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			Votis (CERTH), Dimitrios Vlachakis, Konstantinos Deltouzos, Spiridon Kalogiannis, Vasilis Megalooikonomou (UoP), Panagiotis Sabatakos, Emmanouil Viennas, Kosmas Petridis (HYPERTECH)	comments.

Review Form

No.	Officer Comment	Answer
1	However, the self-adaptation of user profile models (TO3) and the relation to offline data collected are not properly reported, as T4.3 of DoA instead requires.	Answered by sections 4.4 , detailing the self-adaptation procedures followed, and 4.3.1 , describing how offline data of all users are used to construct initial VPMs.
2	-distinction between "Existing state-of-the-art and novel methods …aiming at the semi-automatic creation and maintenance of a VPM";	Answered by sections 2.3 & 2.4 , describing the state-of-the-art methods related to dynamic model adaptation as well as clarifying the contribution of the FrailSafe VPM to the state-of-the-art. Details of how FrailSafe contributes to the state-of-the-art limitations are provided in sections 4.3 , 4.4 and 4.5 .
3	-actions that the system will take based on "… information about the specific co-morbidities the patient is suffering [and symptoms] … when detected";	Answered by section 4.1.2.2 , clarifying the connection of the VPM to the Decision Support System.
4	-which "… manual parameters setup by the clinician (rule-based)," will be included and the rule or, better, a discussion on this issue;	Answered by section 4.3 , covering the semi-automatic creation of a VPM, which involves the manual setting of available user parameters, in section 4.3.1 , as well as the manual setting and adjustment of parameters, for maintenance reasons, in section 4.3.2 .
5	-also, how the "information is provided to him/her via the mobile device and PC to assist in decision-making and promote patient engagement.";	Answered by section 4.1.2 , outlining the connection of the VPM to other FrailSafe components, and especially by subsection 4.1.2.3 , which describes the connection to the information visualization component.
6	-the analytics or procedure(s) and the management of communication and information flow to satisfy the "…need to be responsive to significant changes in older people's behaviour, physiological condition and sensitive to in-person fluctuations that occur on a daily basis".	Answered by section 4.1 , which describes the information flow between the VPM and other FrailSafe components, as well as by section 4.4 , which describes the mechanisms used to dynamically adapt the VPM as new data become available, on a daily and weekly basis.
7	-how, when and where (future deliverable) the profiling will be included in the decision support system beyond the current simple (naïve) level;	Answered by section 4.1.2.2 , where the connection of the VPM to the Decision Support System is described, with references to the related future deliverables.
8	-in which future deliverable the profiling models will be tested and "developed based on data collected from participants belonging to different frailty stages plus healthy participants".	Answered by section 4.1 , which includes notes about the evaluation of the VPM in the activities of the evaluation work package, along with references to the related future deliverable.

EXECUTIVE SUMMARY

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

The main focus of the deliverable **D4.6** is to model older people with a holistic approach, keeping together low-level and high-level clinical, physiological, physical and cognitive 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, behaviour, 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 (VPMs) a) will provide a structured machine-readable patient representation format, b) will allow adaptation of the user interfacing and patient intervention strategies, c) will make the data analysis and feature extraction more efficient, d) will support the healthcare professionals in their decision process, and e) will allow a personalized feedback to the patient (suggestions about behaviour/habits change, reminders, 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 FrailSafe's virtual patient model.

The detailed description of the virtual patient model used in FrailSafe is then provided. The identification and definition of the entities/concepts of interest for the FrailSafe project is analysed for the design and 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 offered. Semi-automatic methods for VPM generation are described, which facilitate the creation of a VPM for new users. The produced VPMs are dynamically and automatically updated when new data become available for the users.

Last but not least, the corresponding database model and the NoSQL databases have been generated followed by the successful integration and connection to the core server database.

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. Jan Komarek		

Deliverable number:	4.6	**Title:**	Dynamic User Profiling models and Patient modelling and representation framework
Work package number:	4	**Title:**	Data Management and Analysis

Date of delivery	**Contractual**	01/01/2017 (M12)	**Actual**	31/12/2016 (initial version), 26/11/2017 (revised version)
Status	Draft ☐		Final ☒ (revised)	
Nature	Report ☒	Demonstrator ☐	Other ☐	
Dissemination Level	Public ☒	Consortium ☐		
Abstract (for dissemination)	The main focus of this deliverable is to model older 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, behaviour, preferences, physical activity, etc. The patient model is dynamically updated when new data become available for a user, in order to be most representative of the user's condition.			
Keywords	FrailSafe, user profiling, virtual patient models			

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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
CRF	Case Report Form
DSS	Decision Support System
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
SQL	Structured Query Language
UML	Unified Modelling 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 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 can support other care-related activities directly or indirectly through various interfaces, including evidence-based decision support, quality management, and outcomes reporting. However, healthcare data is generally too complicated, flexible, and changeable to capture a universal, comprehensive and stable schema of information, which is the foundation of the entire EHR architecture. Highly-specialized and complex EHR systems cannot acclimate to the evolution of healthcare data requirements, which require EHR systems to embrace a dynamic, state-of-the-art, rapidly evolving information infrastructure [1]. To protect EHR systems from changes in the healthcare domain, openEHR [3] has published a series of specifications to guide the development of future-proof EHR systems. Solutions span from information modelling to system architecture, to meet the continually evolving needs of EHR systems.

The exploitation of '*virtual patient models*' (VPM) is increasing in healthcare, partly in response to increasing demands on health care professionals but also because they allow opportunity for students to practice in a safe environment [2]. More specifically, a virtual patient (VP) can be defined as "*an interactive computer simulation of real-life clinical scenarios for the purpose of medical training, education, or assessment*" [3]. VP are based on real patient cases and are obtained with the patient's full consent whose identity is never revealed. Simplest VPs allow the users to think about options and decisions they need to make based on some clinical information. The user is then either given feedback or more clinical information depending on the type of VP the user is playing. On the other hand, more complex VPs offer choices (via a decision support system) to the user at different stages for each potential scenario.

1.1 FrailSafe Virtual Patient Model

1.1.1 Main Goals

One of FrailSafe objectives is to generate reliable advanced intervention services and determine the risk of triggering events that would make a person tip from the pre-frail category to the frail one. To do so, we have designed and developed a detailed definition of a personalized virtual patient model composed of older people, static and dynamic, information. Data will be collected by unobtrusively monitoring their everyday life through a variety of embedded and wireless smart indoors and outdoors sensors,

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

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

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

social interaction, clinical assessment and self-evaluation tests. In other words, this VPM will be the older person's virtual alter ego, reflecting their medical condition.

The model will be personalised, in a sense that the frailty-related entities are categorized into data related to the (i) user identification, (ii) summary of the data recorded from the integrated sensors as well as the questionnaire and game analysis, (iii) archived medical data essential to the clinicians such as comorbidities and test results, and finally (iv) a list of parameters that are linked to the recognition of short-term scenarios (for example, loss of balance and orientation as well as fall detection) and long-term events (change of frailty metric).

The VPM coupled with several modules and tools will (i) facilitate the analysis of the collected data and frailty feature extraction, (ii) support the physician in his/her decision process ranging from general health preservation monitoring to critical situation management, (iii) allow an adaptation of the user interfacing of collected data and notification system supporting also phone call center, family and researcher profiles and (iv) provide a personalized feedback to the older person via lifestyle change suggestions, behaviour guidelines and medical intervention strategies (see Figure 1).

Thanks to integrating this personalised VPM into the FrailSafe framework, the potential users, namely older person, family, clinicians and medical researchers, will benefit from a system that gives them an optimal overview of his/her (pre-) frail state and at the same time assesses them to take the right decision with regard to either preventing frailty or potentially reversing its process.

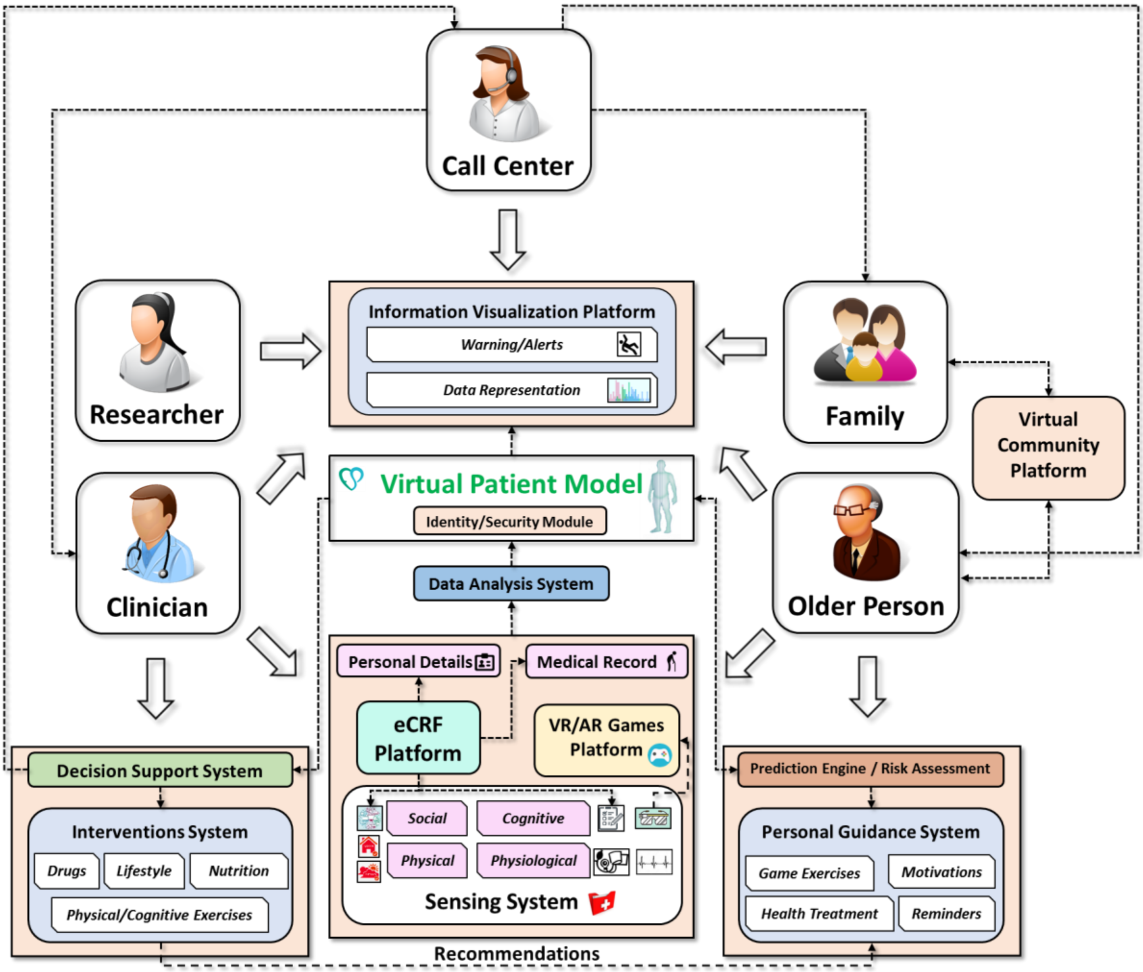


Figure 1: FrailSafe's framework puts the older person profile (VPM) at the core of the system.

