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Lead Author:	Ilias Kalamaras (CERTH)
Lead partners:	Andreas Kanavos (UoP), Vasilis Megalooikonomou (UoP), Kosmas Petridis (HYPERTECH)

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1.0	30/06/2016	final	Ilias Kalamaras (CERTH), Andreas Kanavos (UoP), Vasilis Megalooikonomou (UoP), Kosmas Petridis (HYPERTECH)	Deliverable finalised taking into account internal review's comments.

EXECUTIVE SUMMARY

The aim of workpackage **WP4** is to develop methods for the offline and online management, fusion and analysis of multimodal and advanced technology data from social, behavioral, cognitive and physical activities of frailty older people and apply them to manage and analyze new data. Results from the analysis of existing and new data will be also used to create user-profiling virtual models of elderly patients.

The main focus of the deliverable **D4.5** is to model elderly people with a holistic approach, keeping together low-level and high-level clinical, physiological, environmental parameters, thus providing a detailed conceptual definition of FrailSafe' patient model representation format. In particular, a patient model within FrailSafe is comprised of the personal characteristics of a patient, such as physiological and clinical parameters and factors, co-morbidities, personal profile, preconditions, risk factors, behavior, preferences, physical activity, etc.

In FrailSafe these models will be managed dynamically (based on real-time measurements) and will represent an evolving virtual entity. To this end, the introduction of individual virtual patient models will: a) provide a structured machine readable patient representation format, b) allow adaptation of the patient intervention strategies, c) make the data analysis and feature extraction more efficient, d) support the healthcare professionals in their decision process, e) allow an adaptation of the user interfacing and f) allow a personalized feedback to the patient (suggestions about behavior/habits change, reminder, etc.).

A large amount of studies on the domain of static and dynamic patient modelling representation is briefly covered, followed by an analytical description of the openEHR format, which will be the heart of the FrailSafe's patient model representation. The tools provided by openEHR have important advantages (compared to rest formats) for the development of this project.

The identification and definition of the entities/concepts of interest for the FrailSafe project is then analyzed for the creation of the models, while the adoption and extension of existing openEHR archetypes that have been developed for life-long interoperable electronic health records is finally offered.

DOCUMENT INFORMATION

Contract Number:	H2020-PHC–690140	**Acronym:**	FRAILSAFE
Full title	Sensing and predictive treatment of frailty and associated co-morbidities using advanced personalized models and advanced interventions		
Project URL	http://frailsafe-project.eu/		
EU Project officer	Mr. Ramón Sanmartín Sola		

Deliverable number:	4.5	**Title:**	Dynamic User Profiling models and Patient modelling and representation framework
Work package number:	4	**Title:**	Data Management and Analysis

Date of delivery	**Contractual**	01/07/2016 (M6)	**Actual**	30/06/2016
Status	Draft ☐		Final ☒	
Nature	Report ☒	Demonstrator ☐	Other ☐	
Dissemination Level	Public ☒	Consortium ☐		
Abstract (for dissemination)	The main focus of this deliverable is to model elderly people with a holistic approach, keeping together low-level and high-level clinical, physiological, environmental parameters, thus providing a detailed conceptual definition of FrailSafe' patient model representation format. In particular, a patient model within FrailSafe is comprised of the personal characteristics of a patient, such as physiological and clinical parameters and factors, co-morbidities, personal profile, preconditions, risk factors, behavior, preferences, physical activity, etc.			
Keywords	FrailSafe, user profiling, virtual patient models			

Contributing authors (beneficiaries)	Ilias Kalamaras (CERTH) Andreas Kanavos, Vasilis Megalooikonomou (UoP) Kosmas Petridis (HYPERTECH)			
Responsible author(s)	Ilias Kalamaras		**Email**	kalamar@iti.gr
	Beneficiary	CERTH	**Phone**	+30 2311 257715

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LIST OF ABBREVIATIONS AND ACRONYMS

(*in alphabetic order*)

ADL	Archetype Definition Language
AOM	Archetype Object Model
BMI	Body Mass Index
BSA	Body Surface Area
ECG	Electrocardiography
EHR	Electronic Health Record
FOLP	First-Order Predicate Logic
HCI	Human Computer Interaction
HL7	Health Level 7
HRID	Human Readable ID
JSON	JavaScript Object Notation
GDS	Geriatric Depression Scale
IADL	Instrumental Activities of Daily Living
ICT	Information & Communication Technology
MMSE	Mini Mental State Examination
MNA	Mini Nutritional Assessment
MoCA	Montreal Cognitive Assessment
ODIN	Object Data Instance Notation
RM	Reference Model
UML	Unified Modeling Language
VAS	Visual Analogue Scale
VPM	Virtual Patient Model
XML	Extensible Markup Language

1 INTRODUCTION

The term *'eHealth'*[1], which encompasses the use of information and communication technologies (ICT) in health care, has become inseparable from the vision of modern health care in future. In the last 15 years, many approaches towards 'making eHealth happen' have been developed and many eHealth projects of various scale and success have been implemented.

For example, an *Electronic Health Record* (EHR[2]) is an electronic version of a patient's medical history, that is maintained by the provider over time, and may include all of the key administrative clinical data relevant to that persons care under a particular provider, including demographics, progress notes, problems, medications, vital signs, past medical history, immunizations, laboratory data and radiology reports. The EHR automates access to information and has the potential to streamline the clinician's workflow. The EHR also has the ability to support other care-related activities directly or indirectly through various interfaces, including evidence-based decision support, quality management, and outcomes reporting.

The present document is devoted to the presentation of a comprehensive insight of the heterogeneous electronic health records. An analytic description of openEHR model is offered since we believe that this is the best approach available for realising the goals of FrailSafe due to the key elements its strategic value to future development of next generation healthcare technologies (Section 2).

After the comparison of the available representation frameworks, we present the entities/concepts of interest (in order to meet the project's requirements) and how these are going to be represented in the FrailSafe patients model via existing or new archetypes including monitored parameters, clinical data, diagnosis results, risk factor, action plans, interventions, etc. (Section 3).

[1] https://en.wikipedia.org/wiki/EHealth

[2] https://en.wikipedia.org/wiki/Electronic_health_record

2 PRIOR ART ON ELECTRONIC HEALTH RECORDS

The arrival of computers created new possibilities for storing, retrieving and viewing the information within the medical record, by changing the physical nature of records to an electronic format. Electronic Health Records (EHR) have undergone a historical development parallel to that of its paper correlate. As technology progressed and personal computers became more prevalent, efforts in development focused on clinical areas and other areas where departmental or complementary tests are performed, but there was no integration between them and therefore each one ended up being an information silo. The importance of integrating the information generated by the various departmental systems made it necessary to connect these systems by means of a common clinical data repository, leading to the creation of component-based clinical information systems. One of the premises of these new systems was to respect the care process, making medical acts the backbone of their information model. From that time onward, the decentralization of healthcare into care networks has given rise to the need to connect multiple systems, beyond the walls of an institution, and thus enable fluid communication of clinical information.

Over the last 20 years many attempts have been made to solve the major problems of health data systems that includes (i) *semantic interoperability across and within enterprises as well as between layers of functionality within a system* and (ii) *support of intelligent data computation systems.* Moreover, key realities that contribute to the health computing challenge, that finds standard ICT systems really hard to keep up, are the (i) *massive data richness* and (ii) *high rate of data change* ranging from clinical processes to protocols.

Solution attempts have included many standards and specifications, such as Edifact, HL7v2, DICOM, HL7v3, HL7 CDA, EN/ISO13606, ASTM CCR, SNOMED CT, ICDx, OMG Corbamed and HDTF (RLUS, EIS, CTS2) specifications, and more recently HL7 FHIR. They have also included many implementation technologies, e.g. (free/open) FreeMed, GnuMed, openMRS, Harvard SMART; and of course numerous commercial products and in-house systems. However, none of these are likely to solve the problem on their own, and attempts to connect them together have been far from successful; while the costs of trying to integrate disparate standards as well as systems have far outweighed the benefits. From the perspective of Frailsafe, there are some key realities that are sometimes missed:

- The data inside healthcare provider institutions are the most important asset either as a productive resource or at least as an object of risk management
- A growing amount of data are not all produced inside the institution:
    - lab data come from external lab companies
    - health data come from consumer devices

Despite many specific advances in ICT, and with a few exceptions, the overall experience for healthcare providers procuring both monolithic one size-fits-all systems, and/or numerous best-of-breed systems remains deeply problematic, with the following issues being common:

- Rare support of the data richness actually required by clinicians.
- Several functionality issues from the clinician’s point of view.
    - Time-consuming and expensive customisation.
    - Huge ongoing cost for data and workflow integration.
    - Incremental deployment is not practical due to logistical costs.
    - Loss of in-house expertise since everything has to be converted.
- Small changes result at uncontrollable costs and long waits.
- Costs and risks when moving to a new vendor are massive and great.

- Other users typically cannot have free access to the either the data or system alone.

2.1 EHR representation formats

Different international organizations are or have worked on the definition of an EHR architecture. Health Level 7 (HL7) maintains a set of international standards for transfer of clinical and administrative data between software applications used by various healthcare providers. These standards focus on the application layer, which is "layer 7" in the OSI model. The Health Informatics Technical Committee (TC251) of the European Committee for Standardization (CEN/TC251) has completed a European Standard for the communication of the EHR, called CEN EN13606 whose reference model (RM) became an ISO standard in February 2008 under the name ISO 13606. Exploiting this ISO, the openEHR consortium maintains an architecture designed to support the constructions of distributed, patient-centered, life-long, shared care health records.

2.1.1 HL7[3]

HL7 International specifies a number of flexible standards, guidelines, and methodologies by which various healthcare systems can communicate with each other. The HL7 standards are produced by the Health Level Seven International, an international standards organization, and are adopted by other standards issuing bodies such as American National Standards Institute and International Organization for Standardization.

Such guidelines or data standards are a set of rules that allow information to be shared and processed in a uniform and consistent manner. These data standards are meant to allow healthcare organizations to easily share clinical information, where the following ones can be considered as the most commonly used and implemented:

- **Version 2.x Messaging Standard**
  - an interoperability specification for health and medical transactions.
- **Version 3 Messaging Standard**
  - an interoperability specification for health and medical transactions.
- **Clinical Document Architecture (CDA)**
  - an exchange model for clinical documents.
- **Structured Product Labeling (SPL)**
  - the published information that accompanies a medicine.
- **Clinical Context Object Workgroup (CCOW)**
  - an interoperability specification for the visual integration of user applications.
- **Fast Healthcare Interoperability Resources (FHIR)**
  - a draft standard for the exchange of resources
- **Arden Syntax**
  - a grammar for representing medical conditions and recommendations as a Medical Logic Module
- **Claims Attachments**
  - a Standard Healthcare Attachment to augment another healthcare transaction

[3] http://www.hl7.org/

- **Functional Specification of HER**
  - a standardized description of health and medical functions sought for or available in such software applications
- **GELLO**
  - a standard expression language used for clinical decision support

2.1.2 openEHR[4]

openEHR is an open standard specification in health informatics that describes the management and storage, retrieval and exchange of health data in electronic health records (EHRs). In openEHR, all health data for a person is stored in a "one lifetime", vendor-independent, person-centred EHR. The openEHR specifications include an EHR Extract specification but are otherwise not primarily concerned with the exchange of data between EHR-systems as this is the focus of other standards such as EN 13606 and HL7.

The openEHR specifications are maintained by the openEHR Foundation, a not for profit foundation supporting the open research, development, and implementation of openEHR EHRs. The specifications are based on a combination of 15 years of European and Australian research and development into EHRs and new paradigms, including what has become known as the archetype methodology for specification of content.

The openEHR specifications include information and service models for the EHR, demographics, clinical workflow and archetypes. They are designed to be the basis of a medico-legally sound, distributed, versioned EHR infrastructure. More specifically, the architecture of the openEHR specifications as a whole consists of the following key elements:

- reference models;
- archetypes (plus query language);
- service models/APIs.

The use of the first two enable the development of *'archetypes*' and *'templates*', which are formal models of clinical and related content, and constitute a layer of de facto standards of their own, far more numerous than the base specifications on which they are built. The query language enables queries to be built based on the archetypes, rather than physical database schemata, thus decoupling queries from physical persistence details. The service models define access to key back-end services, including the EHR Service and Demographics Service, while a growing set of lightweight REST-based APIs based on archetype paths are used for application access. The openEHR Architecture Overview provides a summary of the architecture and the detailed specifications.

