as persons, buildings, meeting rooms, organisations and so forth are often given proper names which function as denotators in reality outside the context of a referent tracking system. This sort of information is stored in an RTS by means of one or more 'PtoN-tuples' where 'N' stands for 'name'. These tuples have the form $< IUI_a, t_a, nt, n, IUI_p, t_r, IUI_c >$, where

(1) IUI_a is the IUI of the author asserting that *n* is a name of type *nt* used by IUI_c to denote IUI_p;

(2) t_a is a time-stamp indicating when the assertion was made;

(3) IUI_c is the IUI for the particular that uses the name *n* (this can be a person, a community of persons, an organization, an information system, ...);

(4) IUI_p is the IUI referring to the particular which the author associates with *n*;

(5) *n* is the name which the author associates with IUI_p;

(6) *nt* is the nametype (examples being first name, last name, nick name, social security number, and so forth); and

(7) t_r is a time-stamp representing a time at which the author considers the association appropriate.

4.2.3. Relations between information bearers and portions of reality

RT distinguishes explicitly and formally between various relations that obtain between information bearers and the various types of portions of reality it is capable of describing. These relations are:

(1) ***is-about***, which obtains between an information bearer and a portion of reality, such as, for example, the medical record of a patient (the record being an information bearer) being about parts of that patient and his environment (a combination of several configurations in which figure, besides that patient, various other entities such as his family, doctors, hospital visits, and so forth).

(2) ***corresponds-to***, which obtains between an RT-tuple and a configuration;

(3) ***represents***, which obtains between a specific subtype of information bearer, namely what we call a '*representation*', and some further entity (or collection of entities). A representation is thus such that (1) the information it contains is about an entity, and not a configuration, external to the representation and (2) it stands for or represents that entity. Examples are an image, record, description or floor plan of a hospital. Note that a representation (e.g. a description such as 'the man over there on the corner') represents a given entity even though it leaves out many aspects of its target.

(4) ***denotes***, which obtains between data-elements expressed by means of a '*denotator'* and an entity.

(5) ***contains***, which obtains between information bearers and can be used to express what pieces of information of a specific data type are parts of other pieces of information. An example is a digital message which contains RT-tuples describing configurations of entities in which a specific person figures.

4.3 Setting up an institutional RAPS management system using realism-based application ontologies

It is essential to assign to all relevant particulars in the institution an Instance Unique Identifier (IUI), whereby relevance is determined by the presence of a universal or defined class in the application ontology of which the particular is an instance or member. If environmental factors are to be monitored, then IUIs are to be assigned to each corridor, each handrail, each room, each device, and so forth. If the purpose is to focus on liveware, then that should be done for each staff member, each patient, and so forth.

As a next step, the IUIs should be used in RT-tuples to describe for each particular its relationships to other particulars, its membership in defined classes, and its instantiation of universals. These annotations need to be updated when there are changes in reality, in the perception thereof or in the ontology. A lot of these updates can be done on the basis of changes in the electronic health record or other institutional databases such as the ones maintained in human resource management systems, equipment inventories, and so forth. Certain environmental changes can be captured by means of domotics systems that acquire their input from, for instance, light sensors and motion detectors in rooms and corridors.

5 From the RAPS Taxonomy to RAPS application ontologies

5.1 Choice of development environment

The RAPS Taxonomy described in [47] was one of the sources to determine the scope of the RAPS Domain Ontology [35]. Because of the presence of terms related to the specific needs of the chosen pilots for the ReMINE project, it is also a useful resource for developing the application ontologies. That the RAPS Taxonomy has been made available in OWL would make it possible to use OWL-compatible ontology authoring environments. However, there are currently no ontology authoring environments that support the realism-based approach in full, the main problems being:

(1) the temporal constraints on relations,

(2) the distinction between classes as collections of particulars on the one hand and universals on the other hand, and

(3) the need to have explicit representation of particulars in reality, and not as ‘concepts’ what would render them indistinguishable from ‘concepts’ that correspond to classes.

Another challenge is that – despite the availability of BFO as a realism-based upper ontology and the decision of the most important players in the biomedical ontology arena, i.e. the collaborators of the OBO-Foundry initiative [10, 11], to use it as the common framework of choice – realism-based biomedical domain ontologies are still in full expansion and sometimes undergo important changes from one version to another. For ReMINE, this means that the RAPS Domain and Application Ontologies need to be developed almost simultaneously, while keeping track of the modifications that the OBO-Foundry ontologies undergo.

For these reasons, we decided to develop the application ontologies in a form of predicate logic with a strict referential semantics and in such a way that only formal relations figure as predicates [48]. Thus to express that John is a human being, we do not use the standard

‘human_being(John)’

but rather the strongly typed

‘instance_of(John, human_being, t)’

in which each argument denotes an entity in reality of a very specific type. The sort of entity that can qualify for an argument in a particular position is determined by the relation itself. For the instantiation relation, as discussed in section 3.6.1, the possibilities are:

instance_of(<continuant particular>, <continuant universal>, <time-period>), and

instance_of(<processual particular>, <processual universal>).

This is an advantage over standard, less controlled approaches in which the form of the statements does not give any clue about the nature of what is denoted, everything being qualified as ‘properties’ e.g.

human_being(John) :

sick(John) :

hasLeftLeg(John) :

…

The realist paradigm, in contrast, insists on making it crystal clear that what is expressed by using the same form in the examples above, are portions of reality of very distinct sorts, respectively instantiation of a universal, inherence of a quality, and a part-of relation between John and his left leg.