1.1.2 Design and development steps

The concept of ''*archetype-driven data storage design*'', a two-level modelling approach of information system development, focuses on systems and tools necessary to the computation of complex and constantly evolving health information at a semantic level separating (i) information, domain content models, and terminologies, (ii) responsibilities and (iii) viewpoints. While in the single-level modelling approach, domain concepts that are processed by the EHR system are hard-coded directly into the application and database models, in two-level modelling the semantics of information and knowledge are separated into a small, comprehensible, non-volatile ***reference model*** (RM), which is used to build information systems and knowledge models; while ***archetypes*** are used as formalisms and structures to express numerous and volatile domain concepts [4].

The RM represents the general features of health record components, their method of organization, and necessary contextual information to satisfy both the ethical and legal requirements of the health record. The RM encompasses the stable features of the health record by defining the set of classes that composes the blocks which in turn constitute the record. On the other hand, archetypes define entire, coherent informational concepts from the clinical domain. An archetype is a hierarchical combination of components from the RM with available restrictions placed on names, possible data types, default values, cardinality, etc. These structures, although sufficiently stable, may be modified or replaced by others as clinical practice progresses and evolves [5]. Archetypes are deployed at runtime via ***templates*** that specify particular groups of archetypes to be used for a particular purpose. A template is a specification that creates a tree structure of one or more archetypes, and each constraining instance of various RM types such as composition, section, entry subtypes, etc.

By utilizing a two-level modelling approach for FrailSafe, virtual patient modelling can be built on a stable RM as a general framework, and thus use archetypes as the domain information model to achieve greater flexibility and stability. Furthermore, situations in which the domain concepts are vast in number, have complex relationships, and evolve continuously can efficiently be adopted following this direction. It is important to note that the RM ensures that VPM can always send information to other systems and receive readable information in return, thus ensuring data interoperability. Last but not least, archetypes can be used as the common knowledge repository (see how openEHR system maintains an archetype-based Clinical Knowledge Manager - CKM[4]) to share evolving clinical information that can be processed by the receiving systems, thus enabling semantic interoperability [6].

From an implementation point of view, the responsibilities of specialists from the information technology domain and the healthcare domain are disengaged. Developers focus only on the technical components of VPM system, while specialists develop the structural model based on domain concepts archetypes. This enables domain specialists to directly organize and present healthcare information and interactions, and to control the framework without intervention from the system supplier or re-programming.

To this end, FrailSafe employs an archetype relational mapping (ARM) approach [7] (see Figure 2); capable of efficiently generating relational databases using archetypes and templates and most specifically openEHR ones. First, the data requirements of the VPM system are analysed and organized into archetype-friendly concepts. The openEHR CKM is queried for matching archetypes; when necessary, new archetypes are developed to reflect concepts that are not encompassed by existing archetypes.

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

Finally, a set of rules is designed to map the archetypes to data tables and provide data persistence based on the relational database.

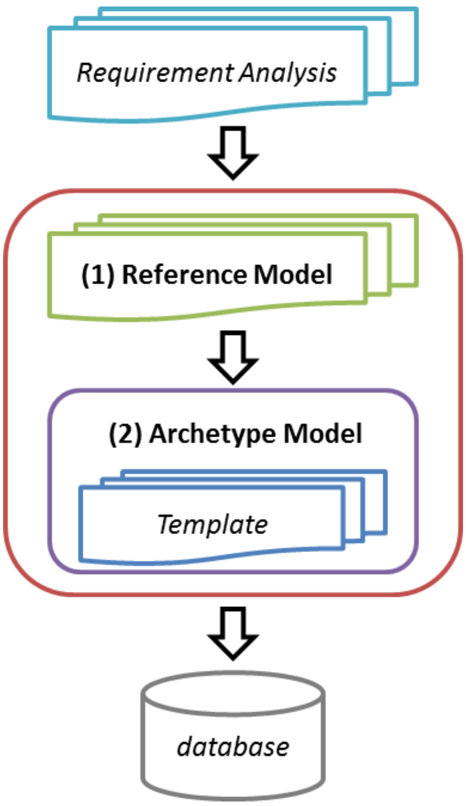


Figure 2: Archetype-driven data storage design. Two-level, reference and archetype, modelling.

1.1.3 Document Structure

To this end, the present document is initially devoted to the presentation of a comprehensive insight of the heterogeneous electronic health records. An analytic description of the openEHR model is offered since we believe that this is the best approach available for realising the goals of FrailSafe due to its strategic value to the future development of next generation healthcare technologies (Section 2). After the comparison of the available representation frameworks, we present the entities/concepts of interest to meet the project's requirements (Section 3). The main part of the deliverable is the description of the Virtual Patient Model to be used in FrailSafe (Section 4). The description starts with an overview of the VPM architecture and its connection to other FrailSafe modules. It continues with the description of the most highly-related existing openEHR archetypes that best-fit the identified parameters, as well as the entirely new archetypes having been designed and created from scratch, for the rest of the parameters. Next, the methods used for semi-automatic generation and dynamic adaptation of the VPM are described, followed by a technical description of the database schema used for data storage. After the above discussion with regard to the VPM construction steps, conclusions are finally offered (Section 5).

2 PRIOR ART ON ELECTRONIC HEALTH RECORDS AND DYNAMIC VIRTUAL PATIENT MODELS

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 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 include (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-centred, life-long, shared care health records.

2.1.1 HL7[5]

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 Labelling (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**

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

    - a Standard Healthcare Attachment to augment another healthcare transaction
- **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[6]

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. 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. **Error! Reference source not found.** 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

[6] http://www.openehr.org

FrailSafe virtual patient models will be based on the openEHR architecture. Before proceeding to the requirements and archetypes presentation of the FrailSafe system, in the following subsection we provide a brief overview of the openEHR's two-level modelling architecture.

Table 1: Comparison between OpenEHR and HL7 representation models.

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*[7]	*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*

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

2.2 openEHR Architecture overview[8]

The openEHR approach to modelling information, services and domain knowledge is based on several design principles, described below. The application of these principles leads to a separation of the models of the openEHR architecture, and consequently, a high level of componentization. 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 3 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.

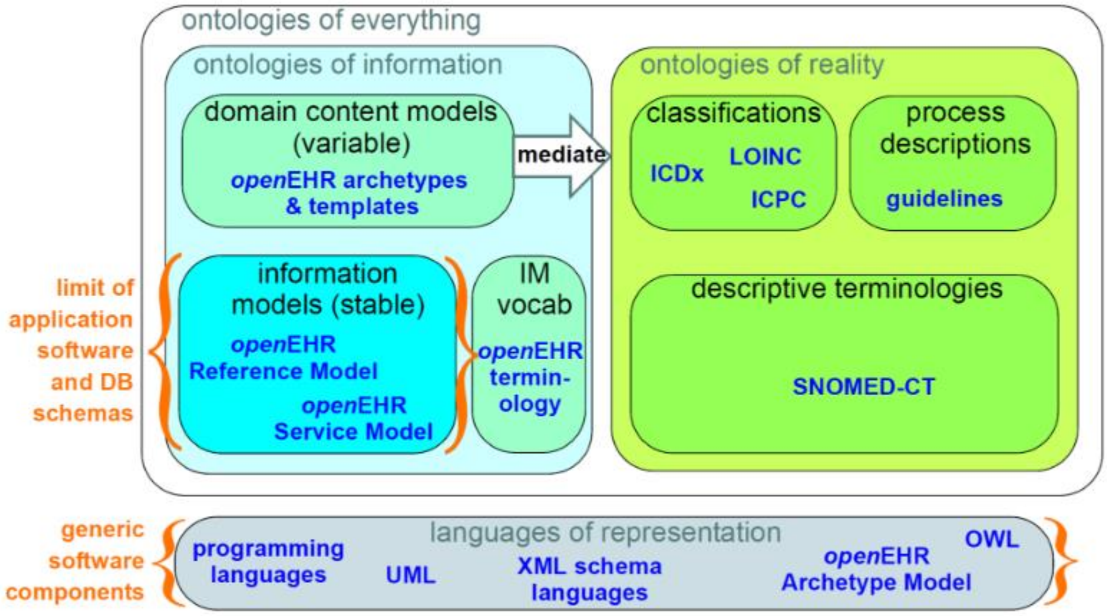


Figure 3: The ontological landscape.

2.2.2 Two-level Modelling

One of the key paradigms on which openEHR is based is known as "two-level" modelling, described in [4]. 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

8 http://www.openehr.org/releases/BASE/latest/docs/architecture_overview/architecture_overview.html

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 languages/models of representation (shown at the bottom of Figure 3). 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.

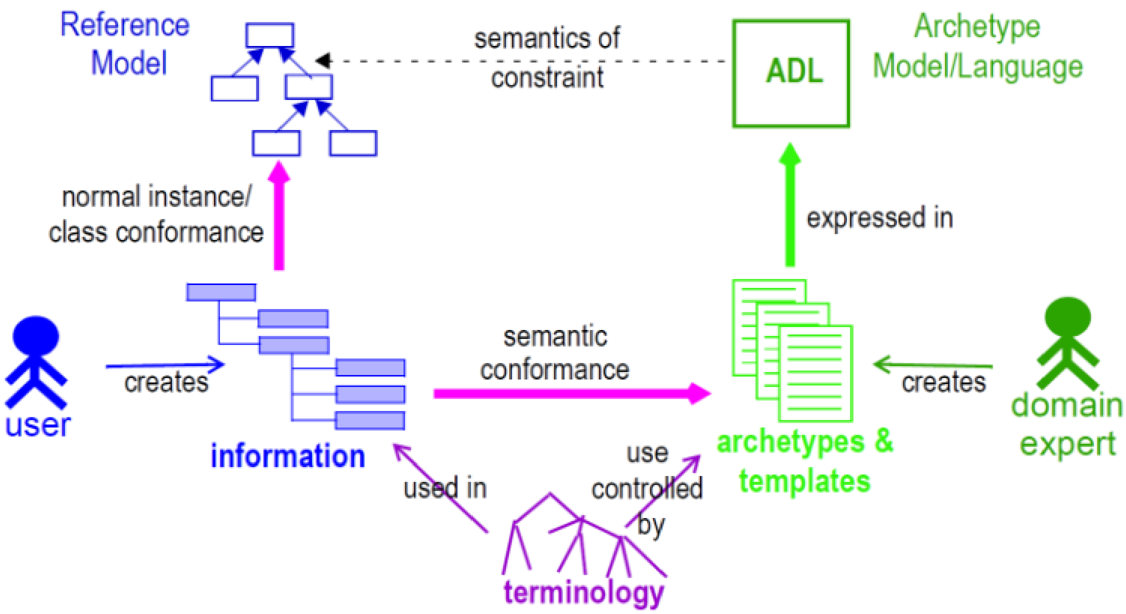


Figure 4: Archetype Meta-architecture.