2.1.3 Comparison

The comparative review of the aforementioned standards allows us to understand their similarities and differences and also to examine their potential use in the user modelling procedures. Table 1 illustrates the most important features and drawbacks on each EHR representation, clearly shows the superiority of the openEHR as compared to HL7. To this end, the representation of the Frailsafe virtual patient models will be based on the openEHR architecture. Before proceeding to the requirements and

[4] *http://www.openehr.org/*

archetypes presentation of the Frailsafe system, in the following subsection we provide a brief overview of the openEHR's two-level modeling architecture.

Criteria	OpenEHR	HL7
ISO standardized	✓	✓
Reference Model (RM)	✓	✓
Allowing deviations from RM	×	×
Implementation	OpenEHR based EHR	Messages, CDA, SPL, FHIR
Two level architecture	✓	✓
Data type specification	✓	✓
Support of coding	✓	✓
Terminology systems	SNOMED-CT[5]	Many
Unique code per data element	✓	✓
Unique ID for the clinical model	✓	✓
Assigning keywords in the clinical model	✓	×
Authorship	✓	×
Versioning	✓	✓
Purpose	Explicitly stated	Derived from name
Evidence base explicit	✓	×
Guidance for documentation	✓	×
Interpretation	✓	×
Deploy once technology	✓	✓
Available in repository	✓	×
Language of the content	Multi-language	Multi-language

Table 1: Comparison of different representation models.

[5] http://www.ihtsdo.org/snomed-ct

2.2 openEHR Architecture overview[6]

The openEHR approach to modelling information, services and domain knowledge is based on a number of design principles, described below. The application of these principles lead to a separation of the models of the openEHR architecture, and consequently, a high level of componentisation. This leads to better maintainability, extensibility, and flexible deployment.

2.2.1 Ontological Separation

The most basic kind of distinction in any system of models is ontological, i.e. in the levels of abstraction of description of the real world. All models carry some kind of semantic content, but not all semantics are the same, or even of the same category. An information model might specify a logical type Quantity. A content model might define the model of information collected in an ante-natal examination by a physician. These types of "information" are qualitatively different, and need to be developed and maintained separately within the overall model eco-system. Figure 1 illustrates these distinctions, and indicates what parts are built directly into software and databases. By clearly separating the categories - information models, domain content models, and terminologies - the openEHR architecture enables each to have a well-defined, limited scope and clear interfaces. This limits the dependence of each on the other, leading to more maintainable and adaptable systems.

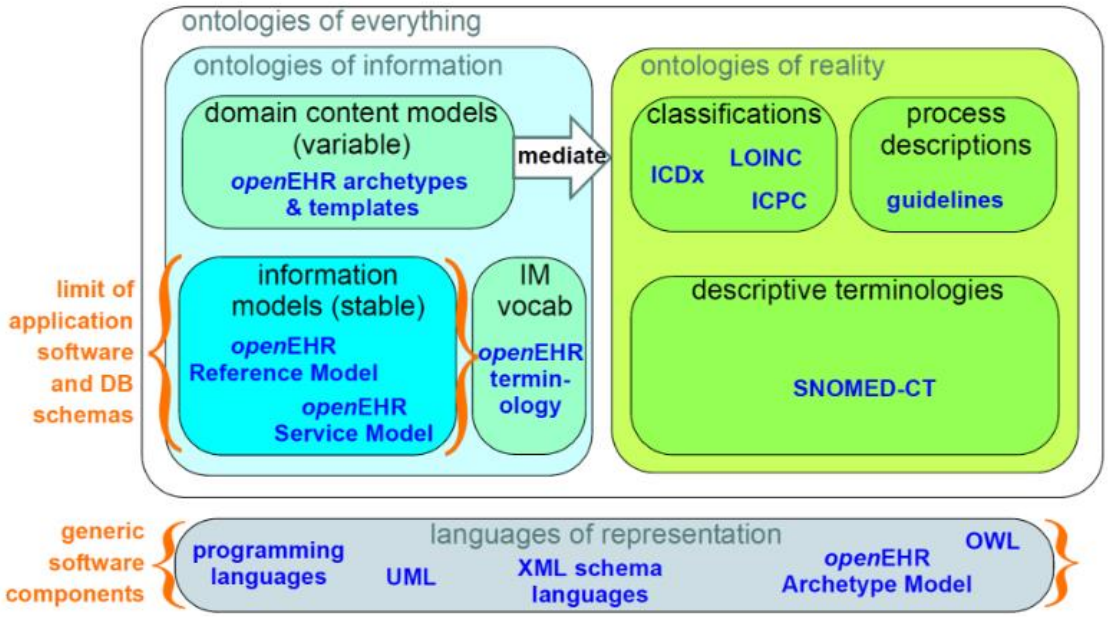

Figure 1: ***The ontological landscape.***

2.2.2 Two-level Modelling

One of the key paradigms on which openEHR is based is known as "two-level" modelling, described in [1]. Under the two-level approach, a stable reference information model constitutes the first level of modelling, while formal definitions of clinical content in the form of archetypes and templates constitute the second. Only the first level (the Reference Model) is implemented in software, significantly reducing the dependency of deployed systems and data on variable content definitions. The only other parts of the model universe implemented in software are highly stable

[6] http://www.openehr.org/releases/BASE/latest/docs/architecture_overview/architecture_overview.html

languages/models of representation (shown at the bottom of Figure 1). As a consequence, systems have the possibility of being far smaller and more maintainable than single-level systems. They are also inherently self-adapting, since they are built to consume archetypes and templates as they are developed into the future.

Archetypes and templates also act as a well-defined semantic gateway to terminologies, classifications and computerised clinical guidelines. The alternative in the past has been to try to make systems function solely with a combination of hard-wired software and terminology. This approach is flawed, since terminologies don't contain definitions of domain content, but rather facts about the real world. The use of archetyping in openEHR engenders new relationships between information and models. In, "data" as we know it in normal information systems (shown on the bottom left) conforms in the usual way to an object model (top left). Systems engineered in the "classic" way (i.e. all domain semantics are encoded somewhere in the software or database) are limited to this kind of architecture. With the use of two-level modelling, runtime data now conform semantically to archetypes as well as concretely to the reference model.

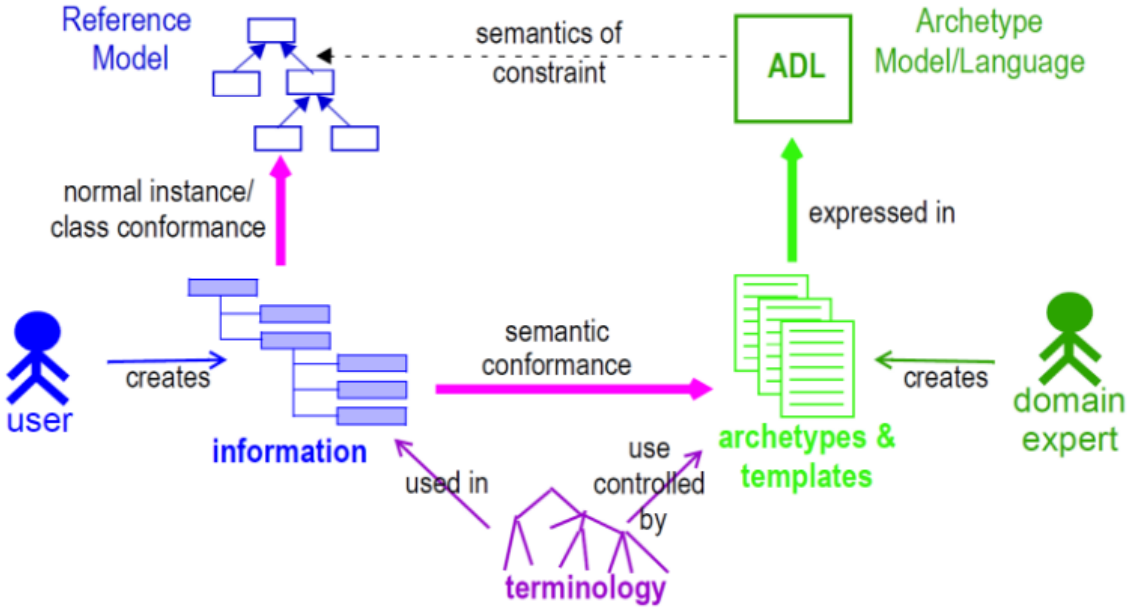

Figure 2: *Archetype Meta-architecture.*

2.2.3 Archetype Technology Overview[7]

The openEHR Archetype formalism is designed to be independent of any specific information model, product, technical format, or industry vertical. It is designed so that instances of the formalism, known as Archetypes, can be computationally processed into desired output forms corresponding to specific technology environments. This is routinely performed in openEHR tooling environments.

The formalism primarily addresses the expression of models of possible data instance structures, rather than higher level concepts such as workflows, clinical guidelines (which are decision graphs) and so on, although its general approach can be applied to any of these, i.e. the use of a model of 'what can be said' and a formalism or mechanism for constraining possibilities to the meaningful subset.

[7] http://www.openehr.org/releases/AM/latest/docs/Overview/Overview.html

Given the two categories of model described above, the archetype formalism, coupled with orthodox information models (typically object-oriented), results in a way to model information from any domain in three logical layers as follows:

- **Information model,** known as the 'Reference Model' here, which defines the semantics of data;
- **Archetypes,** models defining possible arrangements of data that correspond to logical data points and groups for a domain topic; a collection of archetypes constitutes a library of re-usable domain content definition elements;
- **Templates**, models of content corresponding to use-case specific data sets, constituted from archetype elements.

The separation of archetypes and templates from the information model level can also be visualised in Figure 2. In this scheme, the information model (Reference Model) level is consciously designed to be limited to domain-invariant data elements and structures, such as Quantity, Coded text and various generic containment structures. This enables stable data processing software to be built and deployed independently of the definition of specific domain information entities. As noted earlier, a generic information model enables more or less 'any data' instances, while to achieve 'meaningful data', domain content models (archetypes and templates) are required.

Although in the abstract form, Archetypes are easily understood. On the other hand, a Template is an artefact that enables the content defined in published archetypes to be used for a particular use case or business event. In health this is often a 'health service event' such as a particular kind of encounter between a patient and a provider. While, Archetypes define content on the basis of topic or theme e.g. blood pressure, physical exam, report, independently of particular business events, Templates provide the way of using a particular set of archetypes, choosing a particular (often quite limited) set of nodes from each and then limiting values and/or terminology in a way specific to a particular kind of event, such as 'frail patient admission', and so on. Such events in an ICT environment often have a corresponding screen 'form' (which may have one or more 'pages' or subforms and some workflow logic) associated with them; as a result, an openEHR template is often a direct precursor to a form in the presentation layer of application software. In other words, Templates are the technical means of using archetypes in runtime systems.

Underlying all of this are of course formalisms and tooling - the language and tools of archetypes. The remainder of this section provides further high level description of the Archetype-based model environment, essential for understanding the specifications most relevant to the ongoing Frailsafe development:

- **Archetype Identification,** a normative specification of archetype and template model identification, versioning, referencing and lifecycle.

This specification describes the semantics of Archetype identifiers, which is equivalent to describing the structure of the Archetype-based model space. It also describes aspects of lifecycle management and versioning of Archetypes. The Archetype HRID (Human Readable ID) structure corresponds to the structure of the model space created by the combination of Reference Model and Archetypes, and is shown in the following example (Figure 3). The blue segment openEHR-EHR-COMPOSITION indicates the entity in a reference model space, here, the class COMPOSITION in the package EHR from the openEHR Reference Model. The green part 'medication_order' indicates the domain level entity being modelled - a (record of a) medication order (i.e. part of a typical doctor's prescription). The combination of the RM class space and semantic subspaces defines the logical model space created by the archetype formalism. The last part of the archetype identifier is the version.

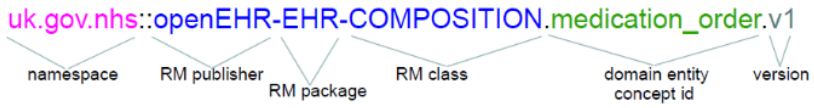

Figure 3: *Typical Archetype HRID.*

- **Archetype Definition Language (ADL)**, a normative abstract syntax for archetypes, templates and terminology binding.