The disadvantage, at first sight, is that what could be expressed in a simple way by means of a more relaxed language, requires often more work. As an example, 'hasleftleg(John)' requires the following statements in our language[7]:

part_of(#1,John, t)

instance_of(#1, left leg, t),

where #1 denotes John's left leg, and not somebody else's left leg. How, after all, would it be possible to disambiguate the pair of statements 'hasLeftLeg(John)' and 'hasLeftLeg(Mary)' as meaning that (1) John and Mary have each a different left leg, (2) as Siamese twins share the same left leg, (3) what once was either one's left leg became after transplantation the other one's left leg, and so forth.

Our approach would have three different sets of statements for each of these possibilities:

- John and Mary have each a different left leg:

  part_of(#1,John, t) part_of(#2,Mary, t)

  instance_of(#1, left leg, t), instance_of(#2, left leg, t),

- John and Mary share the same left leg:

  part_of(#1,John, t) part_of(#1,Mary, t)

  instance_of(#1, left leg, t),

- John's left leg became Mary's left leg:

  part_of(#1,John, t_1) part_of(#1,Mary, t_2)

  instance_of(#1, left leg, t_1), instance_of(#1, left leg, t_2),

  earlier_than(t_1, t_2)

At the other hand, this language forces the ontology developer to analyse reality in greater detail and more principled. OWL gives us logical language constructs, but does not give us any guidelines on how to use them in order to solve our tasks. E.g. modelling something as an individual, as a class, or as an object property is done often quite arbitrary.

In order to make it easier to use the correct referential indices for particulars about which several statements are made – and for which, as a consequence, the same referential index must be used in each of these statements such as '#1'and '#2' in the examples above – we decided to use Microsoft Excel as a temporary development environment, thereby taking advantage of the automatic renumbering and updating of cross-references that this application provides. Once an application ontology is ready for publication, the statements in the Excel worksheets can be translated in a formal language that satisfies the requirements of the application for which the ontology has to provide the knowledge thereby remaining faithful to the ontological structure of that portion of reality which is relevant for that application.

In the following sections, we give a description of the layout of the Excel workbook used and the various sheets that we defined within it.

[7] The notation we use here is a simplified form of the RT-tuples that would be used in an actual application. Indeed, while developing the first version of an ontology, there is no need to express for each statement that this or that ontology author is responsible, or that the expression was added at this or that time. These meta-elements can be added all at once when the ontology is ready for publication

5.2 Structure of the RAPS Ontology Workbook

As shown in Figure 13, our ontology authoring workbook consists of the following sheets:

- one for each version of the RAPS taxonomy, in this case two which are labeled ‘20080602’ and ‘20080808’ respectively corresponding to the delivery data. It is of the latter of which the upper part of the taxonomy is displayed,
- one for the RAPS Domain Ontology (labeled ‘CoreOntology’) which serves as a repository of denotators for universals and classes, including their definition, applicable in broader contexts,
- one for the application ontology based on the terminology provided in the taxonomy, and.
- one for the relations used in either ontology, including their requirements for use

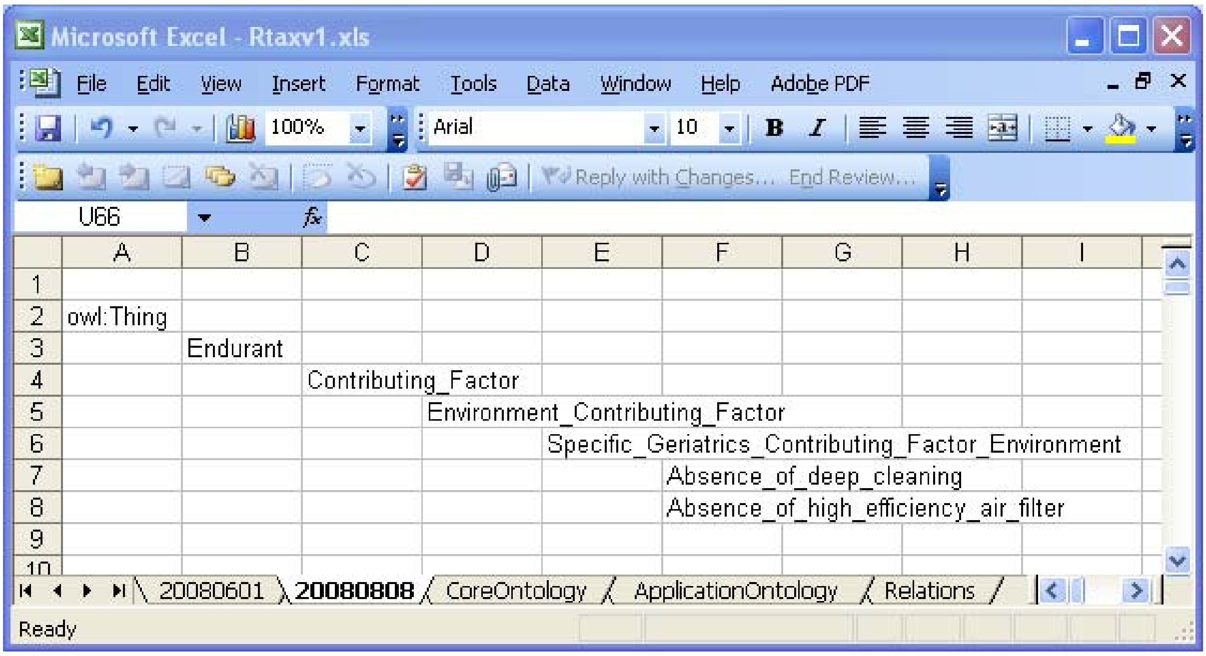

Figure 13: Overview of worksheets in the Excel Workbook serving as ontology authoring environment