2.2.3 Archetype Technology Overview[9]

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

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

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.

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 4. 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 sub-forms 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 5). 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.

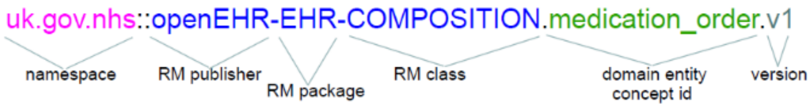


Figure 5: Typical Archetype HRID.

- **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 serializations is available, usually for technical reasons. These include ODIN (Object Data Instance Notation), XML (Extensible Markup Language) and JSON (JavaScript Object Notation) serializations, 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 Modelling 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 6.

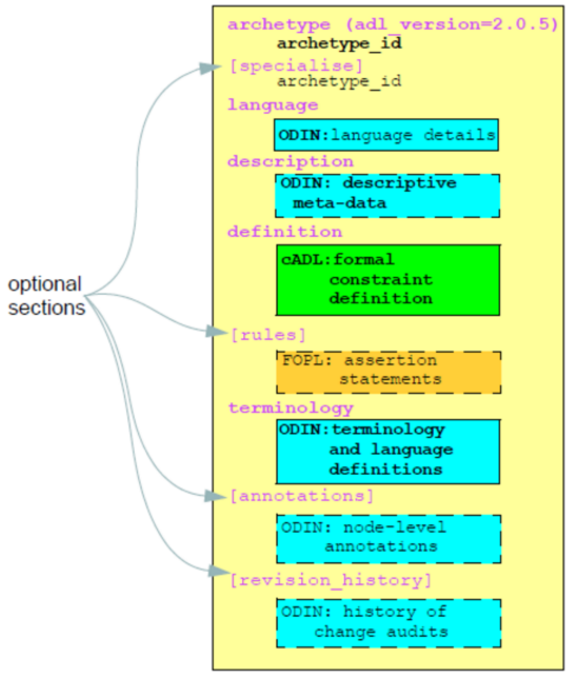


Figure 6: ADL Archetype Structure.

2.3 Adaptive and dynamic user models

User models are representations of certain characteristics of human behaviour, capacities, abilities and preferences, usually recorded and updated in order for a computer-based agent to conceptually understand the human user of a system or service [8]. User models may represent a specific user (personalized) or a user group covering the main characteristics of the majority of users with the best possible accuracy. In intelligent user environments it is expected that the system is capable of adjusting interfaces and interaction to multiple users in a context-dependent and personalized manner, and furthermore it is capable of learning user's model from interaction history [9] [10] [11]. The modelling mechanisms usually employ machine learning approaches in order to allow the models to continuously evolve and dynamically adapt to newly observed situations (e.g. behaviours, contexts, preferences, abilities, etc.) [9] [11] [12]. Though a wide variety of user modelling design patterns have been introduced in various application domains, the vast majority consider a mixture of the following four dimensions: (i) user type – personalized versus group based; (ii) data gathering approach – explicit (e.g. questionnaire) versus implicit (e.g. monitoring or observing the user); (iii) time-dependency of data, and (iv) updating/learning methodology. With respect to time-dependency, user modelling may depend on the time sensitivity of the acquired information since it may include from highly specific information (short-term) to more general information (long-term) data. Finally, user models can be divided by their update strategy to static, where the main data is gathered once and normally not changed again; and dynamic, which allow a more up-to-date representation of user's characteristics.

The model itself is usually based on ontological representations, which allow for definition of entities and properties, along with relationships between them [9] [12] [13]. More specifically, an ontology may be defined as a formal, explicit specification of a shared conceptualization, and it helps modelling a world phenomenon by first identifying its relevant concepts and defining explicitly concepts and related constraints. Formal refers to the fact that the ontology should be machine readable, and shared reflects the notion that an ontology should capture consensual knowledge. The definition and use of ontology in the medical domain is an active research field, as it has been recognized that ontology based systems can be used to improve the management of complex health systems [14]. Early works, such as the GALEN ontology [15], provide reusable terminology resources for clinical systems, while other systems use ontologies for managing organizational knowledge, providing clinical decision support features and supporting continuity of care for specific diseases [16].

The existing methods for user modelling supporting dynamic adaptation over time, such as the above mentioned works [9] [10] [11] [12], are mostly applied to fields such as social media, smart homes and computer usage. There is generally a lack of similar methods in the medical and eHealth domain. A significant effort has been performed the latest few years in the European Union (EU) to develop virtual user models, focusing on several user characteristics, in such a form that would enable their direct simulation, automated or semi-automated, in a variate of interactive scenario platforms. VERITAS[10] in collaboration with three other FP7 projects, namely VICON[11], MyUI[12], and GUIDE[13] have come up, following suggestions of the EC, to a formal Extensible Markup Language (XML) and Web Ontology Language (OWL) representation of patient

[10] http://veritas-project.eu

[11] http://vicon-project.eu

[12] http://myui.eu

[13] http://guide-project.eu

models of people with disabilities, chronic conditions and functional limitations [17]. Actually, the VERITAS project developed an open library of various categories of virtual user models, including cognitive, physical, psychological, behavioural and AR/VR models, covering a wide range of population groups and especially focusing on groups in risk of exclusion, e.g. older people, people with disability (vision, hearing, speech, motor), people with co-existent conditions, etc. [18]. Relevant, the MyUI and GUIDE projects developed virtual user models that aim mainly to be accurate user profiles for interface adaptation and finally the VAALID[14] project developed user models of older people.

The capability of the VERITAS Virtual User Model (VUM) to capture the full-range of behavioural characteristics along with functional limitations and health related parameters makes it a perfect fit for modelling of older people in intelligent health-care systems. Furthermore, the user models are generated based on the analysis of user needs, existing models (physical, cognitive, behavioural and psychological), guidelines, standards, methodologies and existing practices but also based on a multisensorial platform that will sense the needs of real users with functional limitations by measuring their behaviour (task performance) in simulated environments. Through this process, the VUM generator tool transforms of the initial abstract user models into personalized VUMs.

It is worth shortly describing the way VERITAS user models were generated, since they provided inspiration in designing the FrailSafe VPM. In VERITAS, a population of users was used in order to compute probability distributions for a set of monitored parameters. A set of physical and clinical parameters was first considered, such as the maximum angle of knee opening, or the amount of eyesight impairment. Each of these parameters was measured from the population of users. The measurements, along with bibliographic sources, were used to estimate the probability density of the parameter values within the population. Then, the system, through an appropriate interface, allowed the operator to generate a new user by specifying a population percentile for each of the parameters. In this manner, the operator could generate "average" users, or users with an exceptional value for a parameter, belonging in the lower 5% percentile of a parameter range, etc. The process is depicted in Figure 7.

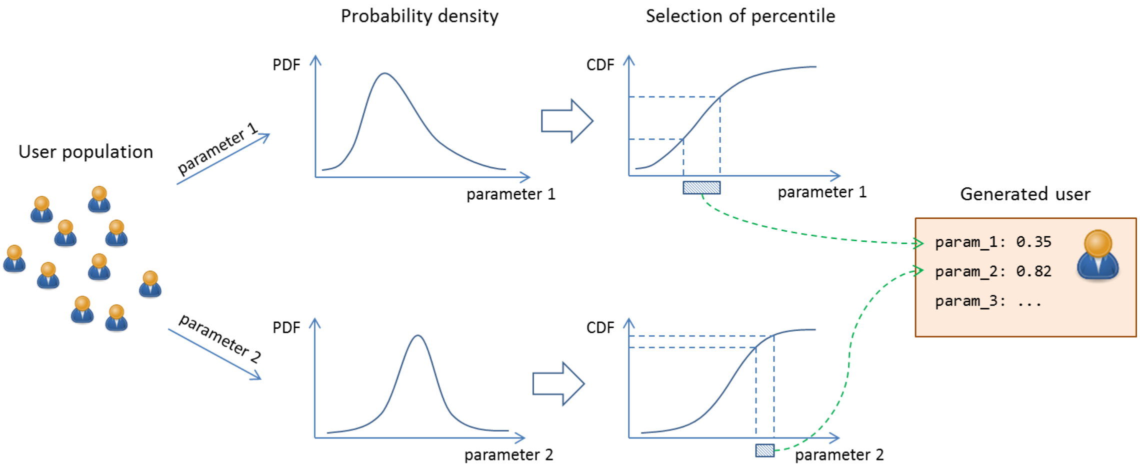


Figure 7: Simulated user generation in the VERITAS project.

However, the VERITAS VUMs have some limitations, with regard to the needs of FrailSafe. First, they were designed with a different purpose in mind, i.e. user simulation, whereas in FrailSafe the goal of a user model is to best describe the older person's current condition and history. Second, the VERITAS VUMs do not provide the

[14] www.vaalid-project.org

mechanisms to dynamically adapt and evolve the generated models over time, taking into account the data history data of a specific user or of a group of users.

2.4 FrailSafe progress beyond the state-of-the-art

The FrailSafe project aims to apply methodologies for dynamically adapted user modelling in the eHealth domain, inspired by the success of such methodologies in other domains, such as social media and smart home environments. The FrailSafe user models are progressing beyond existing state-of-the-art health-related user modelling techniques, in order to address their limitations. With regard to VERITAS VUMs, this is accomplished first by modifying the user generation procedure, since now the goal is not to simulate non-existent users, but to correctly model existing ones. Second, mechanisms for short-term and long-term dynamic adaptation of the models are implemented, so as to take into account in-person fluctuations that occur on a daily basis and respectively, significant changes of the patient's behaviour that is observed on longer time intervals (e.g. per week).

The FrailSafe user profile models employ a modification of the VERITAS VUM generator tool, in order to instantiate the personalized patient profile models, based on a the set of FrailSafe users already enrolled. A library of generic profiles is generated by clustering the population of already enrolled participants, based on the data collected so far from patients belonging to different frailty stages as well as healthy participants.