The Archetype Definition Language is a formal abstract syntax for archetypes, and can be used to provide a default serial expression of archetypes. It is the primary document for human understanding of the semantics of archetypes. An archetype is represented computationally as instances of the Archetype Object Model (AOM). The Archetype Definition Language is used as a normative authoring and persistence language, in the same way as a programming language syntax is used to represent programming constructs (which are, it should be remembered not syntax, but the structured outputs of language compilers). In particular, it is designed to be terse and intuitively human readable. Any number of other serialisations is available, usually for technical reasons. These include ODIN (Object Data Instance Notation), XML (Extensible Markup Language) and JSON (JavaScript Object Notation) serialisations, and may include other representations in the future, such as OWL and OMG XMI, according to the technical needs of emerging development technologies. For the purposes of describing and documenting the Archetype formalism, ADL is generally used.

ADL uses three sub-syntaxes: cADL (constraint form of ADL), ODIN, and a version of first-order predicate logic (FOPL). The cADL and FOPL parts express constraints on data which are instances of an underlying information model, which may be expressed in UML (Unified Modeling Language), relational form, or in a programming language. ADL itself is a very simple ‘glue’ syntax, which connects blocks of the subordinate syntaxes to form an overall artefact. The cADL syntax is used to express the archetype definition, while the ODIN syntax is used to express data which appears in the language ‘description’, ‘terminology’, and ‘revision_history’ sections of an ADL archetype. The top-level structure of an ADL archetype is shown in Figure 4.

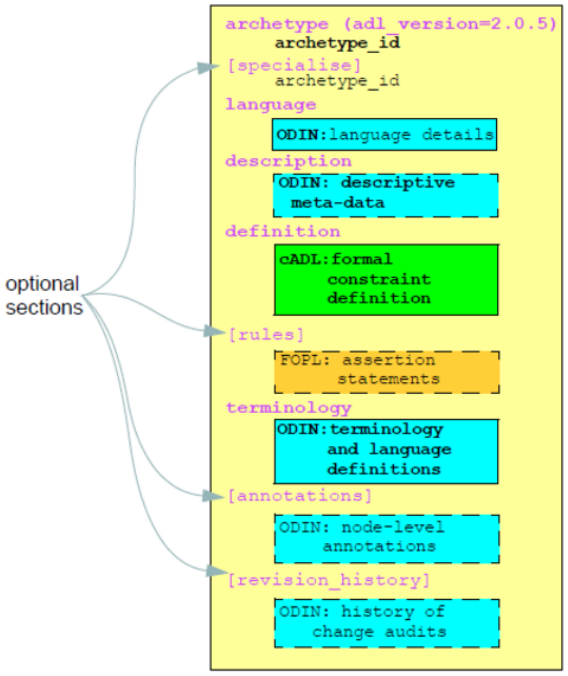

Figure 4: *ADL Archetype Structure.*

3 FRAILSAFE REQUIREMENTS ANALYSIS

Requirements analysis in systems engineering and software engineering, encompasses those tasks that go into determining the needs or conditions to meet for a new or altered product or project, taking account of the possibly conflicting requirements of the various stakeholders, analysing, documenting, validating and managing software or system requirements [2]. Requirements analysis is critical to the success or failure of a systems or software project [3]. The requirements should be documented, actionable, measurable, testable, traceable, related to identified business needs or opportunities, and defined to a level of detail sufficient for system design. Conceptually, requirements analysis includes three types of activities:

1. ***Requirements gathering***: The practice of collecting the requirements of a system from users, customers and other stakeholders.
2. ***Analyzing requirements***: Determining whether the stated requirements are clear, complete, consistent and unambiguous, and resolving any apparent conflicts.
3. ***Recording requirements***: Requirements may be documented in various forms, usually including a summary list and may include natural-language documents, use cases, user stories, or process specifications.

User modeling is the subdivision of human-computer-interaction (HCI) research field which describes the process of building up and modifying a conceptual understanding of the user [4]. The goal of user modeling may be to predict user behaviour, to gain knowledge of a particular user in order to tailor interactions to that user, or to create a database of users that can be accessed by others [5]. In general, user modelling can be seen as a broad mixture of many disciplines including the interaction of the user with interfaces and devices as well as the analysis of user tasks and user characteristics (sensory, physical and cognitive abilities, psychological and behavioural). The notion of user profiling has been introduced in order to record the user context and personalize applications so as to be tailored to the user needs.

Throughout the years, extensive research has been conducted and introduced in the literature by exploiting the field of ontology design [6]. In [7], an ontology-based context model as well as a related context management system providing a configurable and extensible service-oriented framework to ease the development of applications for monitoring and handling patient chronic conditions are described. The context model and context management system provide configurable and extensible services for: 1) acquiring data from heterogeneous context sources (e. g., biomedical and environmental sensors); 2) representing knowledge about patient's situation by means of ontology-based formalisms; 3) reasoning over knowledge using rule-based and ontology-based engines; and 4) applying reasoning techniques in order to specify personalized health-care plans. Authors define five general categories for context items: location, physical data, activity, instrumental, and social context. Authors in [8] introduce ontology for the care of chronically ill patients and implement two personalization processes and a decision support tool. Concretely, the first personalization process adapts the contents of the ontology to the particularities observed in the health-care record of a given concrete patient, thus automatically providing a personalized ontology containing only the clinical information that is relevant for health-care professionals to manage that patient. On the other hand, the second personalization process uses the personalized ontology of a patient to automatically transform intervention plans describing health-care general treatments into individual intervention plans. The OpenEHR initiative emphasizes the sharing of flexible specifications of healthcare information pieces in the form of archetypes. However, the OpenEHR ADL language does not provide support for rules and

inference which are important pieces of clinical knowledge. As a result, authors in [9] present an approach for converting ADL definitions to OWL and then attach rules to the semantic version of the archetypes. They aim at reusing knowledge expressed in the form of rules which is also flexible and follows the same philosophy of sharing archetypes. In [10], a multiagent architecture in which users and environments are represented by agents that negotiate tasks execution and generate results according to user in context features is introduced. Authors implemented a context-aware To-Do-List application that reminds tasks to the user by considering the situational context and also the ability to perform tasks, entirely or in part, on the user behalf is added.

FrailSafe aims to better understand frailty and its relation to co-morbidities; to identify quantitative and qualitative measures of frailty through advanced data mining approaches on multi-parametric data and use them to predict short and long-term outcome and risk of frailty; to develop real life sensing (physical, cognitive, psychological, social) and intervention (guidelines, real-time feedback, AR serious games) platform offering physiological reserve and external challenges; to develop and test pharmaceutical and non-pharmaceutical interventions; to create “prevent-frailty” evidence-based recommendations for the elderly; to strengthen the motor, cognitive, and other “anti-frailty” activities through the delivery of personalised treatment programmes, monitoring alerts, guidance and education; and to achieve all with a safe, unobtrusive and acceptable system that consists of a digital patient model sensitive to several dynamic parameters, including physiological, behavioural and contextual. Therefore, in this section we describe the different entities/concept of interests (e.g., devices, procedures and data sources) that will be exploited to assess the different aspects of frailty (measure and control) and define the clinical state that is to be predicted by the intelligent information processing.

3.1 Identification of entities/concepts of interest

This subsection is dedicated to the presentation of the most appropriate entities of interest with regard to the main Frailsafe’s goals: enhancement of the patients’ quality of life by (i) better understanding of frailty and (ii) generating of personalized guidelines, suggestions or even risk alerts. Figure 5 illustrates a multilevel schematic representation of the most significant, best-fitted to the project, entities. These are divided into five (5) main classes which are further separated into subcategories and so on. More specifically, the Personal Details class consists of three subclasses which are related to patients’ personal information: identification information (e.g. name, passport, id etc.), demographics details (e.g. age, gender, country of birth, educational level) and communication parameters (e.g. phone number, email). The ***Sensor-based & Questionnaires Data*** is divided into six subcategories, which all are of essential value:

1. *Physiology related parameters*
   i. Heart rate
   ii. Respiration rate
   iii. Blood pressure
   iv. Arterial stiffness
   v. Body mass
2. *Physical related parameters*
   i. Posture
   ii. Strength
   iii. Motion
3. *Social related parameters*
   i. Social media interaction
   ii. Social media questionnaire
4. *Cognitive related parameters*
   i. Games progress

ii. Questionnaires
    1. Montreal Cognitive Assessment (MoCa)
    2. Mini Mental State Examination (MMSE)
    3. Big 5 Questionnaire
    4. Geriatric Depression Scale (GDS-15)
    5. Visual Analogue Scale (VAS)
iii. Data collection of written text

5. Lifestyle parameters
i. Diet Habits (Mini Nutritional Assessment)
ii. Indoor/Outdoor Activities (Beacons and IADL Index Scales)

6. Frailty metric
i. Freid Frailty Index Questionnaire

The ***Clinician Input*** class is further separated into *Diagnosis Parameters* which are related to the doctor's opinion and *Intervention Parameters* which are about doctor's instructions and medication plans. The ***Electronic Health Record*** entity represents the patient and family medical history and last ***Events*** entity which is responsible for short-term (as *falls* or *loss of orientation*) and long-term (*change of frailty status* and medical adherence progress) event recognition of frailty events.

The list of the most significant, best-fitted to the project, data can be classified, according to the sampling frequency they are collected, into two categories: (i) static (offline) and (ii) dynamic (continuous or fixed sampling). In the former class, general information related to the patient identification, demographic information and contact details is mainly included. Current version of patient's electronic health record can also be part of this class. In the contrary, apart from the recorded sensor measurements which might have significant predictive value for frailty, the data essential to the clinical expert for performing diagnosis and interventions is also included in dynamic entities category. The latter data can be classified, according to the sampling collection rate (see for full details Table 2), into

1. *real-time measurements*:
    a. Heart rate
    b. Respiration rate
    c. Mobility (Steps, Posture, Location)
2. *daily/weekly measurements*:
    a. Strength
    b. Blood pressure
    c. Arterial stiffness
    d. Body mass/weight/surface
    e. Cognitive state (games, questionnaires)
    f. Social interaction (social media)
    g. Adherence (nutrition, medical instruction)
    h. Indoor/Outdoor Activities

Measurements	High level data	Frequency
Heart Rate	• **Mean value when sitting** • **Mean value when sleeping** • **Mean value when walking** • **Mean value when lying** • **Mean value when walking upstairs and downstairs**	for each day - sampling every 5sec (250 Hz)
Respiration Rate	• **Mean value when sitting** • **Mean value when sleeping** • **Mean value when walking** • **Mean value when lying** • **Mean value when walking upstairs and downstairs**	for each day - sampling every 15sec (25 Hz)
Steps	• **Number of steps** • **Number of walking activity initiation** • **Mean duration of the walking activity**	for each day sampling (25 Hz)
Instability/Falls	• Falls rate • Almost/failed falls rate • Places where falls/almost falls happen (indoors/outdoors) - what type of activity performed • Fall consequences • Physiological state of the subject one minute before • Number of fear of fall instances	for each block
Posture	• Mean time spent standing/day • Mean time spent sitting/day • Mean time spent lying/day	for each day
Strength	• Mean max strength value	for each block
Blood Pressure	• **Mean value when sitting** • **Mean value when standing**	for each day sampling (3 times)
Arterial Stiffness	• **Stiffness values over time**	for each day
Game Analysis	• **Played the game?** • **Number of times/block** • **Success rate** • **Mean reaction time** • **Mean Duration** • **Mean Time of pauses**	for each block

	• **Number of pauses/block** • **Events triggered** • **Concentration index**	
Social Interaction	• Mean number of phone calls • Mean time spent on phone • Mean time spent on Skype • Mean number of text messages • Mean number of minutes in social media • (FB, Twitter, Instagram)	for each block
Adherence	• Percentage of times followed the doctor's instructions • Number of meals/day (nutrition)	for each day
Indoor Activities	• Mean time spent sitting in the living room • Mean time spent lying in bed • Mean time spent in the restroom • Mean time spent walking inside • Mean time spent with friends • Mean time spent using tablet/pc	for each day
Outdoor Activities	• Mean time spent walking outside • Mean time spent driving car • Mean time spent riding bike • Mean time spent carrying things (e.g. shopping bags)	for each day