5.2.1. Taxonomy worksheets

In a taxonomy worksheet (Figure 15, p41), the columns ‘A’ through ‘L’ contain the RAPS Taxonomy in its original structure. The other columns serve the following purposes:

M: Indicates to what a reference is made in the corresponding statement, e.g.

- U: a universal
- c: a continuant (particular)
- o: an occurrent (particular)
- R: a relation
- DC: a defined class

N: Indicates more specifically to what reference is made:

- U-xxxxx: a specific universal as denoted in the ***ApplicationOntology*** worksheet,
- c-xxxxx: a variable for the particular that would be annotated in a specific case:

- e.g.: the specific site (room B1.206 of the healthcare facility where the ReMINE system is used) where the filter is lacking,

  – R-xxxxx: an identifier for the relational expression (RT-tuple) that asserts something about entities already referred to.

O: Further specification (if any) of:

- – For universals: nothing (column contains a copy of the UUI)
- – For particulars: either the universal of which the particular denoted in the previous column is an instance, or the class of which it is a member
- – For relations: the identifier (from the list provided in the ***Relations*** worksheet) for the relation used in the relational expression.

P: The term for the portion of reality denoted by the identifier in the 'O' column.

Q-T: Specifies the relata of the relational expression, and, if so required, an indication that the relationship holds during some time.

- To find what the denotators for the relata stand for:
  - – For universals and classes: look in the ***ApplicationOntology*** worksheet to the row indicated by the numeric part of the denotator,
  - – For particulars: look at the specified row in the taxonomy worksheet itself.

U: A natural language expression for what the represented entity stands for.

5.2.2. ApplicationOntology Worksheet

As shown in Figure 14, the Application Ontology worksheet contains columns of which the cells denote respectively whether the representational unit is a universal or any of the classes (column 'A'), a temporary identifier for the unit which is automatically generated and updated with each change in the hierarchy and re-used in the other worksheets (column 'B') and the actual hierarchy of the application ontology itself. Terms are prefixed by the source ontology where 'BFO' stands for Basic Formal Ontology and 'ReM' for ReMINE.

A	B	C	D	E	F	G	H	I	J	K	L
U	U-00001	BFO:Entity									
U	U-00002		BFO:Occurrent								
U	U-00003			BFO:Processual entity							
U	U-00004				BFO:Process						
U	U-00005					ReM:Cleaning					
U	U-00006						ReM:Deep cleaning				
U	U-00007						ReM:Regular cleaning				
U	U-00008					ReM:Motion					
U	U-00009			BFO:Temporal region							
U	U-00010				BFO:Scattered temporal region						
U	U-00011					ReM:Day temporal region					
U	U-00012					ReM:Night temporal region					
U	U-00013		BFO:Continuant								
U	U-00014			BFO:Independent continuant							
U	U-00015				BFO:Material entity						
U	U-00016					BFO:Object					
U	U-00017						ReM:Device				
U	U-00018							ReM:Air filter			
U	U-00019								ReM:High efficiency air filter		
U	U-00020							ReM:Silver ion based object			
U	U-00021							ReM:Ventilation system			
U	U-00022							ReM:Handrail			
U	U-00023							ReM:Bed			
U	U-00024			BFO:Dependent Continuant							
U	U-00025				BFO:Specifically Dependent Continuant						
U	U-00026					BFO:Quality					
U	U-00027						ReM:Illumination				
DC	DC-00028							ReM:Insufficient illumination			
U	U-00029						ReM:Treedimensional size				