The FrailSafe system will instantiate such a personalized model when a new user is enrolled, and the initial examination and measurements are conducted by the clinicians. The process is semi-automatic, as certain parameters are manually set-up by the clinician (e.g. co-morbidities), while others are automatically inferred by the system, through the aforementioned clustering procedure. Whenever new data are available or at predefined intervals, the two adaptation mechanisms are used to update the short-term and long-term models of the patient. Details about the generation of a VPM for a new user and the dynamic adaptation procedures used in FrailSafe are provided in Sections 4.3 and 4.4 , respectively.

Finally, the adaptability of the FrailSafe VPM extends in another direction as well. The VPM aims to be adaptable to future modifications of the archetypes and the types of information present, by adopting a schema-less database structure, designed to properly represent the ontologies and archetypes of the VPM. Details about the database design are provided in Section 4.5 .

3 REFERENCE/INFORMATION MODEL OVERVIEW

User modelling 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 [19]. The goal of user modelling 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 [20]. 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 to record the user context and personalize applications 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 [21]. In [22], 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: (i) acquiring data from heterogeneous context sources (e. g., biomedical and environmental sensors); (ii) representing knowledge about patient's situation by means of ontology-based formalisms; (iii) reasoning over knowledge using rule-based and ontology-based engines; and (iv) 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 [23] 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. Thus, authors in [24] 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 [25], a multi-agent 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.

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 [26]. Requirements analysis is critical to the success or failure of a systems or software project [27]. 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. ***Gathering requirements***: The practice of collecting the requirements of a system from users, customers and other stakeholders.
2. ***Analysing 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.

In this section we will initially describe the different entities/concept of interests (e.g., system users, data sources, devices, software modules) that should be exploited in order to design and develop a detailed definition of the model representation format (see Section 0) that will be adopted from older people within the FrailSafe project.

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 in physical, cognitive, psychological, social domains; to provide intervention solutions offering physiological reserve, pharmaceutical treatment and external challenges via personal guidelines, real-time feedback, AR serious games; to create "prevent-frailty" evidence-based recommendations for the older people; to strengthen the motor, cognitive, and other "anti-frailty" activities through the delivery of personalised treatment programmes, monitoring alerts (final FS product, after M36), guidance and education; and to achieve all with a safe, unobtrusive and acceptable system that consists of a virtual patient model sensitive to several dynamic parameters (see Figure 1).

3.1 Requirements and Model Analysis of final FrailSafe framework

In FrailSafe, we have identified a number of the end-users that will benefit from the outcomes of the final system and can be divided into four groups (for more details see D1.2), namely

- **Older people**
- **Families of older people**
- **Clinician healthcare professionals**
- **Clinician researchers**
- **Phone call center**

Different user access roles with separate authorizations to each part of the FrailSafe system have been identified allowing variable sectors activation to limited user groups ensuring safety to sensitive personal information.

FrailSafe can be divided into several distinct modules (for more details with respect to data flow between them as well as identity and security issues, we refer readers to deliverable D1.3):

- **eCRF platform**

An electronic Case Report Form (eCRF) is designed to store the participant's personal information including his/her clinical history as well as to collect clinical measurements during home trials. Data information to be saved consists of the participant filling (i) some questionnaires relating to different contents (Cognitive Evaluation, Nutritional Assessment, written text, sketch etc.) or uploading file created by specialized medical devices (FORA).

- **Sensing System**

A mechanism that represents the variety of novel sensing mechanisms including body-worn and ambient sensors for monitoring a multitude of physiological, physical, cognitive and behavioural parameters of older people in an unobtrusive manner both indoors and outdoors (for more details see deliverable D3.1).

- **Data Analysis System**

This module consists of the (i) Offline Analysis, that will serve as the central storage and organization of the multi-parametric data as well is responsible for the data processing and frail-related knowledge discovery; and on the other hand, (ii) Online analysis will concentrate on the final monitoring system aiming to cover specific situations during day time normal activity of the patient both indoors and outdoors (for more details see deliverables D4.1 and D4.2).

- **Risk Assessment Module**

This module is responsible for evaluating short-term and long-term event recognition of frailty events. This way several, critical clinical parameters could be predicted, both in short-term scenarios such as predict falls, loss of orientation and balance, as well as in long-term scenarios like predict frailty level change (for more details see deliverable D4.5).

- **Personal Guidance System**

A module that embeds personalized guidelines outputted from VPM-based trained mechanism (Prediction Engine) as well as the clinician's suggestions and recommendations to achieve early medical assessment combined with personal motivation and adjustment to frailty changes.

- **Interventions System**

An (semi-)automatic model with advanced decision making capabilities (Decision Support System) that supports the healthcare professionals by assisting the diagnosis and by suggesting a number of potential pharmaceutical strategies (drug & dose selection) and non-pharmaceutical intervention solutions (guidelines, feedback, serious games).

- **Information Visualization Platform**

The module provides all necessary means for the direct and intuitive visualization of all monitoring parameters. The aim is to provide knowledge to users in an optimal way via information (warnings, alerts), processes and experiences. Different front-ends targeting the different end-user groups of FrailSafe will be implemented (for more details see deliverable D5.4).

- **Virtual Community Platform**

The objective of this component is to offer social media patient support community for caregivers, older people, and their families supporting interactions among peers having similar health issues, exchange disease and health related information as well as the promotion of positive health-related activities (fitness, daily habits), education and training whenever required (for more details see deliverable D6.1).

- **Identity and Security Module**

The aim of this component is to control the accesses to the system resources, this means for example to avoid that unauthorized individuals have access to the system or an authorized user requests a forbidden resource for own specific role.

Figure 1 illustrates an analytic schematic representation of the data flows between the VPM and the rest components as well as shows how each actor interacts in high level with the each submodule. Observe that VPM information cannot be directly accessed by any user group. This can happen indirectly via the specialized graphical user interfaces (GUI) implemented for each module. More specifically,

- **Older people** will be able to (i) overview the clinical status of his/her health condition (Information Visualization Platform) and to (ii) have access to interactive preventive rehabilitation information (Personal Guidance System) based on their frailty risk factor (Risk Assessment Module). A combination of new and existing sensing mechanisms (unobtrusive body-worn and ambient sensors) wiil be explored to continuously monitoring of a multitude of physiological, physical, behavioural and lifestyle (social) data of older subjects (Sensing System). Social interaction between frail-oriented older people for feedback and education is also an option (Virtual Community Platform).

- **Families** will be able to (i) receive notifications in case of emergency situations as well as to (ii) remote monitoring the health condition of the older person via intuitive, but restrictive, data visualizations (Information Visualization Platform).

- **Researchers** will be able to conduct analysis and experimentation by accessing to the dataset collected as part of this study without compromising privacy issues (Information Visualization Platform).

- **Clinicians** will be responsible for (i) the medical monitoring of the older people (Information Visualization Platform) as well as (ii) the delivery of personalised treatment programmes (Interventions System) through advanced intervention solutions designed to delay, arrest or even reverse the transition to frailty. Optimal planning of the intervention strategies will be delivered in a self-management manner or automated (Decision Support System).

- **Phone call centres** will be responsible to check for intervention compliance and to give support to users when a risk is identified (Information Visualization Platform). Moreover, patient retention and satisfaction and operational efficiencies improvement can also be a potential role of this user group.

Considering completeness, a detailed summary of the user modelling and requirements analysis as well as the architecture and system specifications that the FrailSafe system should fulfil and follow can found in Deliverables D1.2 and D1.3, respectively.

3.2 FrailSafe Virtual Patient Model Representation

A list of requirements that covers the objectives of the FrailSafe project and describes the basic characteristics of the corresponding virtual patient model representation scheme is analytically presented. Figure 7 illustrates a multilevel schematic representation of these entities. These are divided into five (5) main classes which are further separated into subcategories and so on:

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 older people, 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 older people.
2. **Health record:** This category should describe the systematic documentation of a patient's health summary, family history and care across time.
3. **Monitoring parameters**: This category should include 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. ***Psychological related data***: This subclass contains the requirements related to psychological measurements such as depression and anxiety.

   d. ***Social related data***: This subclass focuses on the requirements concerning the social interaction and behavioural parameters such as social media.
   e. ***Cognitive related data***: This subclass contains the requirements related to cognitive measurements such as progress in VR/AR games and deficiencies in electronic written text.
   f. ***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.

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. Thus should involve any parameter that is necessary for the quantitative definition of a frailty metric.
   b. ***Interventions***: This category includes the requirements for the documentation of care plans, medicines as well as life-style and game 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. NB: alerts will be functional in the final FrailSafe product after month 36.
6.
   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.

This list of data can be classified, according to the sampling frequency they are collected, into two categories: **static** (or offline) and **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 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.

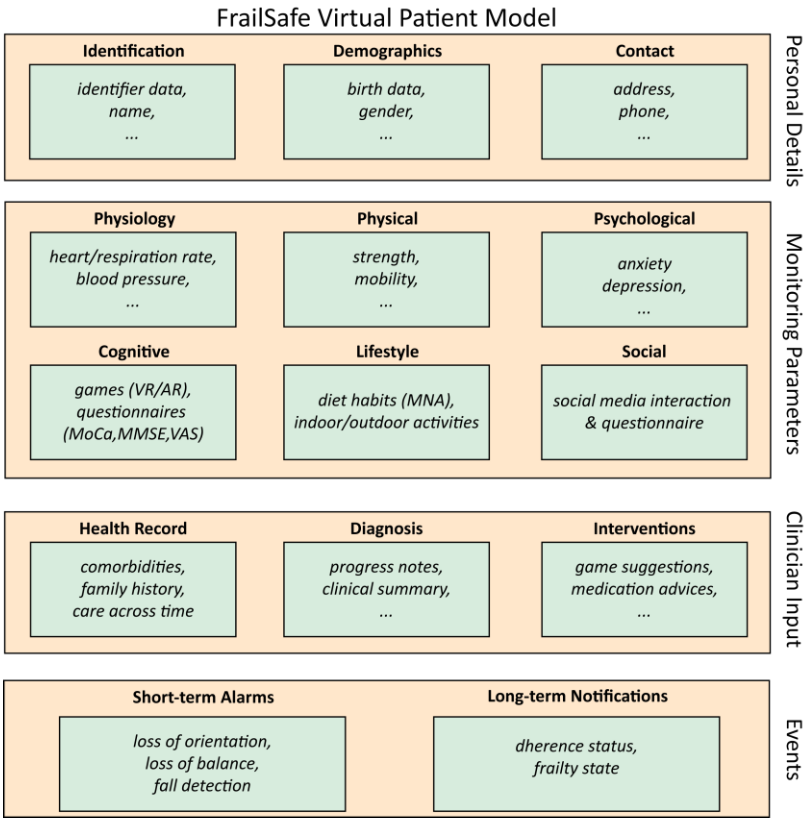


Figure 8: Overview of the core entities that will be included in the FrailSafe virtual patient model.