Table 2: *Detailed measurement performed in Frailsafe system.*

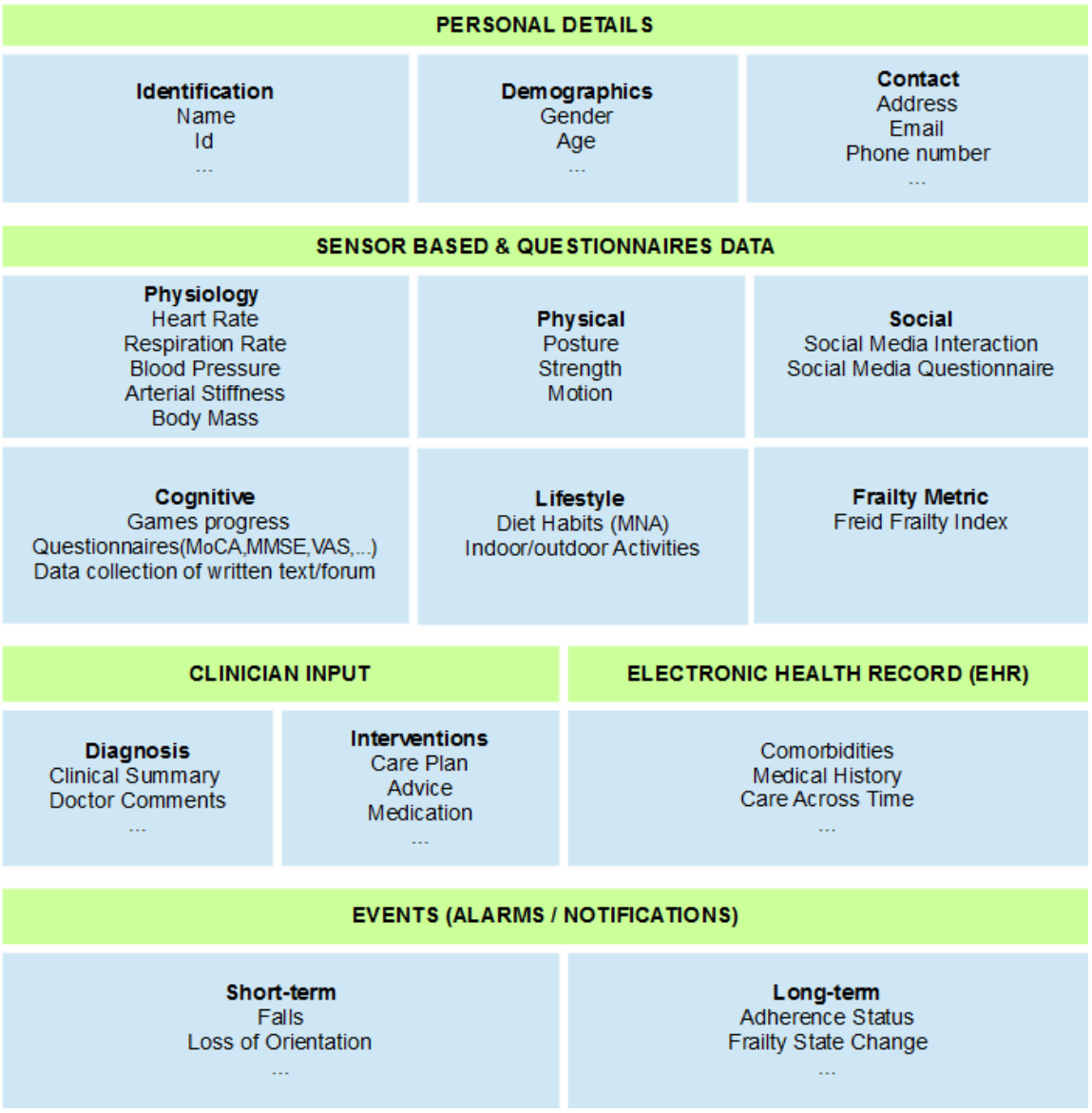

Figure 5: Overview of the core entities that will be included in the FrailSafe virtual patient model.

3.2 Requirements for the Virtual Model Representation

In order to formulate and standardize the collection of potential requirements within the Frailsafe project and towards the definition of the foreseen virtual modelling framework the *Volere Requirements Specification*[8] method was adapted. Each use case (see T1.2) represents something that you want the framework to do, so it has a number of associated functional requirements. The framework use case also has a number of non-functional requirements and a number of constraints. The Frailsafe specification template (a modification of *Volere Snow Card,* see Figure 6) is a guide to the knowledge that you need to gather in order to specify the requirements for a product (see Table 3). The product is often a piece of software, but it could also be a piece of hardware, a consumer product, a set of procedures or anything else that is the focus of Frailsafe system. The template acts as a checklist of the requirements knowledge with which you need to be concerned. Each of the requirements you gather whether they

[8] http://www.volere.co.uk/template.htm

are functional, non-functional or constraint have multiple attributes. One attribute is the unique identifier for the requirement. Another is a connection to each of the product use cases that has this requirement. The description, rationale and fit criterion together specify the meaning of the requirement and make it measurable and testable.

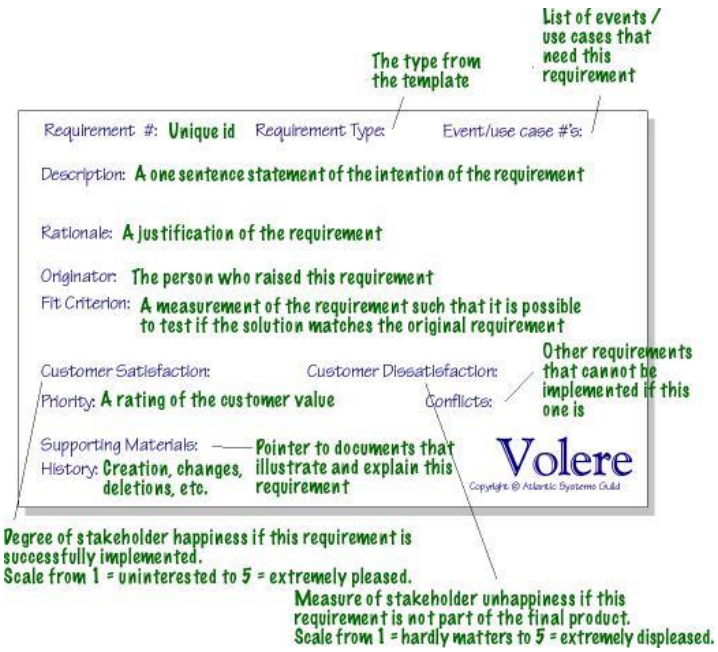

Figure 6: ***The Volere Snow Card is a guide for collecting the attributes.***

ID	A unique identifier of the requirement.
Name	Title of the requirement.
Description	Analytical details in order to describe the requirement.
Rationale	A justification of the requirement.
Fit Criterion	Description of the procedures performed to identify if the current requirement has been addressed (if it is met by a representation framework).
Priority	Ranking of the requirement based on the value which users (e.g. doctors/patients) attach to it
Relations/Conflicts	Description of any possible relation between the current requirement and other requirements with emphasis in conflicts that may block the implementation of the other archetypes.
Author	The original owner of the recorded requirement.
Revision	Description of the version of requirement.

Table 3: ***FrailSafe gathering template of model representation requirements.***

A list of requirements (for notation and naming see Table 4) that covers the objectives of the Frailsafe project and describes the basic characteristics of the corresponding virtual patient model representation scheme is analytically presented (see Figure 5), including:

1. **Personal details**: This category should include all the requirements which are related to the patient's personal information. It can be divided into three subcategories:
    a. ***Identification details***: This subclass involves all the requirements which are related to the identification of the elderly patients, such as their name.
    b. ***Demographics details:*** This subclass involves all the requirements concerning their demographic information, such as gender and age.
    c. ***Contact details***: This category should be focused on the requirements related to the documentation of contact details of the elderly patients.
2. **Health records:** This category should describe the systematic documentation of a patient's health summary, family history and care across time.
3. **Sensor measurements and questionnaires**: This category should include the requirements for the representation of the collected data from the sensing devices, questionnaires and games which are captured by the patients in their living environment. More specifically, this category can be further separated into the following subcategories:
    a. ***Physiology related data***: This subclass focuses on the requirements concerning physiological measurements such as heart rate or respiratory rate.
    b. ***Physical related data***: This subclass contains the requirements related to physical measurements such as motor and strength condition.
    c. ***Social related data***: This subclass focuses on the requirements concerning the social interaction and behavioural parameters such as social media.
    d. ***Cognitive related data***: This subclass contains the requirements related to cognitive measurements such as progress in VR/AR games.
    e. ***Lifestyle data***: This subclass is related to requirements concerning parameters that allow the understanding of the patients' lifestyle such as diet habits and indoor/outdoor activity levels.
    f. ***Frailty metric:*** This type of requirements should involve any parameter that is necessary for the quantitative definition of a frailty measurement.
4. **Clinician input**: This category should include all the information that is provided by the doctors such as details about patient's co-morbidities or their prescriptions. This information is more based on doctors' opinion rather than the use of medical devices. More specifically, this category can be further separated into:
    a. ***Diagnosis***: This category should include requirements for the representation of the clinical diagnosis that the doctors made.
    b. ***Interventions***: This category includes the requirements for the documentation of care plans, medicines and life-style recommendations offered by the clinicians for their patients.
5. **Events:** This category should include the different events responsible for notifying/alerting the clinician, older people and his closest family members in case of emergency.

a. ***short-term alerts***: This category includes the requirements regarding sudden change events such as instability prediction and fall detection.
b. ***long-term notifications***: This category includes the requirements regarding long-range change events such as frailty state transition.

Requirements	**Notation**
General information	GEN-RE
User identification	ID-RE
User demographic details	DEM-RE
User contact details	COM-RE
Health record details	HR-RE
Sensor measurements	SM-RE
Questionnaires measurements	QM-RE
Physiology related data representation	PHYSIOL-RE
Physical related data representation	PHYSIC-RE
Social related data representation	SOC-RE
Cognitive related data representation	COG-RE
Lifestyle related data representation	LIF-RE
Doctor input representation	DOC-RE
Diagnosis representation	DIAG-RE
Interventions representation	INTERV-RE
Short-term events representation	SEV-RE
Long-term events representation	LEV-RE

Table 4: ***Naming and notation of Frailsafe requirements.***

3.3 OpenEHR Archetypes

In an effort to create a patient model framework based on the OpenEHR platform, the most relevant archetypes need to be retrieved from the OpenEHR clinical knowledge manager[9] (CKM) with regard to the entities/requirements presented above. If an entity cannot be represented by the existing archetypes, modifications can be performed and new archetypes can be created using the Archetype Editor[10] in order to meet the goals of the project.

3.3.1 Personal details

3.3.1.1 Identification details

The identification input relevant archetype needs to include the name of the patient. For this purpose, ***openEHR-DEMOGRAPHIC-CLUSTER.person_identifier.v1*** and ***openEHR-DEMOGRAPHIC-CLUSTER.provider_identifier.v1*** can be used to represent the data about person and healthcare provider identifiers, respectively. The structure of the aforementioned archetypes is shown in Figure 7 and Figure 8:

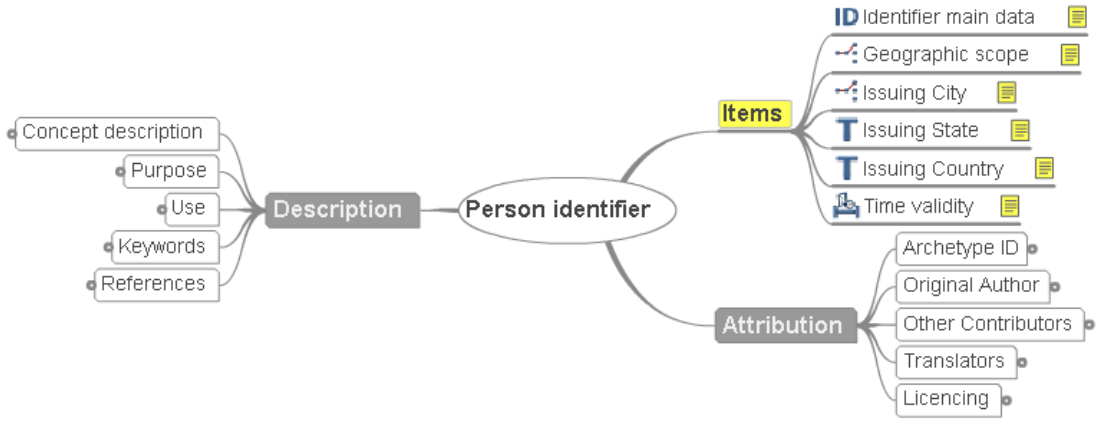

Figure 7: ***Person identifier archetype.***

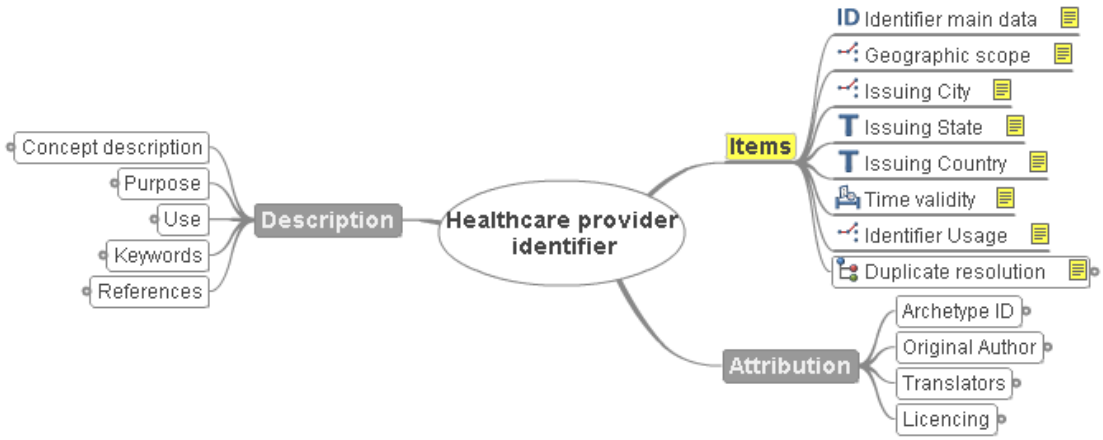

Figure 8: ***Healthcare provider identifier.***

[9] http://www.openehr.org/ckm/

[10] http://www.openehr.org/downloads/archetypeeditor/home

3.3.1.2 Demographic details

The demographic input relevant archetype needs to include personal demographics details of external parties. For this purpose, **openEHR-DEMOGRAPHIC-ITEM_TREE.person_details.v1** can be used to represent a person's demographic data such as birth data, death data, sex, marital status, ethnic group and biometric identifier. The structure of the aforementioned archetype is shown in Figure 9.