Figure 14: ApplicationOntology worksheet

	A	B	C	D	E	F	M	N	O	P	Q	R	S	T	U	V
1								ID								
2	owl:Thing															
3		Endurant														
4			Contributing_Factor													
5				Environment_Contributing_Factor												
6					Specific_Geriatrics_Contributing_Factor_Environment											
7						Absence_of_deep_cleaning	U	U-00006	U-00006	ReM:Deep cleaning						meaning?
8						Absence_of_high_efficiency_air_filter	U	U-00018	U-00018	ReM:High efficiency air filter						
9							c	c-00009	U-00035	BFO:Site					the site where such filter is lacking	
10							R	R-00010	F-00038	lacks-contains	c-00009	U-00018	at	o-00011		
11							o	o-00011	U-00009	BFO:Temporal region					the temporal region during which R-00010 holds	
12						Absence_of_regular_cleaning	U	U-00007	U-00007	ReM:Regular cleaning						absence where?
13						Absence_of_silver_ion_fabrics_and_systems	U	U-00019	U-00019	ReM:Silver ion based object						absence where?
14						Absence_of_ventilation_Systems	U	U-00020	U-00020	ReM:Ventilation system						
15							c	c-00015	U-00035	BFO:Site					the site where such ventilation system is lacking	
16							R	R-00016	F-00038	lacks-contains	c-00015	U-00020	at	o-00017		
17							o	o-00017	U-00009	BFO:Temporal region					the temporal region during which R-00016 holds	
18						Absense_of_handrails_in_corridors	U	U-00021	U-00021	ReM:Handrail						
19							c	c-00019	U-00036	ReM:Corridor					the corridor where handrails are lacking	
20							R	R-00020	F-00038	lacks-contains	c-00019	U-00021	at	o-00021		
21							o	o-00021	U-00009	BFO:Temporal region					the temporal region during which R-00020 holds	
22						Insufficient_day_lighting	c	c-00022	DC-00027	ReM:Insufficient illumination						
23							o	o-00023	U-00011	ReM:Day temporal region					the temporal region during which it is day at c-00024	
24							c	c-00024	U-00035	BFO:Site						
25							R	R-00025	F-00020	inheres-in	c-00022	c-00024	at	o-00026		
26							o	o-00026	U-00010	BFO:Scattered temporal region					the temporal region during which R-00025 holds	
27							o	o-00027	U-00010	BFO:Scattered temporal region					the temporal region during which o-00023 and o-00026 overlap	
28							R	R-00028	F-00006	part-of	o-00027	o-00026				
29							R	R-00029	F-00006	part-of	o-00027	o-00023				
30						Insufficient_night_lighting	o	o-00030	U-00012	ReM:Night temporal region					the temporal region during which it is night at c-00032	
31							c	c-00031	DC-00027	ReM:Insufficient illumination						
32							c	c-00032	U-00035	BFO:Site						
33							R	R-00033	F-00028	inheres-in	c-00031	c-00032	at	o-00034		
34							o	o-00034	U-00018	BFO:Scattered temporal region					the temporal region during which R-00033 holds	
35							o	o-00035	U-00018	BFO:Scattered temporal region					the temporal region during which o-00030 and o-00034 overlap	
36							R	R-00036	F-00014	part-of	o-00035	o-00034				
37							R	R-00037	F-00014	part-of	o-00035	o-00030				

20080601 | 20080808 | CoreOntology | ApplicationOntology | Relations

Figure 15: Taxonomy worksheet

5.2.3. Relations Worksheet

The relations worksheet (Figure 16) contains the following information:

A: The sort of relation in terms of RT-tuples

- PtoP: particular to particular
- PtoU: particular to Universal
- …

B: First relatum

C: Second relatum

D: A unique identifier for the relation which is re-used in the Taxonomy worksheet and becomes updated each time the structure of the relation ontology changes

E: A natural language term for the relation

F: Whether a time stamp is required

Depending on the sort of reasoning that will be implemented at the pilot sites, additional information such as formal definitions and axioms in line with the OBO Relation Ontology [13] will be added in future releases.

	A	B	C	D	E	
1		**Relatum-1**	**Relatum-2**	**ID**	**Formal Relation**	**at time**
2	**PtoP**	continuant	continuant	F-00002	genidentical-with	N
3		independent continuant	independent continuant	F-00003	transformation-of	
4		independent continuant	independent continuant	F-00004	derivation-of	
5		continuant	continuant	F-00005	part-of	
6		occurrent	occurrent	F-00006	part-of	
7		continuant	occurrent	F-00007	segmentation-of	
8		independent continuant	processual entity	F-00008	participates-in	
9				F-00009	perpetrates	
10				F-00010	initiates	
11				F-00011	perpetuate	
12				F-00012	terminates	
13				F-00013	influences	
14				F-00014	facilitates	
15				F-00015	hinders	
16				F-00016	prevents	
17				F-00017	mediates	
18				F-00018	patient-of	
19		dependent continuant	processual entity	F-00019	realizes	
20		dependent continuant	independent continuant	F-00020	inheres-in	
21		processual entity	independent continuant	F-00021	involves	
22				F-00022	creates	
23				F-00023	sustains-in-being	
24				F-00024	degrades	
25				F-00025	destructs	
26				F-00026	affects	
27				F-00027	demarcates	
28				F-00028	blurs	
29		processual entity	dependent continuant	F-00029	affects	
30				F-00030	creates	
31				F-00031	sustains-in-being	
32				F-00032	degrades	
33				F-00033	destructs	
34		continuant	continuant	F-00034	located-in	
35		continuant	continuant	F-00035	contained-in	Y
36		continuant	continuant	F-00036	contains	Y
37		spatial region	spatial region	F-00037	adjacent-to	N
38	**PtoU**	continuant	continuant	F-00038	lacks-contains	Y

Figure 16: Relations Worksheet

5.2.4. Core Ontology worksheet

The details of this worksheet are described in Deliverable D4.2 [35]. For the sake of completeness, we show here just part of a table that is further explained there.

Denotation	Unit Type	Particular Type	Description (role in risk management)	Comment
act of care	U	process	**process** (1) which has agent a care giver and (2) underwent by a subject of care, and (3) is motivated by an underlying disease and a care intention	• (3) excludes that **processes** whose agents are care givers but that are not performed under the care giver role would be qualified as acts of care (e.g. a doctor hurting a patient in a car accident on the parking lot of a care facility)
act under scrutiny	DC	act of care	act of care which is member of process under scrutiny	
adverse event	DC	process	**process** denoted by a denotator in a RAPS adverse event repository	• If the RAPS adverse event repository were faithful to reality, each member of adverse event would be a member of harm. • If he RAPS adverse event repository were *locally complete*, each member of harm that occurred in the RAPS system's realm in which the RAPS adverse event repository is installed would be a member of adverse event
…				•

5.3 An example: analysing the RAPS Taxonomy term '*Insufficient day lighting*'

For 'insufficient day lighting' to be a faithful annotation for a contributing factor to an adverse event, there must have been:

(1) a site (room, corridor, …),

(2) at least one period of time during which there was insufficient illumination of site (1),

(3) at least one period of time during it was day at site (1),

(4) (at least one period of time during which (2) and (3) overlap.