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*[15] method was adapted. Each use case (see D1.2) 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*) is a guide to the knowledge that you need to gather in order to specify the requirements for a product. 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 VPM need to be concerned. Each of the gathered requirements whether they 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.

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

Table 2: Naming and notation of FrailSafe requirements regarding VPM.

Requirements	Notation	Requirements	Notation
General information	GEN-RE	Questionnaire measurements	QUE-RE
User identification	ID-RE	Frailty indicators	IND-RE
User demographic details	DEM-RE	Clinician input representation	CLI-RE
User contact details	COM-RE	Events representation	EVE-RE
Sensor measurements	SM-RE		

3.2.1 Requirements to be addressed for the general VPM representation

The following table contains requirements regarding general VPM characteristics.

ID	GEN-Re01
Name	Representation of Text
Description	VPM should allow the representation of text in different languages
Rationale	A variety of inputs by patients and doctors are collected in the form of open text, and therefore the patient model should be able to include such type of data
Fit Criterion	Ability to define a parameter of text format for all FrailSafe users
Proposed Solution	VPM will allow the representation of text as well as scalar and discrete types of information
Priority	High
Conflicts/Relations	No conflicts currently identified
Author	CERTH
Revision	Initial Version V1.0
ID	GEN-Re02
Name	Representation of Scalar Multi-dimensional Values
Description	VPM should allow the representation of scalar values of single and multiple dimension
Rationale	VPM will mainly comprise from numerical data of single or multiple dimensions. This data may represent clinical assessments, monitoring conditions, activity levels, alerts, suggestions or any other parameter foreseen in the framework of the project.
Fit Criterion	Ability to define a two-dimensional parameter for all FrailSafe users
Proposed Solution	VPM will allow the representation of scalar values of multiple dimensions when their size is fixed. For the case where multidimensional matrices of unknown dimensions are needed to be represented, the data should be represented and stored as text (e.g. JSON format) or as a separate file.
Priority	High
Conflicts/Relations	No conflicts currently identified
Author	CERTH
Revision	Initial Version V1.0

3.2.2 Requirements for the Personal Details class

This class should contain three subclasses which are related to patients' personal information and will be collected by the eCRF platform:

1. **Identification information**

ID	ID-Re01
Name	Creation of a unique system ID

Description	VPM should be based on a unique ID that will be generated for each user
Rationale	The unique ID of users will be the basis for the discrimination between them
Fit Criterion	An automatically generated unique ID is assigned to every new user of the system
Proposed Solution	A unique ID is generated for each user.
Priority	High
Conflicts/Relations	No conflicts currently identified
Author	CERTH
Revision	Initial Version V1.0
ID	ID-Re02
Name	Anonymization of virtual patient model
Description	VPM should allow the exclusion of nulling of all identification information
Rationale	This requirement will allow the creation of a repository of open data that can be used by the research community for the study of frailty.
Fit Criterion	An anonymized model should be compatible with all system components and allow the processing by all modules of FrailSafe system
Proposed Solution	The user identifying information are stored in separate entities and not within the main modelling framework
Priority	High
Conflicts/Relations	No conflicts currently identified
Author	CERTH
Revision	Initial Version V1.0
ID	ID-Re03
Name	User authentication & authorization of virtual patient model
Description	VPM should avoid unauthorized individuals have access to the system or an authorized user requests a forbidden resource for own specific role.
Rationale	Authorization is mandatory for specifying access rights to resources related to information security and to access control for the different end users.
Fit Criterion	A unique generated password must be generated of every new user of the system
Proposed Solution	Identity and security module (not part of the actual VPM) will control the accesses to the patient data information.
Priority	High
Conflicts/Relations	No conflicts currently identified
Author	CERTH
Revision	Initial Version V1.0

Following requirements ‘ID-Re01-03’, we have chosen to hold these identification parameters:

- ID number

A 4-digit index number, having the first referred to the site (1 = Patras, 2 = Cyprus, 3 = Nancy, 9 = External) and the other digits free.

- Name

First and Family names.

- Identification (Passport)

A (travel) document, usually issued by a country's government, that certifies the identity and nationality of its holder.

- Password

A string of at least 6 characters long which can contain letters, numbers or symbols without restrictions.

2. Demographics details

ID	DEM-Re01
Name	Inclusion of important demographics information to the VPM
Description	VPM should include an extendable list of demographic information
Rationale	The collected demographic data can be used for the personalization of FrailSafe functionalities. Some examples include the use of age and gender for the understanding of clinical status of patients. The educational level can reveal important parameters of medication adherence. The occupation may reveal important conclusions regarding the frailty risks in the different environments. Language and ethnicity will allow the customization of user interfaces
Fit Criterion	VPM allows the representation of demographic information.
Proposed Solution	Demographic data are represented under the virtual patient record including but not confined to: Year of birth, Gender, Educational level, Main occupation, Language.
Priority	High
Conflicts/Relations	No conflicts currently identified
Author	CERTH
Revision	Initial Version V1.0

Following requirement ‘DEM-Re01’, we have chosen to hold these demographic parameters:

- Year of birth

A 4-digit number.

- Gender

Male or Female.

- Country of birth

A string of at least 20 characters long.

- Years of education

A 4-digit number.

- Profession

The main profession during his/her life, can be ‘Housewife’, ‘Agricultural worker’, ‘Worker’, ‘Craftsman-merchant’, ‘Intermediary professional’, ‘Employee’, ‘Executive employee and intellectual professional’.

3. Communication parameters

ID	CONT-Re01
Name	Multiple contact details
Description	VPM should allow the definition of more than on contact details for one system user
Rationale	Older people can be contacted in different phone numbers of addresses (e.g. home or work). The system should allow the definition of such multiple contact details for all users
Fit Criterion	A user can define any number of details for a specific type communication, e.g. phone number, email

	address
Proposed Solution	The separation of contact details in separate matrices allows the definition of more than one record for each type of contact. The email address was chosen to be unique for each user and define his/her username for the login process.
Priority	Low
Conflicts/Relations	No conflicts currently identified
Author	CERTH
Revision	Initial Version V1.0

Following requirement 'CONT-Re01', we have chosen to hold these communication parameters:

- Phone number

A 10-digit number.

- Email address

A string of at least 20 characters long which must contain one '@' symbol.

3.2.3 Requirements for the Monitoring Parameters class

ID	SM-Re01
Name	Representation of sensor measurements from continuously monitoring devices.
Description	In the case when patients are using a sensor such a modern health wearables the collected measurements should be compatible with the data structures of the FrailSafe framework
Rationale	A fundamental component of the project is the collection of measurements in the everyday life of patients to support the better management of frailty
Fit Criterion	The data collected by the collection of exploited sensors can be stored in the record of the respective older person. VPM should cover a variety of parameters related to frailty condition.
Proposed Solution	A separate archetype will be explored for each sensor measurement. Available OpenEHR archetypes can be used for the common types of monitoring. New types of archetypes will be created to cover the rest ones.
Priority	High
Conflicts/Relations	No conflicts currently identified
Author	CERTH
Revision	Initial Version V1.0
ID	QUE-Re01
Name	Representation of responses to Questionnaire
Description	VPM should allow the representation of questionnaire responses.
Rationale	Questionnaires are an important tool for the assessment of the clinical condition of patients as well as other types of parameters such as lifestyle and cognitive level.
Fit Criterion	Questionnaires can be integrated to the FrailSafe model representation framework.
Proposed Solution	The combination of text and discrete scalar values can cover the representation of questionnaires
Priority	High
Conflicts/Relations	No conflicts currently identified
Author	CERTH
Revision	Initial Version V1.0
ID	IND-Re01
Name	Representation of frailty indicators
Description	VPM scheme should be able to include informative attributes that are strongly correlated with frailty condition worsening situations

Rationale	The evaluation of hidden correlations between different clinical, behavioural, physiological, and other parameters and frailty episodes is a crucial component of the FrailSafe objectives
Fit Criterion	Indicators of the frailty state should be represented in the VPM.
Proposed Solution	New types of archetypes will be created to cover the frailty indicators and to allow automatic assessed by the prediction information processing engine module
Priority	High
Conflicts/Relations	No conflicts currently identified
Author	CERTH
Revision	Initial Version V1.0

The sensing and clinical measurements that have been selected, which all are of essential value for this project, can be divided into five subcategories:

1. **Physiology related parameters**
   - Heart rate
   - Respiration signal/rate
   - Electrocardiogram (ECG)
   - Blood pressure
   - Arterial stiffness
   - Body weight

2. **Physical related parameters**
   - Posture
   - Strength
   - Mobility Activity

3. **Psychological related parameters**
   - Anxiety
   - Depression

4. **Social related parameters**
   - Social media interaction
   - Social media questionnaire

5. **Cognitive related parameters**
   - Games progress
   - Questionnaires
     - Montreal Cognitive Assessment (MoCa)
     - Mini Mental State Examination (MMSE)
     - Big 5 Questionnaire (Big-5)
     - Geriatric Depression Scale (GDS-15)
     - Visual Analogue Scale (VAS)
   - Lifestyle parameters
     - Diet Habits (Mini Nutritional Assessment)
     - Indoor/Outdoor Activities (IADL Index Scales)

6. **Frailty metric**
   - Fried Frailty Index Questionnaire

To provide more timely and accurately prediction of potential upcoming dangerous events in real-time, online management, fusion and analysis of a reduced monitoring subgroup is necessary (see deliverable D4.2). The rest measurements aim to cover specific situations during day time normal activity of the patient both indoors and outdoors (see deliverable D4.1). To this end, the latter list can be classified, according to the sampling collection rate into (also see Table 2):

- **Real-time measurements:**
  - Heart rate
  - Respiration rate
  - Mobility Activity
  - Instability/Falls
- **Daily/weekly measurements:**
  - Blood pressure
  - Arterial stiffness
  - Body weight
  - Strength (via games)
  - Cognitive state (games, questionnaires)
  - Phychological state (natural language analysis)
  - Social interaction (social media)
  - Adherence (nutrition, medical instruction)
  - Indoor/Outdoor Activities

➢ *Pre-processed output for statistical analysis*

The system will be able to integrate the results of the different sensors, questionnaire and self-reports as depicted in Table 3 (combination of all the acquired data) in order to provide the user with the appropriate feedbacks, incentives, and actions. The data analysis processing unit (see Figure 1) will use as input all the aforementioned parameters. From the information processing perspective, these parameters can be categorized into Time Series and Questionnaire datasets.

Questionnaire datasets consist of a set of items/questions as attributes and a set of answers in Likert scale (say, from 1 to 5) from multiple individuals as subjects. A trivial way to extract subject scores from questionnaire data is row-wise addition or weighted averaging. That way, a single attribute is extracted from the questionnaire data, that is the sum or average of the subject responses.