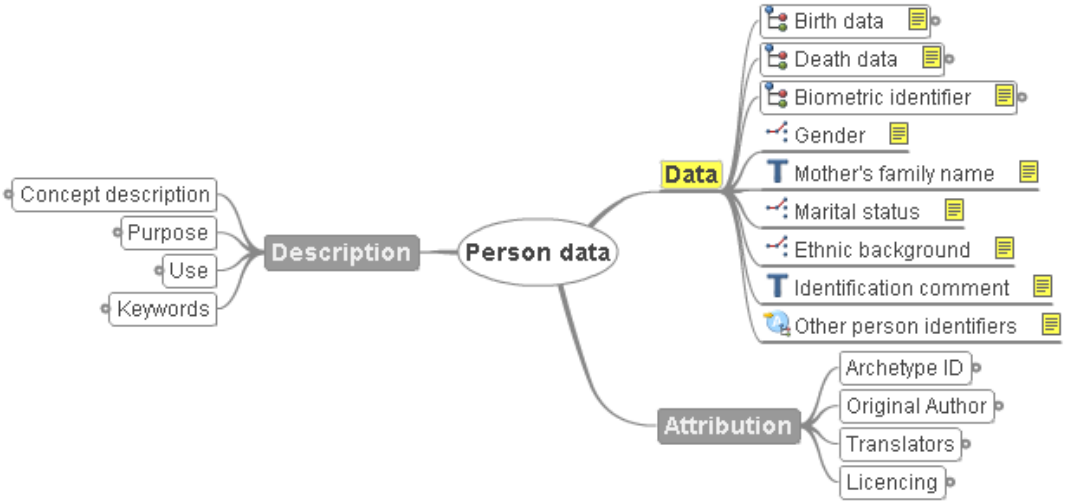

Figure 9: *Personal data archetype.*

3.3.1.3 Contract details

For the contact and communication information relevant fields, the archetypes that can be explored are the ***openEHR-DEMOGRAPHIC-ADDRESS.address.v1*** and ***openEHR-EHR-CLUSTER.telecom_details.v0***. Figure 10 and Figure 11 illustrate these archetypes:

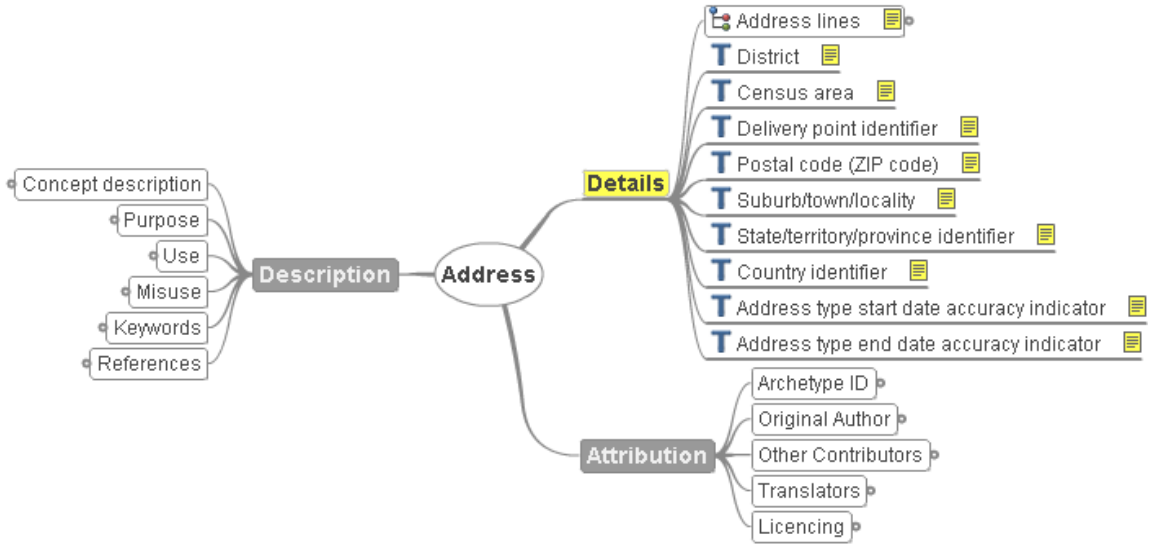

Figure 10: *Address archetype.*

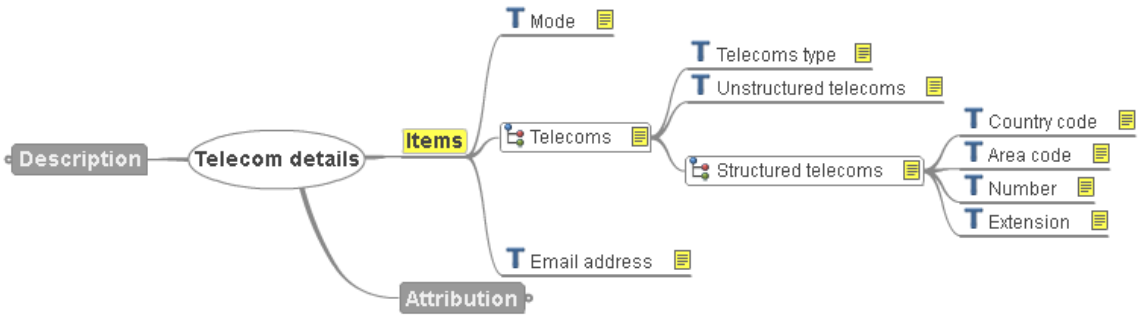

Figure 11: *Telecom details archetype.*

3.3.2 Sensor measurements and questionnaires

In general, the ***openEHR-EHR-COMPOSITION.report-result.v1*** archetype can be used to carry information about the result of a stand-alone test or assessment, or a group of related results (see Figure 12).

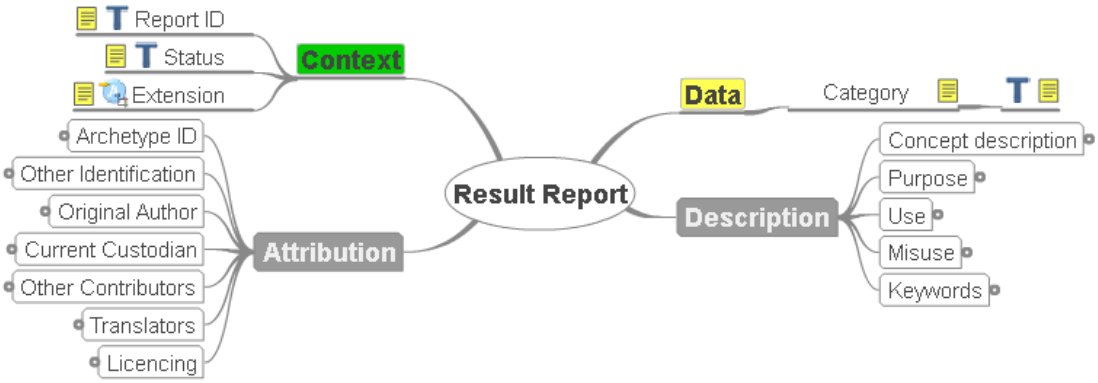

Figure 12: *Result report archetype.*

3.3.2.1 Physiology related data

For the physiological data relevant fields, the archetype that can be explored for each measurement is:

- To record the electrocardiographic interpretation of the electrical activity of the heart by a medical device.
  - ***openEHR-EHR-OBSERVATION.ecg.v1*** (see Figure 13)
  - ***openEHR-EHR-CLUSTER.device.v1*** (see Figure 14)
- To record details about the rate and associated attributes for a *heart beat*:
  - ***openEHR-EHR-OBSERVATION.pulse.v1*** (see Figure 15)
- To record the observed characteristics of spontaneous breathing (*respiration rate*):
  - ***openEHR-EHR-OBSERVATION.respiration.v1*** (see Figure 16)
- To record the systemic arterial *blood pressure*:
  - ***openEHR-EHR-OBSERVATION.blood_pressure.v1*** (see Figure 17)
- To record the *body weight* of an individual - both actual and approximate:
  - ***openEHR-EHR-OBSERVATION.body_weight.v1*** (see Figure 18)

- To record the *body surface area* (BSA) of a subject; the measured or calculated surface area of a human body:
  - ***openEHR-EHR-OBSERVATION.body_surface_area.v0*** (see Figure 19)
- To record the *length of the body* from crown of head to sole of foot of an individual - both actual and approximate, and either in a standing or recumbent position.
  - ***openEHR-EHR-OBSERVATION.height.v1*** (see Figure 20)
- To record the *body mass index* (BMI) of a person; a calculated ratio describing how an individual's body weight relates to the weight that is regarded as normal, or desirable, for the individual's height.
  - ***openEHR-EHR-OBSERVATION.body_mass_index.v1*** (see Figure 21)