Illumination is defined as a 'determinable' BFO quality [49] for which there is a 'determinate' value which can be described by the term 'insufficient illumination'. The latter is a defined class because what counts as 'insufficient' is a matter of judgment.

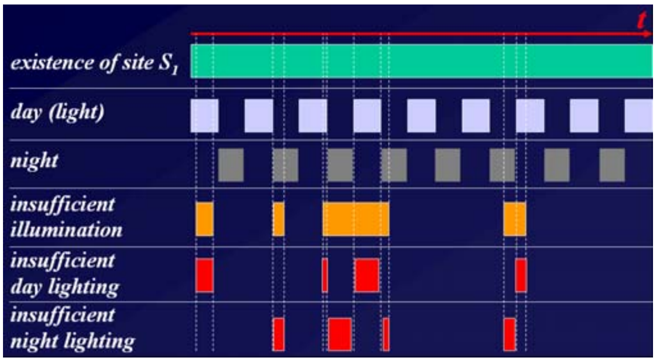

Figure 17: Time chart with entities relevant in the context of insufficient day lighting

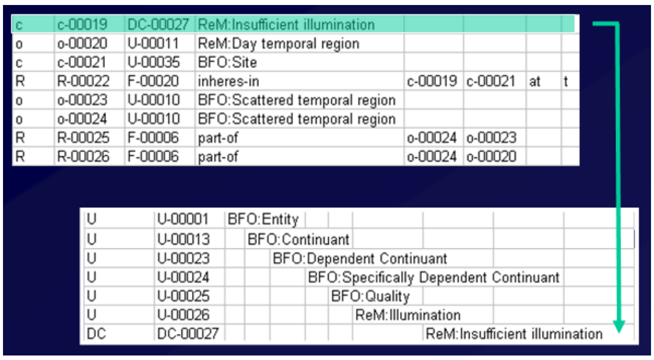

Figure 18: Cross-linking Taxonomy entries to the application ontology

In general, dependent entities inhere in independent entities, thus here: the illumination inheres in the site. The insufficient quality of illumination does not need to be present all the time. Therefore, a temporal region (in this case o-00026) must be specified for the relationship.

c	c-00022	DC-00028	ReM:Insufficient illumination				
o	o-00023	U-00011	ReM:Day temporal region				
c	c-00024	U-00036	BFO:Site				
R	R-00025	F-00020	inheres-in	c-00022	c-00024	at	o-00026
o	o-00026	U-00010	BFO:Scattered temporal region				
o	o-00027	U-00010	BFO:Scattered temporal region				
R	R-00028	F-00006	part-of	o-00027	o-00026		
R	R-00029	F-00006	part-of	o-00027	o-00023		
o	o-00030	U-00012	ReM:Night temporal region				

There exists also a temporal region during which it is day at site c-00024, namely o-00023. Finally, there is a temporal region (o-00027) which is the one that overlaps with the region during which it is day at the site and the region during which there is insufficient illumination

c	c-00022	DC-00028	ReM:Insufficient illumination				
o	o-00023	U-00011	ReM:Day temporal region				
c	c-00024	U-00036	BFO:Site				
R	R-00025	F-00020	inheres-in	c-00022	c-00024	at	o-00026
o	o-00026	U-00010	BFO:Scattered temporal region				
o	o-00027	U-00010	BFO:Scattered temporal region				
R	R-00028	F-00006	part-of	o-00027	o-00026		
R	R-00029	F-00006	part-of	o-00027	o-00023		
o	o-00030	U-00012	ReM:Night temporal region				

6 Reasoning with realism-based application ontologies

6.1 Referent Tracking and action-oriented formalisms

RT, at first sight, might look similar to other approaches. For instance, the need to track objects through time as they change, and to reason (and to have machines sometimes reason) over information that describes such changes, is what motivated calculi such as the situation calculus, the event calculus, and the fluent calculus, as well as some Knowledge Representation and Reasoning Systems. These approaches seek an efficient solution to the *projection problem* [50]: given an action theory that specifies the preconditions and effects of actions (including sensing), and a knowledge base about the initial state of the world, determine whether or not some condition holds after a given sequence of actions has been performed [51].

The situation calculus is a logic formalism that was first introduced by John McCarthy in 1963 [52] and since then underwent a few modifications [53]. The basic elements of situation calculus are:

(1) *actions* that can be performed in the world,

(2) *fluents* that describe the state of the world, each fluent thus being the representation of some property, and

(3) *situations*.

McCarthy and Hayes considered a situation to be '*a complete state of the universe at an instant of time*' [54], a position which is also maintained in fluent calculus [55], whereas others redefined situations as finite sequences of actions, thus a history of actions [53]. Event calculus does without situations, and uses only actions and fluents, whereby the latter are functions – rather than predicates as is the case in situation calculus – which can be used in predicates such as *HoldsAt* to state at what time which fluents hold [56].