Regarding time series data, one has to extract characteristic measurements of the time series subjects, in order to perform meta-analysis, such as clustering or classification. New techniques for data reduction and summarization of the streaming sensor data exploring meaningful measuring units for frailty have been designed as shown in Table 3 and will be combined in informatics tools for data preparation and organization. We intend to perform the trivial and more sophisticated statistical calculations attempting to generate from time series subjects the following global characteristic measurements: *mean and standard deviation*.

Concerning natural language analysis, the development of LingTester component will be able to detect signs of mental frailty and personality trait shifts by linguistic processing of a person's electronic written messages (see deliverable D4.5).

Data mining techniques combined with Hidden Markov Models (HMMs) will be exploited to predict falls, loss of orientation and balance risk events (see Risk Assessment Module see deliverable D4.7).

Table 3: Detailed measurement performed in FrailSafe system.

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)
Walking	• Number of steps • Number of walking activity initiation • Mean duration of the walking activity	for each day sampling (25 Hz)
Posture	• Mean time spent standing/day • Mean time spent sitting/day • Mean time spent lying/day	for each day
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
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 • Number of pauses/block • Events triggered • Concentration index	for each block

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
Natural Language Analysis	• Anxiety detection • Depression detection	for each block
Weight	• Weight • BMI	for each block

Table 4: Mapping of the monitoring parameters and devices.

Parameter	Sensor/device	Questionnaire
Weight	*FORA bio-impendence scale*	-
Blood Pressure	*FORA blood pressure monitor*	
Arterial stiffness	*Mobilograph*	
Strength	*Hoggan dynamometer*	
Electrocardiogram (ECG)	*Wearable WBan System*	
Heart rate		
Respiration Signal/Rate		
Posture		
Mobility Activity		
Instability/Falls	*IMUs, Smartphone*	
Indoor Activities	*Bluetooth iBeacon, smartphone*	*IADL Index Scales*
Outdoor Activities	*Smartphone*	
Games Analysis	*PC, Tablet and AR glasses*	-
Social Interaction	*Smartphone*	*Social media*
Natural Language Analysis	*eCRF, email*	*Big-5*
Cognitive Evaluation	*Games*	*MoCa, MMSE, GDS-15, VAS, MNA*
Frailty Evaluation	-	*Fried Frailty Index*

3.2.4 Requirements for the Clinician Input class

ID	CLI-Re01
Name	Representation of doctor assessments
Description	Clinician should be able to add to the record of their patients, their assessments for any type of parameter and indicate the methodology for this measurement (e.g. device used, procedure followed etc.)
Rationale	The assessments of clinicians should be district and separated from their diagnosis, prescriptions and interventions
Fit Criterion	A clinician can add a clinical assessment (e.g. measurement of body scale) in the record of one patient
Proposed Solution	Available OpenEHR archetypes can be used for the common types of assessments. For less common exams custom archetypes and the respective data structures can be created.
Priority	High
Conflicts/Relations	No conflicts currently identified
Author	CERTH
Revision	Initial Version V1.0

ID	CLI-Re02
Name	General field of doctor inputs not related to diagnosis or prescriptions
Description	VPM should allow the creation of custom types of doctor inputs based on their needs.
Rationale	Clinical practice is highly complicated and dynamic. Therefore, clinicians should be able to create document their inputs for types of parameters that are not covered by the current form of the modelling framework
Fit Criterion	Doctors can create a custom record by defining its title and text content
Proposed Solution	New archetypes of data can be created and integrated with the main modelling structure of the database for this purpose
Priority	Low
Conflicts/Relations	No conflicts currently identified
Author	CERTH
Revision	Initial Version V1.0
ID	CLI-Re03
Name	Compatibility with terminology standards
Description	The clinician should be able to select a type of diagnosis based on standardized terminology
Rationale	The collection of diagnosis should be comparable and use of different terminology by different doctors should be avoided for the better function of the system
Fit Criterion	A clinician cannot diagnose a condition that is not included in standardized terminology
Proposed Solution	An archetype can be created for the expression of diagnosis that will get values from standardized clinical terminology
Priority	Low
Conflicts/Relations	No conflicts currently identified
Author	CERTH
Revision	Initial Version V1.0
ID	CLI-Re04
Name	Documentation of frailty related interventions (prescriptions and action plans)
Description	VPM should be able to include pharmaceutical prescriptions (type of medication and dosage) and non- pharmaceutical suggestions (e.g. games exercises)
Rationale	Interventions are a crucial component of the medical record of a patient and as such should be included in the patient modelling framework.
Fit Criterion	Clinicians should have the capability to document their prescription in the FrailSafe system
Proposed Solution	Archetypes can be created for the expression of interventions based on accurate medication naming and scalar representation of dosage for medical prescriptions as well as physical and cognitive action instructions.
Priority	High
Conflicts/Relations	No conflicts currently identified
Author	CERTH
Revision	Initial Version V1.0

The ***Clinician Input*** class can be separated into

- *Heath Record* which represents medical history as well as ongoing clinical assessments.
- *Diagnosis* which are related to patient notes and the doctor's opinion that should be compatible with terminology standards.

- *Interventions* which are about doctor's instructions, action and lifestyle plans.

3.2.5 Requirements for the Events class

ID	EVE-Re01
Name	Representation of events
Description	VPM should be able to include short-term alerts & long-term notifications to inform about adverse events. The system should support the following types of events: Falls, Loss of balance, Loss of orientation, Heart or respiration problems, medical adherence and frail state modifications. Alerts refer to the final FrailSafe product (after M36) and not to the developing platform while the project is ongoing (Figure 8).
Rationale	It is important for customer service, family, clinicians to know as soon as possible when an adverse event happens to act according to each situation immediately.
Fit Criterion	Clinicians should have the capability to check for frailty-related events in the FrailSafe system
Proposed Solution	Archetypes can be created for the expression of the specific events based on accurate naming and scalar representation of them per situation.
Priority	High
Conflicts/Relations	No conflicts currently identified
Author	CERTH
Revision	Initial Version V1.0

This entity is responsible for recognition of several frailty events:

- *short-term* that includes falls, loss of orientation, loss of balance and heart/respiration problems
- *long-term* that includes change of frailty status and medical adherence progress.

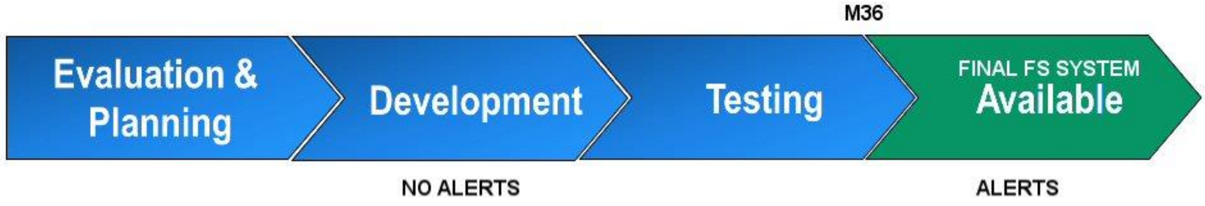


Figure 9: Overview of alert handling in FrailSafe.

4 FRAILSAFE VIRTUAL PATIENT MODEL

This section presents in detail the Virtual Patient Model (VPM) that will be used in FrailSafe. The FrailSafe VPM will be based on existing OpenEHR archetypes, modifying them or adding new archetypes, when necessary, in order to cover the needs and requirements of the FrailSafe project. The FrailSafe VPM will be adapted dynamically based on data collected and analysed by the offline data analysis tools of WP4. The information stored in the VPM will be the main information representing all the aspects of the older person, and will be the input to the Decision Support System and the visualization modules.

4.1 Architecture

This section contains architectural information about the general design of the FrailSafe VPM and its connection to other FrailSafe components. Figure 10 depicts the high-level architecture of the VPM and its connection to the other FrailSafe components. The VPM receives input from the FrailSafe data acquisition methods of WP3 and WP5, as well as from the online and offline data analysis methods of WP4. All collected data are stored in the VPM database, which contains all measurements collected for the older persons.

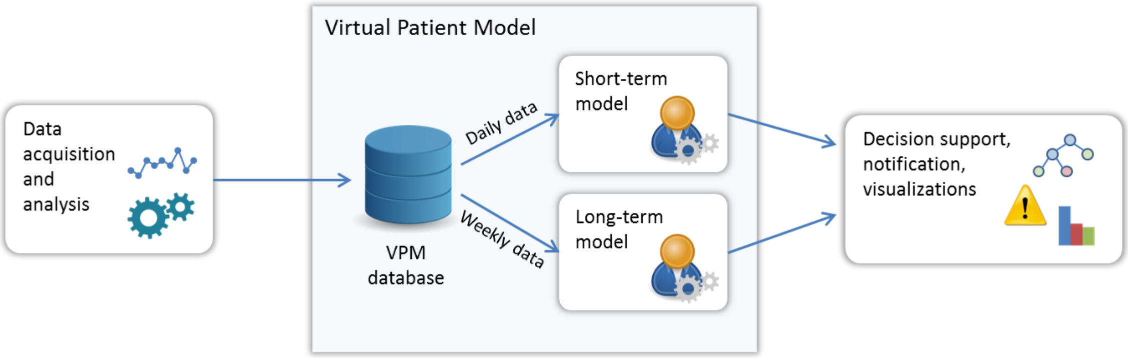


Figure 10: High-level architecture of the FrailSafe Virtual Patient Model.

There are two internal models for a user, which aggregate data from the VPM database in different granularities, in order to maintain short-term and long-term information for a user. The constructed and dynamically updated models are used in higher-level FrailSafe components, such as the Decision Support System, the production of alerts and notifications, and information visualization.

The ultimate evaluation of the FrailSafe VPM design and usage will be performed within the evaluation trials of WP7. The trials will result in an amount of data capable of allowing the assessment of the user VPMs in terms of user representation accuracy and assistance in decision making. The evaluation results will be reported in future deliverable D7.4, due in month M36.

The following sections describe the architectural characteristics of the VPM in more detail.

4.1.1 Types of models

The goal of the Virtual Patient Model is to provide an up-to-date representation of the user, to be used by other system components. This representation should cover both short-term variations in the user behaviour and characteristics, in order to allow the production of alerts and notifications, as well as long-term variations, which will allow the system users to have a general overview of the older person's condition over time.

In order to capture these two different granularities, two models will be maintained for each older person:

- A short-term model, which contains recent information, updated on a daily basis.
- A long-term model, which contains aggregate information of a large period of time, updated on a weekly basis.

These two types of models will be similar in the kind of information they contain; however, they will differ in the dynamic adaptation process, as new data are constantly collected. Details about how the two different models are dynamically adapted are presented below, in Section 4.4 .