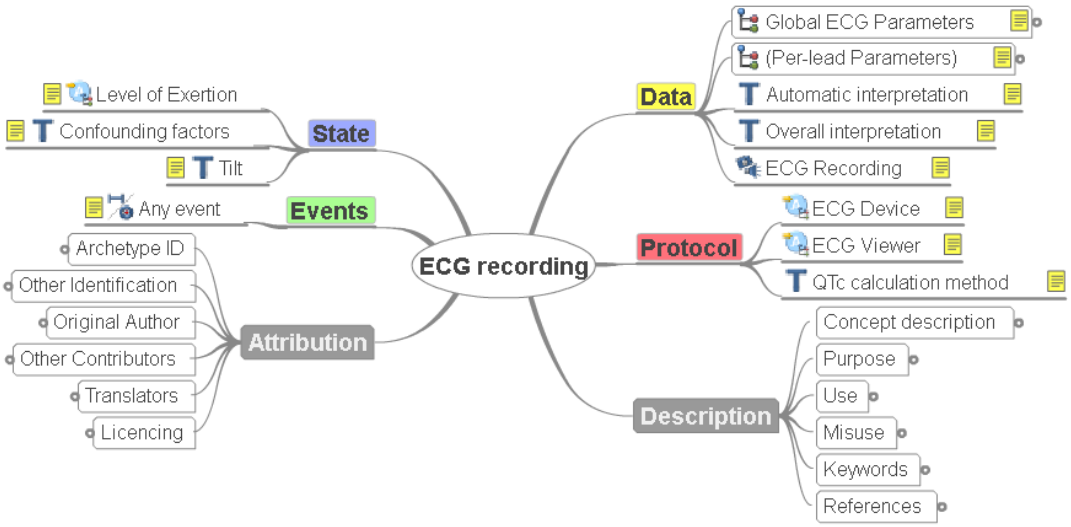

Figure 13: ***ECG recording archetype.***

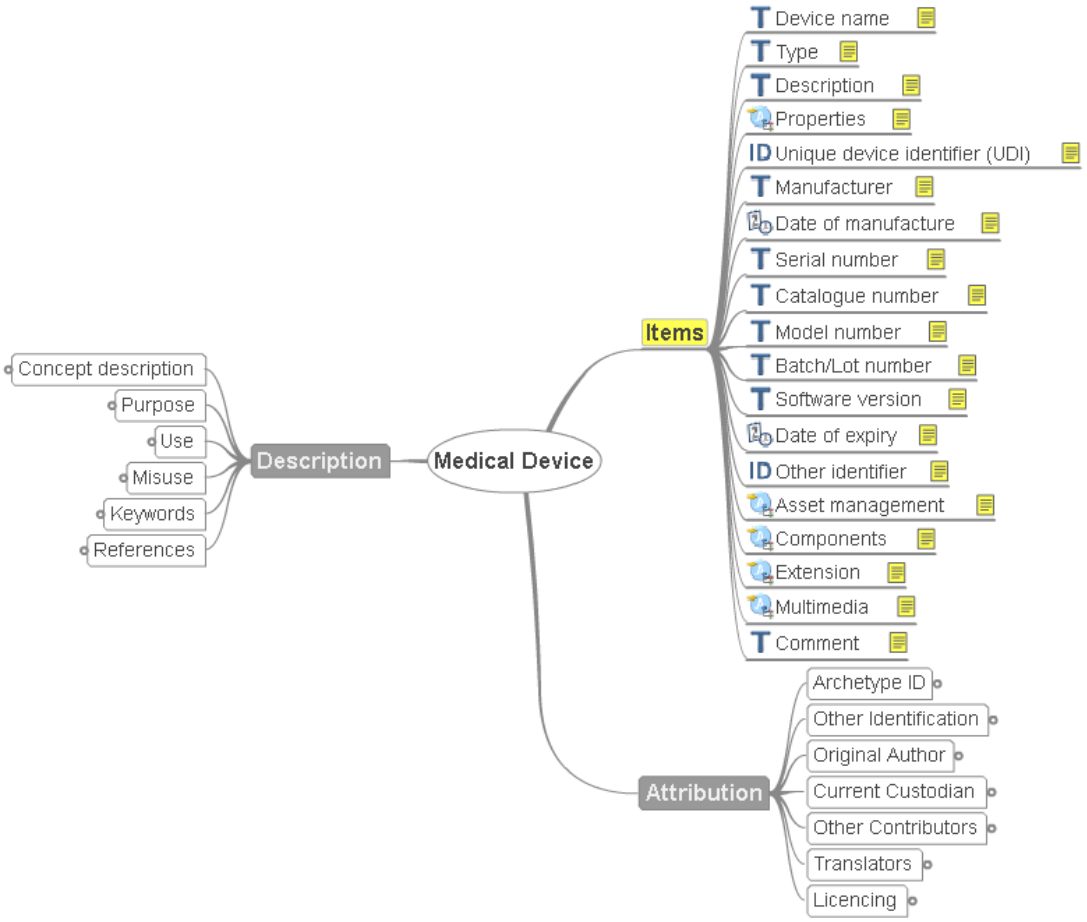

Figure 14: *Medical device archetype.*

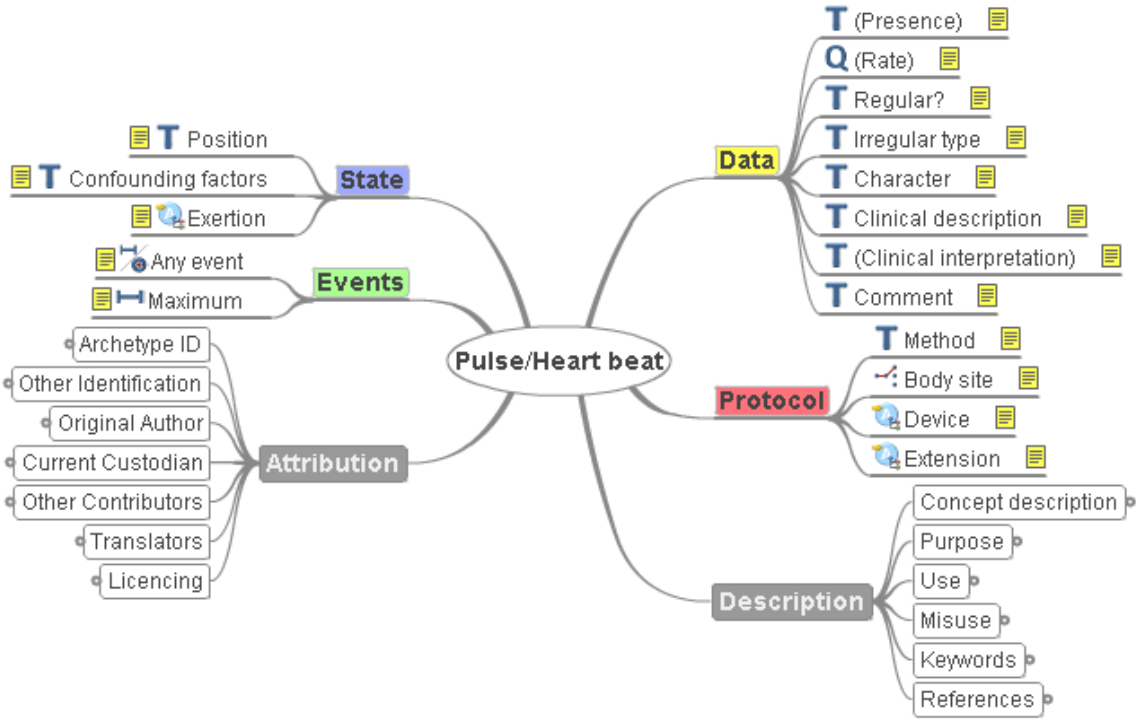

Figure 15: *Heart beat archetype.*

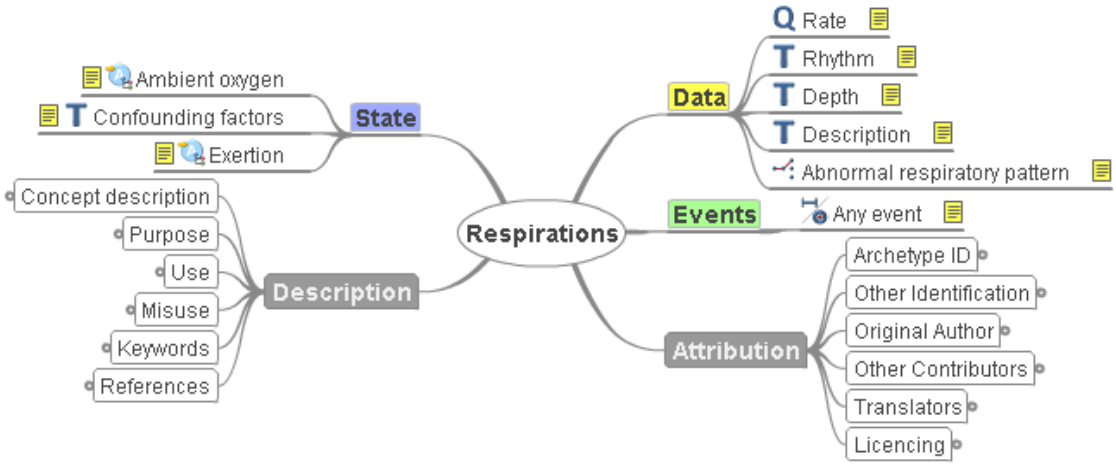

Figure 16: *Respiration rate archetype.*

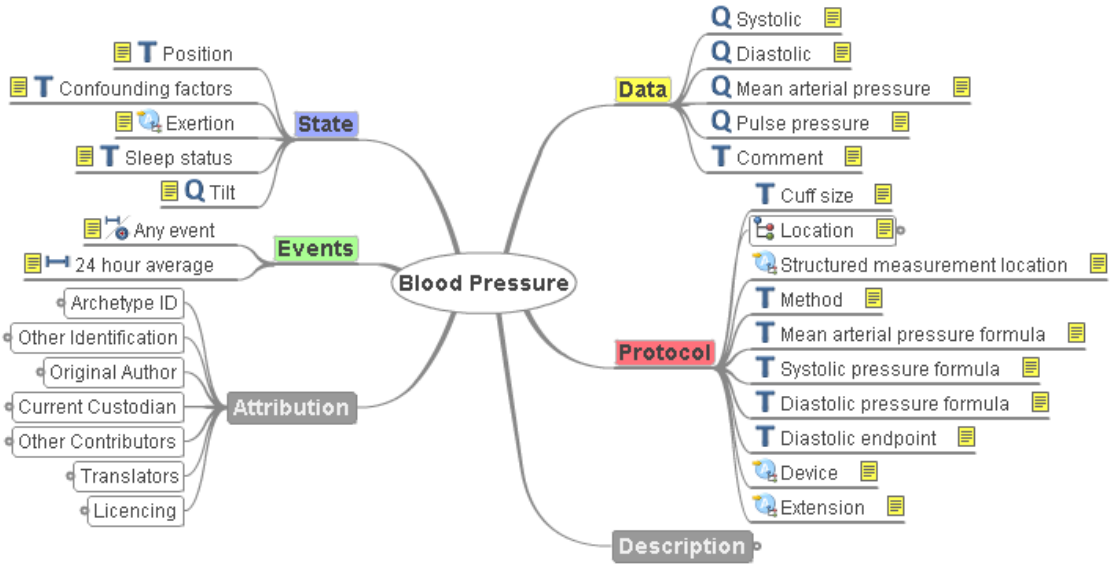

Figure 17: *Blood pressure archetype.*

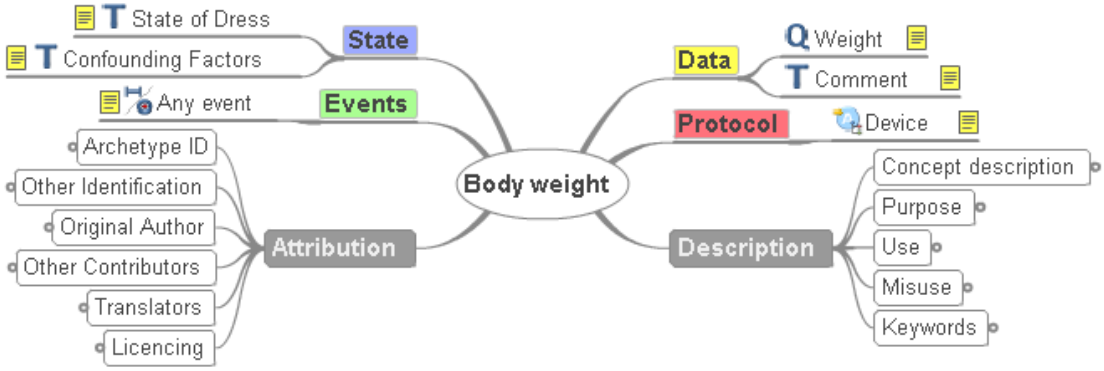

Figure 18: *Body weight archetype.*

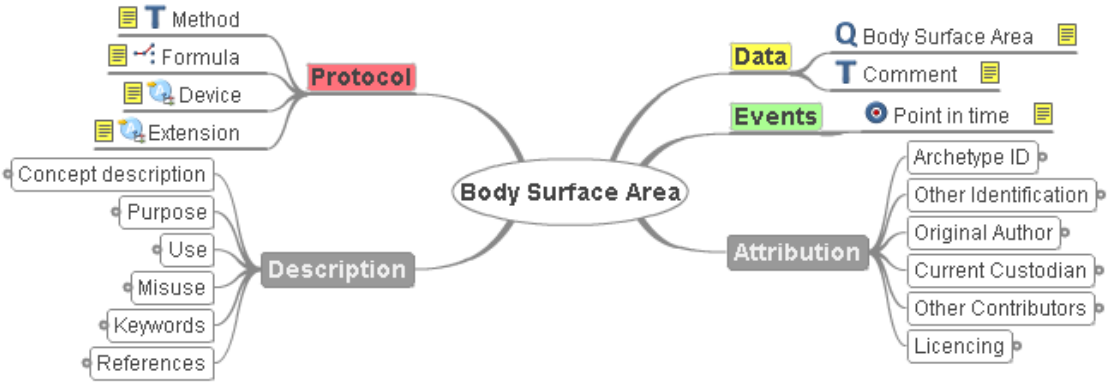

Figure 19: *Body surface area archetype.*

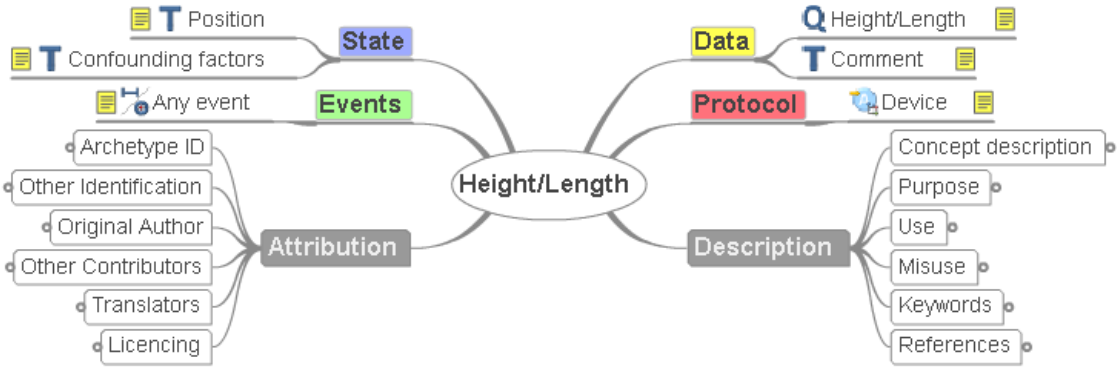

Figure 20: *Height/Length archetype.*

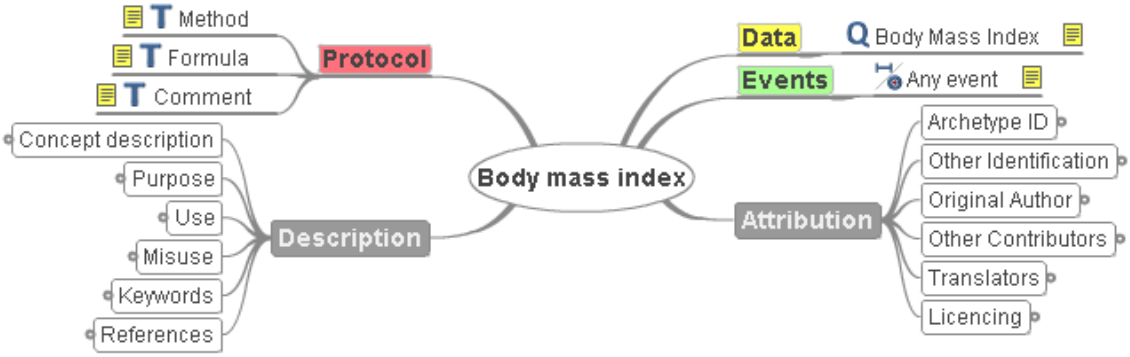

Figure 21: *Body mass index archetype.*

3.3.2.2 Physical related data

For the physical data relevant fields, the archetype that can be explored for each measurement is:

- To record details about the movement as part of physical examination:
  - ***openEHR-EHR-CLUSTER.move.v1*** (see Figure 22)

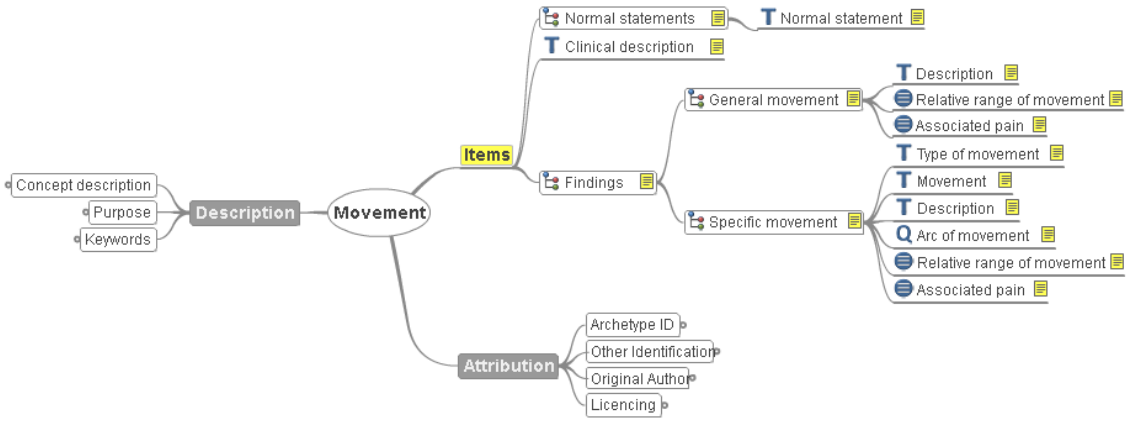

Figure 22: *Movement archetype.*

3.3.2.3 Lifestyle related data

The lifestyle relevant archetype needs to include nutrition summary and activities levels details of the elderly. For this purpose, ***openEHR-EHR-COMPOSITION.lifestyle_factors.v1*** can be explored to record a persistent and evolving summary record of information about lifestyle choices and activities that may influence clinical decision-making and care provision. The scope of this record can includes, but is not limited to an overview of:

- smoking and tobacco use,
- alcohol consumption,
- substance use,
- physical activity,
- diet and nutrition.

Furthermore, ***openEHR-EHR-OBSERVATION.barthel.v1*** can be used to record a score of dependency on help to undertake important activities of daily living. The structure of the aforementioned archetypes is shown in Figure 23 and Figure 24.

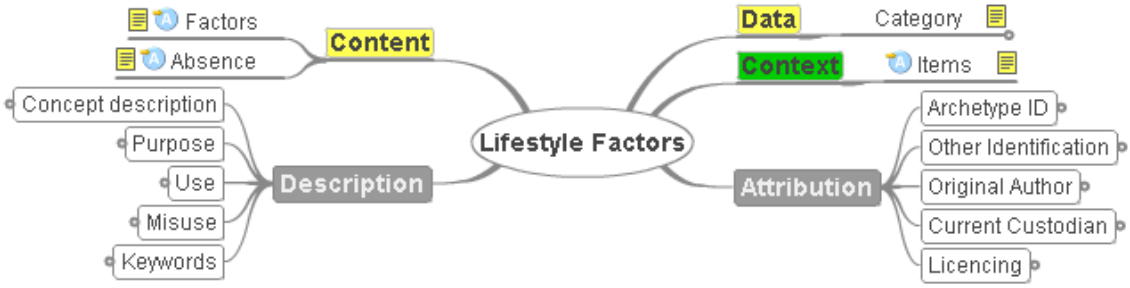

Figure 23: *Lifestyle factors archetype.*

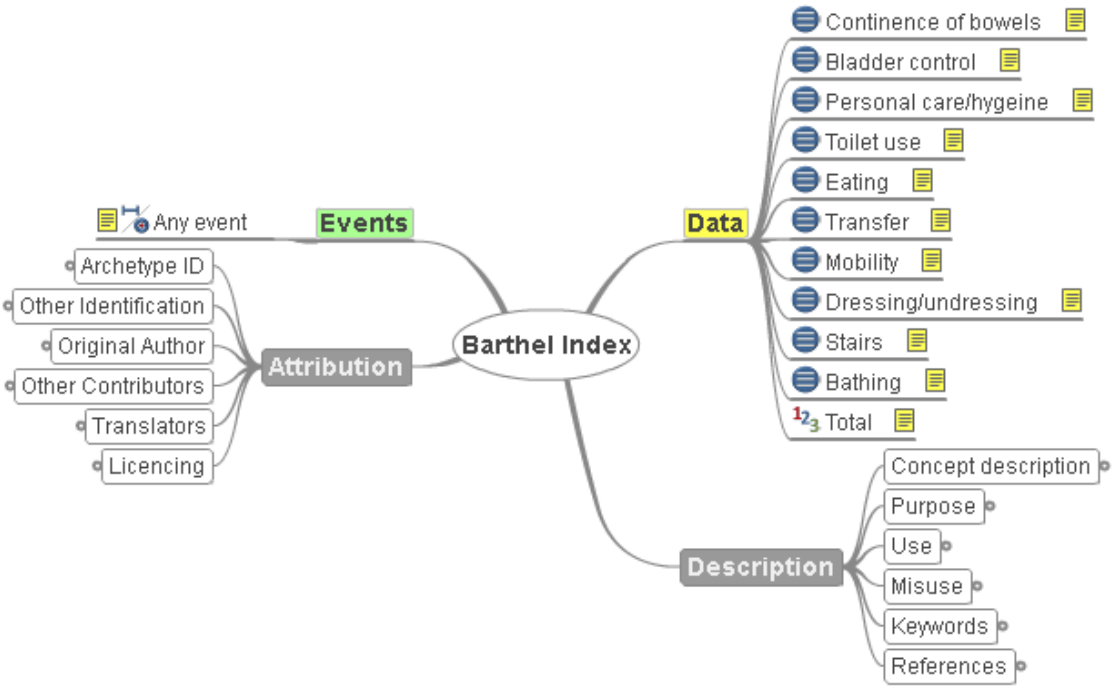

Figure 24: *IADL Barthel index archetype.*

3.3.3 Health records