RT differs in substantial ways from these logical formalisms. First of all, the goal of RT is not just to represent actions and changes, but all entities that exist in reality. Furthermore, these sorts of logics focus on computational aspects, but do not provide an integrated ontological characterization of entities such as actions, plans, and, because of their four-dimensionalist nature, for sure not of objects. It has been shown that it pays off to add more ontological rigor to formalisms such as situation calculus, for instance by using it only as one component for causal reasoning within a more elaborate, multi-component system [57].

RT, in contrast, is not in the first place a computational framework, but rather a representational one anchored in the realist view adhered to in Basic Formal Ontology (BFO) [33]. BFO distinguishes, for instance, continuants (such as patient John Doe) from occurrents (such as John Doe's life or his last visit to the hospital). These distinctions, including BFO's treatment of locations, positions and location schemes, was deemed essential in building a robot navigation model on top of situation calculus as embedded in Kuipers' Spatial Semantic Hierarchy [58]. Relationships of the sort expressed by, for instance, RT's PtoP- and PtoU-tuples hold only during certain time-periods [13, 59], and when they hold is expressed in the corresponding tuples themselves. In addition, PtoU-tuples express what universals a particular instantiates, thus also whether the entity described is an action or an object. Although no attempt has been made thus far, it seems plausible to assume that it is possible to express part of an RT database in terms of situation or event calculus.

6.2 Facts versus beliefs

The requirements within RT that tuples must make direct and explicit reference to that what they are about, and that this can only be done for entities that exist or have existed, would seem to make it very difficult to represent uncertain, or possibly deceptive knowledge. One can wonder if, for example, beliefs can be recorded in the system. Similar questions can be asked about things in the future: isn't it important for a representational framework to be able to state knowledge about future happenings and entities that might not exist until the future, such as the laparoscopy that a patient will undergo tomorrow?

It is here that the distinction between three levels of reality as discussed in section 3.4.1 and the assignment of IUIs to RT-tuples themselves play a role. If a PtoP-tuple to which IUI-457 is assigned states that John Doe suffered from pneumonia in 2007, then the latter is taken to be a representation of reality – which of course may be a mistake – whereas IUI-457 is the proposition that the latter is the case. That this proposition is entertained (or not) by a specific person can be expressed by additional PtoP-tuples that relate the tuple in question to that person by referring also to adequate belief-related relations or processes depending on what sort of ontology is used. As in the case of action logics, RT itself does not come with a logic of beliefs, but from the representations, so we believe, secondary representations in terms of a belief logic can be generated.

For entities in the future, RT offers the possibility to *reserve* IUIs, rather than to *assign* IUIs [40]. Thus it is possible to assign an IUI to the plan to have a patient undergo certain diagnostic tests, whereas the detailed RT representation of that plan itself would contain a reserved IUI for the particular tests.

6.3 Maintaining integrity

There are several challenges in maintaining the representational integrity of an RT compatible system, specifically with respect to the requirements that an IUI within an RTS should denote only one entity, and that there is only one IUI for a specific entity. If, for instance, one doesn't know that 'John Doe' and 'Johnny Doe' denote the same individual, how could one possibly know to relate both names to the IUI denoting that individual? Here responsibility for faithful representation is shared between the user and the user interface. Whereas the former must devote enough effort to find out in each specific case what individual a name denotes, the latter, assisted by additional applications, must make it possible to reduce the effort required. Term comparison algorithms might be used to inform a user that a name similar to the one entered is already registered. Triggers and alerts can be implemented to warn a user that distinct individuals have the same name, and so forth. All this, however, does not guarantee that the right decision will be made in every case, and errors will very likely occur. So there have to be procedures to detect and correct mistakes. It is here that the D-tuples play an important role [44].

Easy to solve, once detected, are mistakes in which a particular has been assigned more than one IUI. In this case, only one of these IUIs would be used in future tuples, whereas all tuples in which the other IUIs are used will be replaced by tuples in which that one IUI will replace the redundant ones. This mechanism guarantees that it still remains known that during some period in the past, information concerning one particular was believed to be about two or more particulars.

More work would be required in the opposite case, i.e. when the same IUI is used to denote distinct particulars. Here it might be necessary to perform a manual revision of the tuples in which that is used.

To detect mistakes, the ontologies in whose terms RT-tuples are expressed can be used to guide integrity-checking routines that run over the RTDB. Because, for instance, persons (or any material continuant) cannot be at two distinct places in the same time, the presence of RT-tuples in the RTS that suggest this to be the case, indicates a mistake of the type 'one IUI for distinct particulars'. Logically, because two distinct material continuants cannot occupy the same spatial region, any collection of RT-tuples representing that this would be the case must contain an error of the type 'distinct IUIs for the same particular'.

6.4 An example: preventing accidents because of insufficient light

Imaging that at a ReMINE pilot hospital a domotics system is used that acquires input from light sensors and motion detectors in rooms and corridors, and that representations thereof are in the RAPS management system. Similarly, patients and staff wear RFID tags, and relevant data, as explained further, is stored in the RAPS management system as well. A possible configuration is shown in Figure 19.