4.1.2 Interconnection with other FrailSafe components

As depicted in Figure 1 and Figure 10, the VPM is connected to the following FrailSafe components:

- Data acquisition modules (WP3, WP5)
- Data analysis (online and offline) (WP4)
- Decision Support System (WP4)
- Information visualization (WP5)

4.1.2.1 Interconnection with online and offline data analysis modules

The information stored in the VPM is primarily drawn from the data acquisition and data analysis components. Measurements that can be directly used as parts of the VPM archetypes, such as measurements of clinical aspects (e.g. blood pressure, average heart rate, etc.), game performance measurements or questionnaire scores, are collected directly from the data acquisition modules of WP3 and WP5 (games). More precisely, the data flow starts from the data acquisition modules, which send the collected data (either directly or through the clinical web portal) to the FrailSafe cloud. The uploaded data are then retrieved by the VPM module and stored in the VPM database.

Other types of measurements need first to pass through the online data analysis modules, in order to be stored in the VPM. For instance, the real-time description of daily activities (standing, walking, falling, etc.) is computed by the online data analysis modules of WP4, using raw input from the IMU sensors. Thus, a second type of input from the VPM is collected from the online data analysis modules.

4.1.2.2 Interconnection with the Decision Support System

On the other side of the VPM interactions, the information that is stored in the short-term and long-term virtual patient models are provided as input to higher-level FrailSafe components, specifically the Decision Support and Personal Guidance system, and the information visualization.

The interconnection between the VPM and the Decision Support System is accomplished in the following manner. The Decision Support System maintains a set of rules, which describe which type of action or notification needs to be taken, based on the current condition of the older person, such as clinical status, specific co-morbidities, or performance in games. Details about the construction of these rules and the means by which they are applied are provided in the DSS-related deliverables D4.16 and D4.17. However, the important point regarding the VPM is that these rules depend on several thresholds for the involved parameters. For instance, a rule may be that a notification needs to be sent to the clinician and the older person’s family, once the older person’s blood pressure surpasses the value of 16 mmHg, which may be the symptom of a specific co-morbidity. Since decision support is personalized, this threshold value is specific for each individual, and dependent on his/her personal medical history. It is precisely this medical history that is encoded in the VPM, so it is the VPM which holds the specific value for this threshold.

In short, the connection between the VPM and the Decision Support System is that they both contribute in taking a decision, separating their concerns as follows:

- The Decision Support System contains the rule associating a specific action with a specific condition which depends on some threshold value(s), not specified within the DSS.
- The VPM holds the specific threshold value(s) for each older person, needed by the Decision Support System.

The details of how the rules are created and maintained are described in the DSS-related future deliverables D4.16 and D4.17, due in months M24 and M28, respectively.

4.1.2.3 Interconnection with information visualization

Finally, the information contained in the VPM is the primary input to the information visualization module (Task 5.4). The information visualization component provides visual overviews of an older person's condition to the users, either older persons or clinicians, through a mobile or Web interface. The information of both the short-term and the long-term models are used in these visualizations:

- The short-term information is used to display the current status of the older person. It can be used in timelines or other types of charts, to show the progression of the user's condition on a daily basis (by also retrieving the short-term models of previous days from the VPM database). This allows a higher older person engagement in trying to improve with respect to certain frailty-related parameters (e.g. their nutritional habits or game performance), or to follow more precisely the clinician recommendations.
- The long-term information is used to display the overall condition of the older person, through a large period of time. This information is displayed in the form of threshold values, which, combined with the short-term information, can reveal cases where the current status of the older person is significantly different than their normal or expected status. This can be of value to the clinician, in order to be alarmed when an unexpected condition is observed and make a decision, or in order to have an overview of the cases in which such unexpected conditions have occurred in the past.

Figure 11 shows an example of a timeline visualization, where the contribution of both the short-term and the long-term models is apparent. Each successive point corresponds to the daily information stored in the short-term model. They display the progression of the user's parameters in a high granularity, able to capture short-term variations in the corresponding values. The dashed line represents the threshold value, which is stored in the long-term model. This threshold value is computed by the longer history of the user and represents the general expected status of the user. Through such kinds of visualizations, both the older person and the clinician can have an overview of the occasions in which the older person's condition was unusual or alarming.

Details about the specific visualizations used in FrailSafe will be demonstrated in future deliverables D5.4 and D5.5, due in months M24 and M28, respectively.

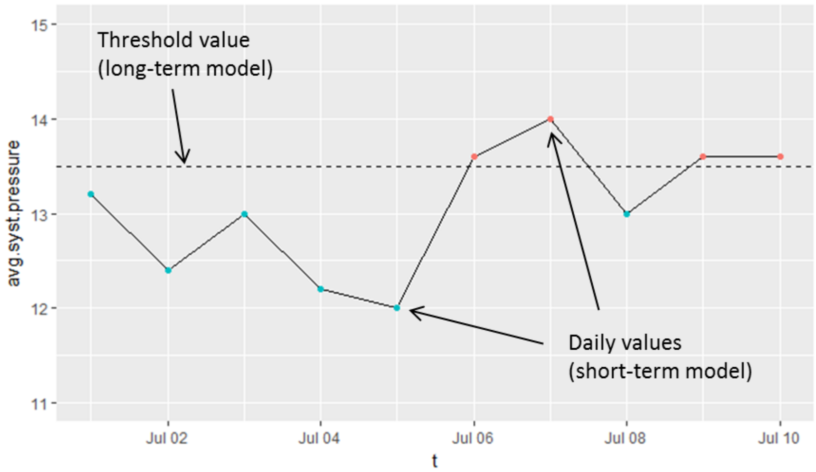


Figure 11: Example of visualization, where both the short-term and long-term VPM information is used.

4.2 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[16] (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[17] in order to meet the goals of the project (see Table 5).

Table 5: Mapping between VPM parameters and Archetypes.

Parameters	High Level Information	openEHR Archetypes Existing/New	Parameters Used/Added
Personal Details	Patient Identification Demographic Details Contact Details	**EHR-CLUSTER.individual_personal.v1** **EHR-CLUSTER.person_name.v1** **DEMOGRAPHIC-ITEM_TREE.person_details.v1** **DEMOGRAPHIC-ADDRESS.address.v1** **EHR-CLUSTER.telecom_details.v0**	Identifier main data Given name, Family Name Birth Data, Gender, Ethnic backgroup, other identifiers Address.Details Telecom_Details.Items
Heart rate	Mean value over time when 1. sitting 2. sleeping 3. walking 4. lying 5. walking upstairs 6. walking downstairs	**EHR-OBSERVATION.pulse.v1** **EHR-CLUSTER.device.v1** **EHR-CLUSTER.level_of_exertion.v1**	Data.Rate *(beats per min),* State.Position *(standing/upright, sitting, reclining, lying),* Protocol.device Events.Maximum Items.Execise.Description *(sleeping, walking, walking upstairs/downstairs)*

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

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

Respiration rate	Mean value over time when 1. sitting 2. sleeping 3. walking 4. lying 5. walking upstairs 6. walking downstairs	**EHR-OBSERVATION.respiration.v1** **EHR-CLUSTER.device.v1** **EHR-CLUSTER.level_of_exertion.v1**	Data.Rate (beats per min) State.Position (Standing/upright, sitting, reclining, lying) *Protocol.device* *Events.Any event* Items.Execise.Description (sleeping, walking, walking upstairs/downstairs)
Blood Pressure **Arterial Stiffness**	Mean value when 1. sitting 2. standing Mean value	**EHR-OBSERVATION.blood_pressure.v1** **EHR-CLUSTER.device.v1**	Data.Mean arterial pressure (mm[Hg]) State.Position (standing/upright, sitting, reclining, lying), Protocol.device Events.Any event Events.24 average Data.Systolic
Body Weight	Mean Boby weight (for each block)	**EHR-OBSERVATION.body_weight.v1** **EHR-CLUSTER.device.v1** **EHR-OBSERVATION.body_surface_area.v0** **EHR-CLUSTER.device.v1** **EHR-OBSERVATION.body_mass_index.v1**	Data.Body Weight (kg or lb) Protocol.device Data.Body Surface Area (m^2 or in^2) Protocol.device Data.Body Mass Index (kg/m^2 or lb/in^2)
Posture	Mean time spent 1. standing 2. sitting 3. lying	**EHR-OBSERVATION.posture.v0** **EHR-CLUSTER.device.v1**	State.Posture (Standing, Sitting, Lying) Data.Duration (min or sec) Protocol.device (IMUs)
Steps	1. Mean Number of Steps 2. Number of times a walking activity is initiated 3. Mean Duration of walking activities	**EHR-OBSERVATION.steps.v0** **EHR-CLUSTER.device.v1**	Data.Steps Data.Walking Activities Duration (min or sec) Protocol.device (phone)
Strength	1. Mean strength value 2. Max strength value	**EHR-OBSERVATION.strength.v0**	Data.Strength (Newton)
Instability/ Falls	1. Falls rate (per block) 2. Almost/failed falls rate (per block) 3. Places where falls/almost falls happen (indoors/outdoors) - what type of activity performed 4. Fall consequences 5. Physiological state of the subject one minute before for each fall/almost fall	**EHR-OBSERVATION.falls.v0** **EHR-CLUSTER.level_of_exertion.v1**	State.Category (Fall, Almost Fall) Data.Place Consequences Physiological State Protocol.device Events.Any event Events.Physiological_state Items.Execise.Description (walking, running, going upstairs/downstairs)