The health records relevant archetypes need to include summary of medical information related to frailty. For this purpose, ***openEHR-EHR-COMPOSITION.health_summary.v1*** can be used to record a summary of health information about an individual and his/her family, representing a subset of their health record at a specified point in time. Furthermore, ***openEHR-EHR-COMPOSITION.family_history.v1*** can be explored to record a persistent and managed list of all relevant family history for the subject, or statements about positive exclusion or actual absence of information about adverse reactions, that may influence clinical decision-making and care provision. The structure of the aforementioned archetypes is shown in Figure 25 and Figure 26.

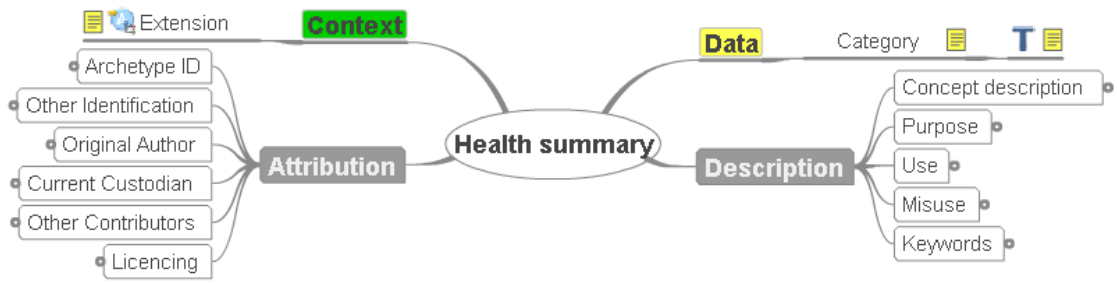

Figure 25: *Health summary archetype.*

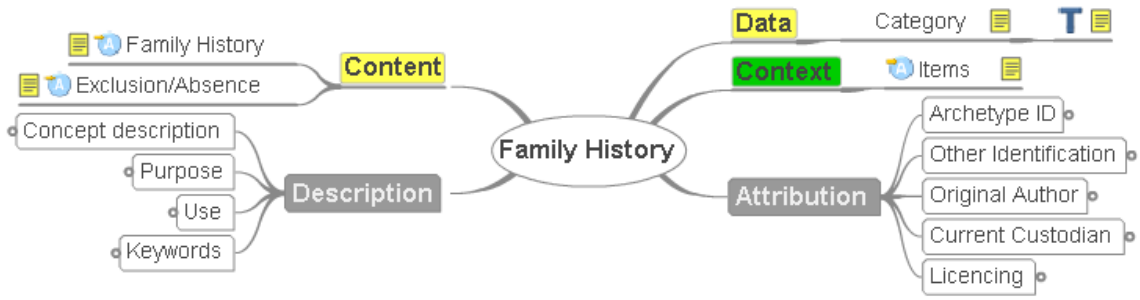

Figure 26: *Family history archetype.*

3.3.4 Clinician Input

3.3.4.1 Diagnosis

The diagnosis relevant archetype needs to include both analytic details, progress notes and conclusions of the patient's health from the perspective of a healthcare provider. For this purpose, ***openEHR-EHR-EVALUATION.clinical_synopsis.v1*** can be explored to represent a meta observation that will complement the existing structured clinical record, allowing for expression of subtle, subjective or interpretive information about the patient that might not otherwise be obvious through structured data alone, providing balance and context to the EHR record. Moreover, ***openEHR-EHR-COMPOSITION.problem_list.v1*** and ***openEHR-EHR-EVALUATION.problem_diagnosis.v1*** archetypes can be used to record a persistent and managed list of diagnoses identified, problems experienced by the subject (disabilities), previous procedures performed or any other issue which impacts on the physical, mental and/or social well-being of an individual. Furthermore, ***openEHR-EHR-COMPOSITION.progress_note.v1*** can be exploited to record details of health-related events that have occurred as part of the subject's care, and/or the subject's health status, findings, opinions and plans that are current at the time of recording. Finally, ***openEHR-EHR-SECTION.conclusion.v1*** can be used to record conclusions of an encounter with a patient. The structure of the aforementioned archetypes is respectively shown in Figure 27, Figure 28, Figure 29, Figure 30 and Figure 31.