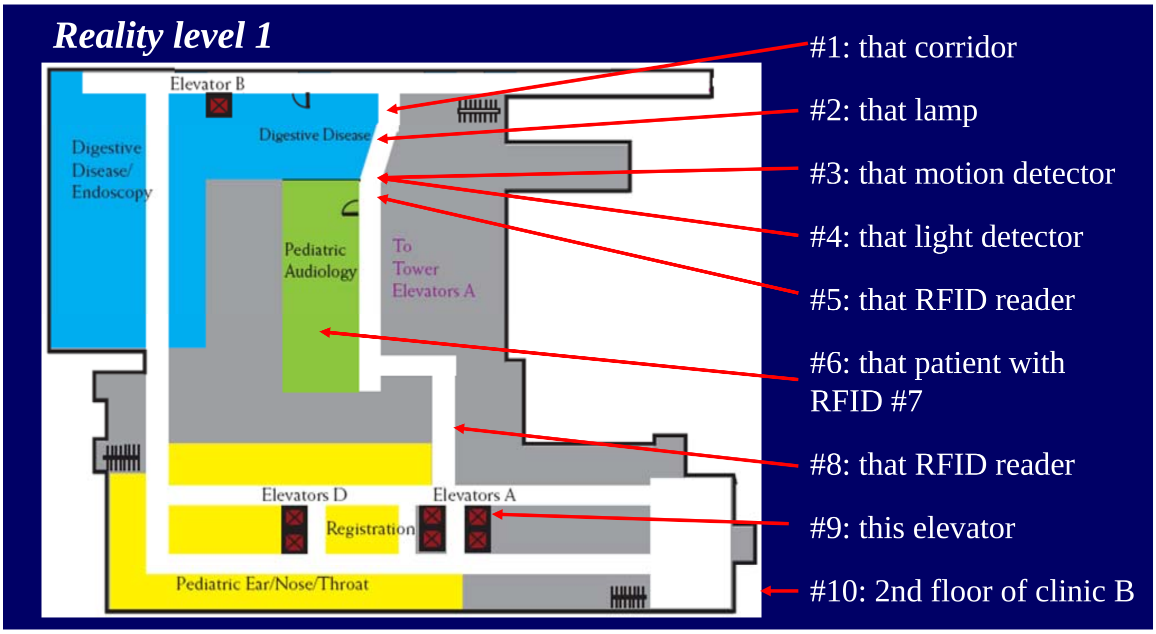

Figure 19: Assignment of IUIs to relevant entities for the prevention of accidents

Relevant parts of the floor plan are represented in the RAPS management system by RT-tuples describing semi-stable relationships such as:

(1) #1 **instance-of** ReM:Corridor **since** t1

(2) #2 **instance-of** ReM:Lamp **since** t2

(3) #2 **contained-in** #1 **since** t3

(4) #6 **member-of** ReM:Patient **since** t4

(5) #6 **adjacent-to** #7 **since** t4

(6) #18 **instance-of** ReM:Illumination **since** t1

(7) #18 **inheres-in** #1 **since** t1

(8) …

The relationships are 'semi-stable' because changes may happen: lamps may be replaced, persons are not patients all the time, and so forth. Keeping track of these changes provides a history for each tracked entity.

What are 'sufficient' illumination levels for specific sites is expressed in defined classes. Each change in a detector is registered in real time in the RAPS management system and an action-logic is implemented in a rule-base system, for instance to generate alerts. As an example, the illumination requirements for lamp #2 can be specified as:

(1) #18 **member-of** ReM:Insufficient illumination **during** t_y

a. if

i.	t_x	**part-of**	ReM:Daytime	
ii.	#y_1	**instance-of**	ReM:Motion-detection	
iii.	#y_1	**has-agent**	#3	**at** t_y
iv.	t_y	**part-of**	t_x	
v.	#y_2	**instance-of**	ReM:Illumination measurement	
vi.	#y_2	**has-agent**	#4	**at** t_y
vii.	#y_2	**has-participant**	#18	**at** t_y
viii.	#y_2	**has-result**	imr_z	**at** t_y
ix.	imr_z	**less-than**	30 lumen	

b. else

i.	t_x	**part-of**	ReM:Night time
ii.	…		

c. endif

Now imagine patient #6 (wearing RFID tag #7) walking through corridor #1. The changes observed by the various detectors, via the domotics system connected to the RAPS management system, would give rise to the following RT-tuples

o	#2345	**instance-of**	ReM:Motion-detection	
o	#2345	**has-agent**	#3	**at** t4
o	#2346	**instance-of**	ReM:RFID-detection	
o	#2346	**has-agent**	#5	**at** t4
o	#2346	**has-participant**	#7	**at** t4
o	…			

In this example, the happening of #2345 fires the rule above. If imr_z turns out to be too low, that might invoke another rule which sends an alert to the ward that lamp #2 might be broken. #2346 might trigger yet another rule, namely an alert for imminent danger for an adverse event with respect to patient #6.

7 Future work

Several tasks need to be performed in continuation of the efforts conducted thus far. The largest one is the further development of the application ontology underlying the RAPS Taxonomy. Priority must thereby be given to the pilot applications, and specifically the sort of automated processing that they intend to provide. This will lead to a number of 'candidate' application ontologies of which the list will grow in the future.

Another task is deciding on a representation language to be used. It is a serious mistake often committed in computer science and knowledge engineering circles to think that all it takes for something to be an ontology, is to have it expressed in OWL [20]. This mistake should not be made in ReMINE. It is true that if an ontology is expressed in OWL, it can, for instance, be loaded in applications such as Protégé. But most often, it ends there! As we have shown earlier, OWL does not provide a standard mechanism to deal with the temporal aspects of instantiation and other relationships.