Figure 27: *Clinical synopsis archetype.*

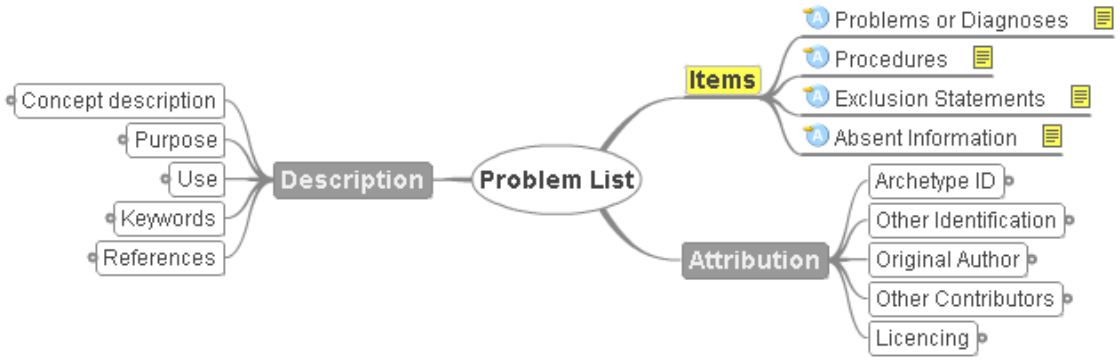

Figure 28: *Problem list archetype.*

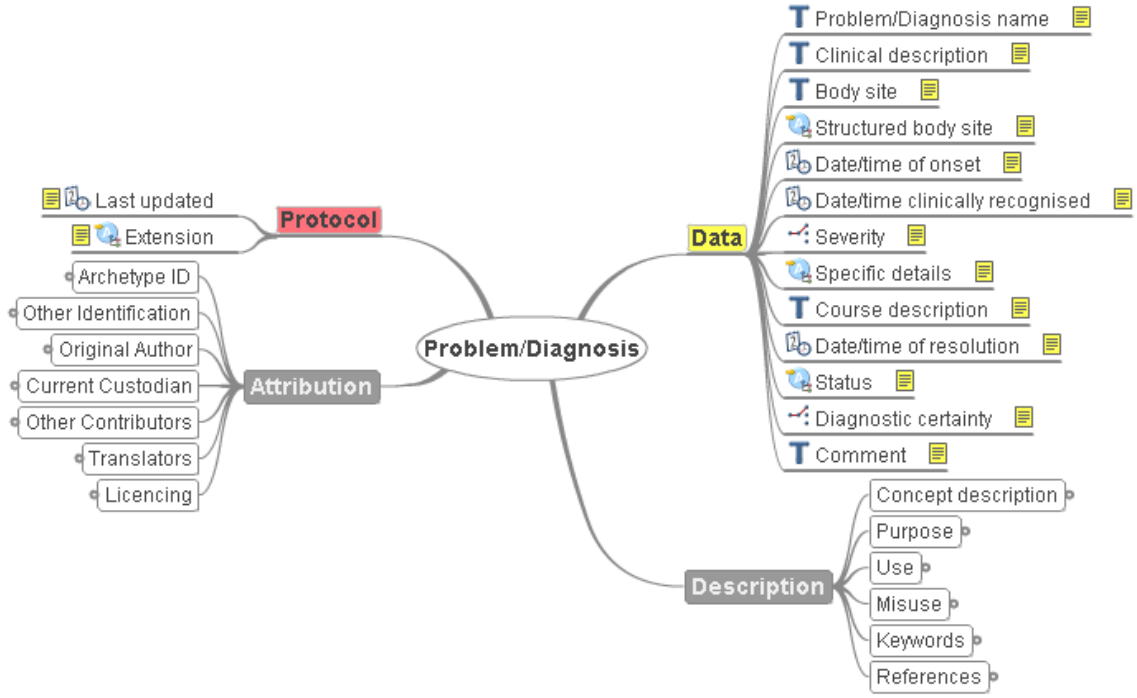

Figure 29: *Problem/Diagnosis archetype.*

Figure 30: *Progress note archetype.*

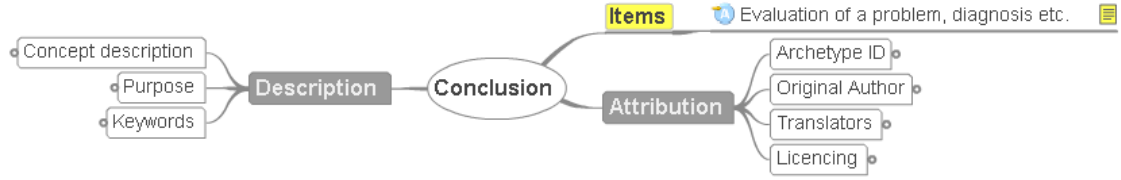

Figure 31: *Conclusion archetype.*

3.3.4.2 Interventions

The intervention relevant archetype needs to include potential medication and action advices and care plans. For this purpose, ***openEHR-EHR-EVALUATION.recommendation.v1,*** ***openEHR-EHR-INSTRUCTION.medication_order.v0*** and ***openEHR-EHR-INSTRUCTION.care_plan.v1*** can be utilized to record the order or instruction regarding the planning, initiation and carrying out of a single recommendation (suggestion, advice or proposal for clinical management), medication order or a care plan as a whole, respectively. The structure of the aforementioned archetypes is shown in Figure 32, Figure 33 and Figure 34.

Figure 32: *Recommendation archetype.*

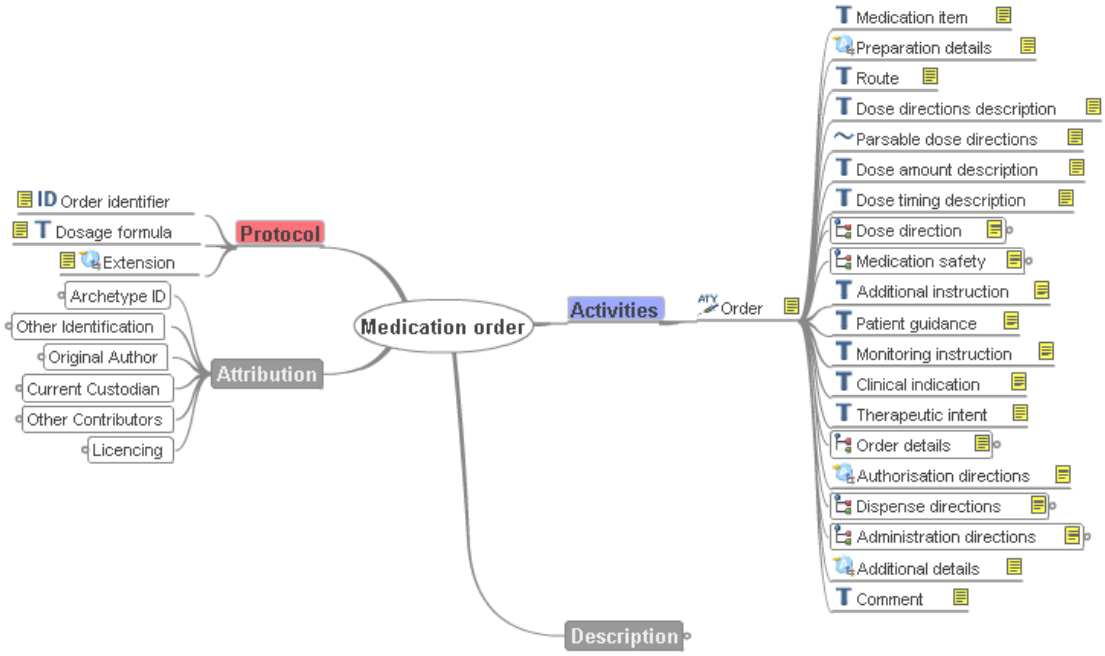

Figure 33: *Medication order archetype.*

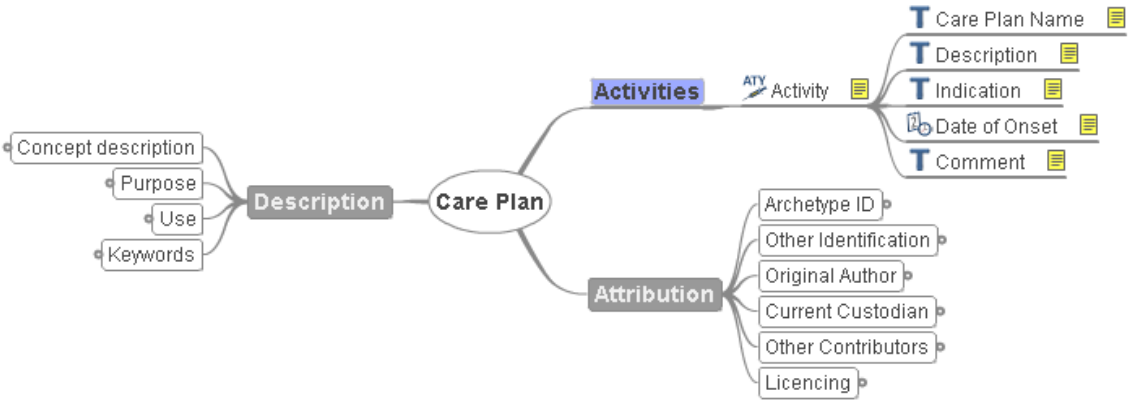

Figure 34: *Care plan archetype.*

3.3.5 Events

This archetype needs to include short-term and long-term recognition of frailty events. For this purpose, ***openEHR-EHR-INSTRUCTION.notification.v0*** can be utilized to enable clinical systems to generate a notice or announcement containing non-clinical information, which will be triggered at certain time/s or by occurrence of an event. The structure of this archetype is shown in Figure 35.

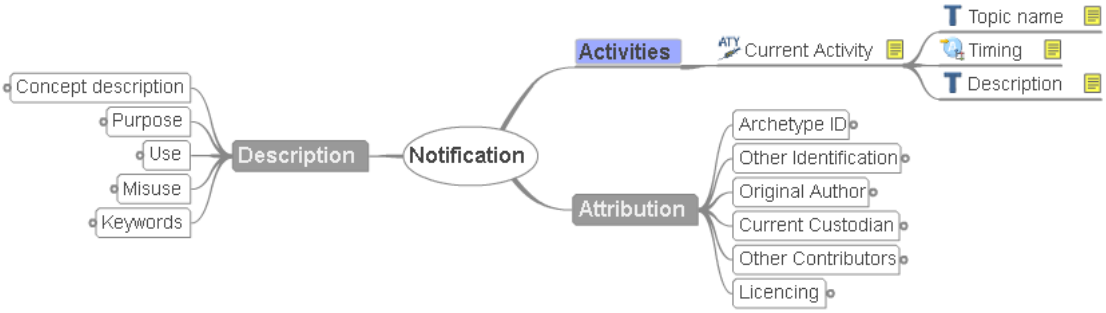

Figure 35: *Notification archetype.*

4 CONCLUSIONS

In this deliverable, we have presented how virtual user modeling research has attempted to address critical issues of FrailSafe' human-computer interaction through a large number of analytic, usability-oriented approaches by providing patients and caregivers with interface and tools fitting to their specific needs. More specifically, we have provided a detailed definition of the patient model representation format adopted within the FrailSafe project. To this end, openEHR; a multi-layer reference model for building VPM using archetypes (supported by an open source community and a variety of tools), has been adapted due to its clear benefits against its competitors and has been extended to fulfil the goals and functional requirements of FrailSafe system.

The identification and classification of the entities/concepts of interest that have been included in the patient models is offered. These entities have been categorized into data related to the user identification, data essential to the clinician and data recorded from the wireless body area network, the integrated sensors and games. In addition to the aforementioned parameters a list of parameters that are related to the statistical offline and real-time processing is also introduced, however the inclusion of these parameters to the patient models will be further investigated in the final version of this deliverable. Finally, the last part of this deliverable presents how the identified parameters are translated into existing openEHR archetypes.

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