7.1 Candidate application ontologies

7.1.1. First Aid Transfer

The *Ospedale Niguarda Ca' Granda* has elaborated a procedure to streamline the transfer of a patient from First Aid (FA) to a next level of care. The procedure, as outlined in Table 9, starts from the time the patient is evaluated by a First Aid Doctor (FAD) and ends with an internal or external transfer.

Table 9: Example of a patient transfer protocol

Step	Description	Responsible party
1	**Accepted patient evaluation**: after a rapid evaluation at triage, the patient is reevaluated by the FAD. The FAD evaluates vital parameters and possible alterations, acquires possible personal health documentation and asks for diagnostic services.	FAD
2	**Stabilization vital parameters and first treatments**: the FAD carries out basic therapeutic operations to protect the patient, suitable to stabilize vital parameters. In this phase, the FAD can ask for the consultation of specialist doctors in relation to particular diagnostic questions.	FAD, specialists, nurses
3	**Filling out First Aid record**: after evaluation, stabilization of vital parameters and giving first therapies, the FAD definitely assigns a priority code to the patient and fills in the F.A. record.	FAD
4	**Admission arrangement**: if the FAD thinks admission of the patient is required, he arranges admission to an internal or external care facility. This includes checking for available internal beds which occurs every day at 8.00 am, 2.00 pm and 8.00 pm by the Health Activity Office and is communicated in real-time to F.A. admittance and Medical Direction of Hospital Facilities (MDHF).	FAD
5	**Bed search**: if there are no beds inside the Ospedale Niguarda Cà Granda H.C., the patient will be guaranteed admittance in other institutes. The FAD assisted by the Doctor specialist in the field of interest on duty, looks for beds at other Hospital institutes by telephone communications, agreeing on modes and times with the Doctor of the accepting facility.	FAD
6	**Transfer agreement**: once the hospital bed and the destination structure have been identified, the FAD and the Doctor of the accepting facility agree on transfer of the patient (in particular a time limit for transfer is noted on the F.A. Record).	FAD, Doctor of the new facility

7	**Communication to the patient**: the FAD tells the patient that admission is needed indicating the reasons, expected times and relative modalities.	FAD
8	**Registration of transfer**: the head nurse of F.A. registers the transfer of the patient, sends a copy of the F.A. Record to the Admittance Administrative Office that formalizes admittance to the facility using the "Accenet" application.	F.A. head nurse, Administration Admittance Fluxist
9	**Organization of transfer**: the Head Nurse of F.A. organizes transfer of the patient to the care facility, follows preparation of the patient, prepares the clinical documentation, alerts the operators of internal transport, guarantees protected conditions using all aids and necessary machinery for transfer.	F.A. Head Nurse, F.A. Nurse
10	**Transfer of the patient**: transfer of the patient is carried out in conditions of maximum protection with an ambulance for internal movement, together with all the clinical documentation. Waiting times for transfer are of 5/10 minutes in urgency, and 30 minutes normally.	F.A. Head Nurse, Transport operators
11	**Identification of responsibilities in the destination facility**: inside the destination facility, the Doctor and Nurse responsible for the patient are identified (Doctor on duty/shift nurse)	Director of C.S./ S.S.
12	**Briefing to the patient in the destination facility**: the patient is informed about the functioning of the destination facility and to what operators one can turn to for any information or need.	Head Nurse Accepting Structure Nurse
13	**Evaluation of the patient and filling in of clinical documentation**: the Doctor and the Nurse that take care of the patient carry out, compatibly with other urgent priorities, an immediate evaluation of the clinical and assistance conditions of the patient, using the following forms: Entry Sheet, Anamnesis sheets, Objective examination (Doctor), Title page nursing record, Card to point out needs, Scheduling cards of collected NAN (Nurse).	Doctor and nurse who have the patient in charge in the new facility.
14	**Evaluation of the type of external transport**: the head nurse of F.A. organizes transfer, follows preparation of the patient, prepares the clinical documentation, alerts the external transport operators, ensures protected conditions using all necessary aids and machinery (type B ambulance or type B ambulance with specialist medical support (anaesthesist, cardiologist, neonatologist ecc.)). At the time of transfer, the First Aid Record and the medical reports of all examinations carried out have to be delivered to the patient.	FAD, F.A. head nurse

7.1.2. Monitoring foetal heart rate during labour

One of the pilot sites, the *Ospedale Luigi Sacco,* expressed the wish to test the RAPS system in the context of foetal heart rate (FHR) tracing under the currently applied guidelines as summarised here. When FHR tracing is reassuring at admission, the woman should be allowed to move freely, even if membranes are not intact. When FHR tracing is not reassuring it should be continued and a re-evaluation scheduled after a period of 20 minutes because the foetus could be in a quiet period.

After admission, FHR should be auscultated by means of ultrasound or by using a stethoscope for a minimum of 1 minute immediately after a contraction and at least every 2 hours. The maternal pulse should be felt simultaneously to differentiate between maternal heart rate and FHR. Alternatively, a FHR tracing may be performed every two hours for a period of 30'. In case of an abnormal FHR, monitoring should be continuous. Indications for electronic foetal monitoring (EFM) are (1) abnormalities of the FHR on intermittent auscultation, (2) oxytocin administration, (3) amniotic fluid not clear, and (4) fresh bleeding developing in labour.

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