Indoor Activities	Mean time spent 1. sitting in the living room 2. lying in bed 3. in the restroom 4. walking inside 5. indoors with friends 6. using the tablet/pc	EHR-OBSERVATION.activities.v0 EHR-OBSERVATION.barthel.v0 EHR-CLUSTER.level_of_exertion.v1	Data.Day Period (morning, noon,afternoon,evening, night) Data.Duration (min) Protocol.Device (beacons) Data.Total (IADL) Items.Execise.Description (sleeping, walking, walking upstairs/downstairs)
Outdoor Activities	Mean time spent 1. walking outside 2. driving car	EHR-OBSERVATION.activities.v0 EHR-OBSERVATION.barthel.v0 EHR-CLUSTER.level_of_exertion.v1	Data.Day Period (morning, noon,afternoon,evening, night) Data.Duration (min) Data.Total (IADL) Items.Execise.Description (walking, driving)
Game Analysis	1. Played the game? 2. How often (Number of times/block) 3. Success rate (Attempts to start playing but not played) 4. Mean reaction time 5. Mean Duration 6. Number of pauses/block 7. Mean Time of pauses	EHR-CLUSTER.game_analysis.v0	Data.Played (yes, no) Data.Times Data.False Attempts Data.Mean Reaction Time (min or sec) Data.Mean Duration (min or sec) Data.Pauses Number Data.Pauses Mean Duration (min or sec) State.Category (Physical, Cognitive)
Social Interaction	1. Number of phone calls 2. Number of text messages 3. Time spent speaking at the phone 4. Time spent on skype 5. Time spent interacting in social media (fb, twitter)	EHR-OBSERVATION.social_interaction.v0 EHR-COMPOSITION.questionnaire-result.v0	Data.Phone Calls Data.Text Messages Data.Speaking Duration (min) Data.Skype Duration (min) Data.Social Media Duration (min) Data.Value (social media)
Nutrition State	Nutrition Questionnaire	EHR-COMPOSITION.questionnaire-result.v0	Data.Value (MNA)
Cognitive State	Cognitive Questionnaires	EHR-COMPOSITION.questionnaire-result.v0	Data.Value (MoCa, MMSE, GDS-15, VAS)
Clinical Input	Health Record Summary 1. Personal Medical History 2. Family Medical History 3. Lifestyle Factors	EHR-COMPOSITION.health_summary.v1 EHR-COMPOSITION.family_history.v1 EHR-COMPOSITION.lifestyle_factors.v1 EHR-EVALUATION.clinical_synopsis.v1 EHR-COMPOSITION.problem_list.v1	Data.Category.T Content.Family History Content.Factors Data.Synopsis Items.Problems or Diagnoses Data.Problem Data.Clinical description

	Diagnosis 1. Problem 2. Conlusion	EHR-EVALUATION.problem_diagnosis.v1 EHR-SECTION.conclusion.v1	Data.Body site Data.Status Data.Comment Data.Data/time recognized Items.Evaluation of a problem
	Interventions 1. Notes 2. Pharmaceutical Orders 3. Recommendations	EHR-COMPOSITION.progress_note.v1 *EHR- INSTRUCTION.medication_order.v0* EHR-EHR-EVALUATION.recommendation.v1	Data.Catergory.T Activities.Order.Medication Activities.Order.Dose amount Data.Recommendation Data.Rationale
Events	1. Short-term Alerts 2. Long-term Notifications	openEHR-EHR-INSTRUCTION.notification.v0	Activities.Current Activity.Topic name Activities.Current Activity.Timing Activities.Current Activity.Description

4.2.1 Personal details

4.2.1.1 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.person_name.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 12 and Figure 13.

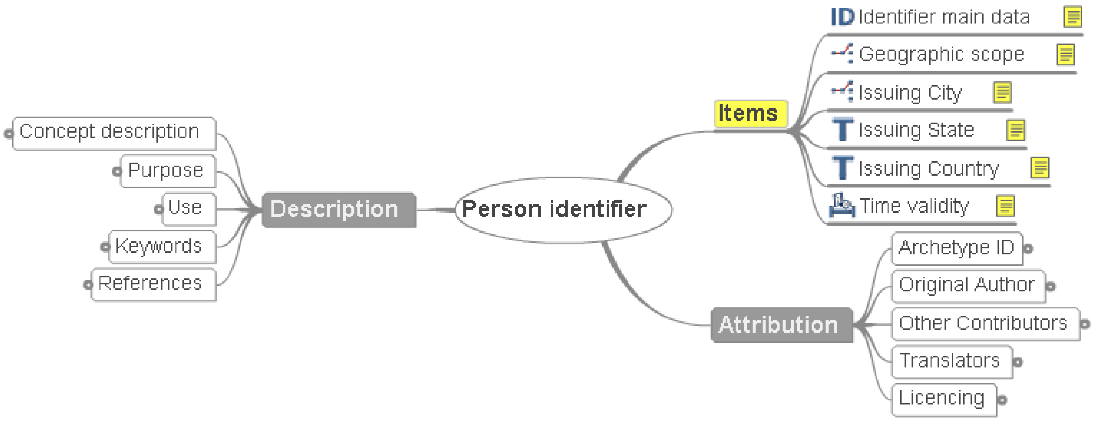


Figure 12: Person identifier archetypes.

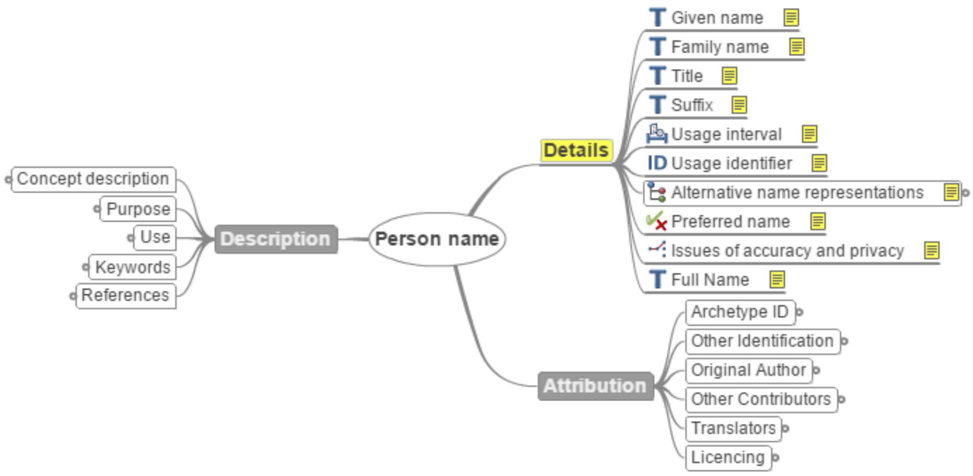


Figure 13: Person name archetypes.

4.2.1.2 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 14.

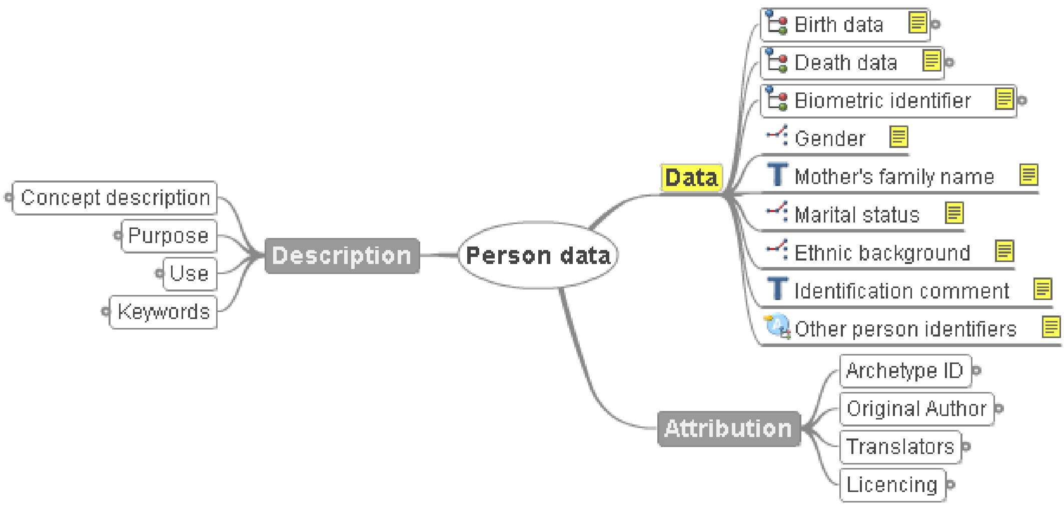


Figure 14: Personal details archetype.

4.2.1.3 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 15 and Figure 16 illustrate these archetypes:

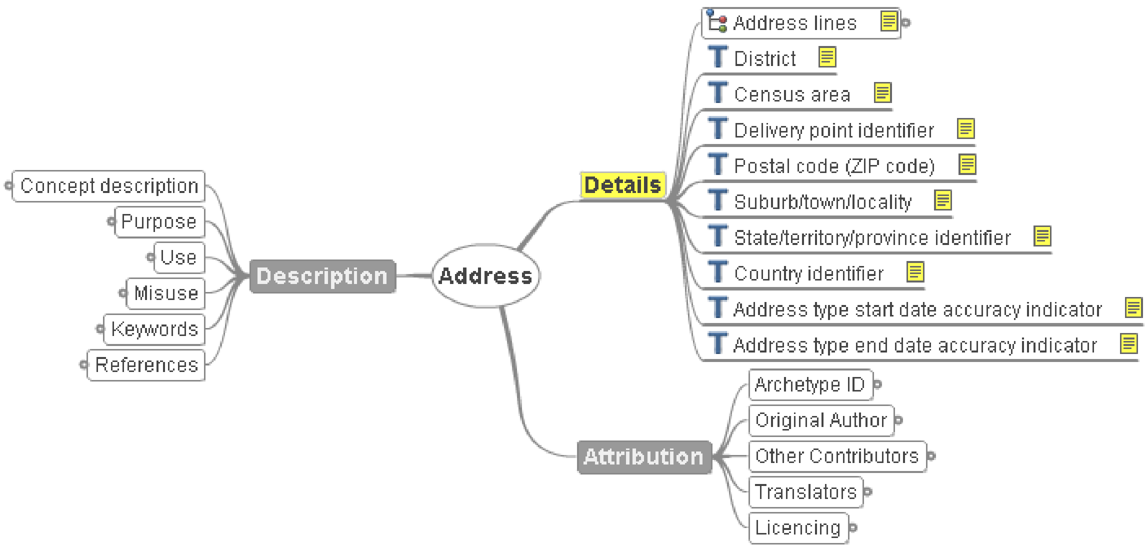


Figure 15: Address archetype.

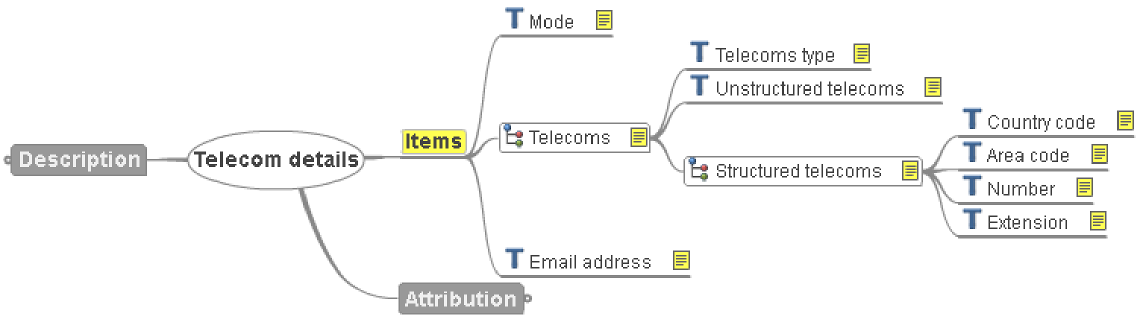
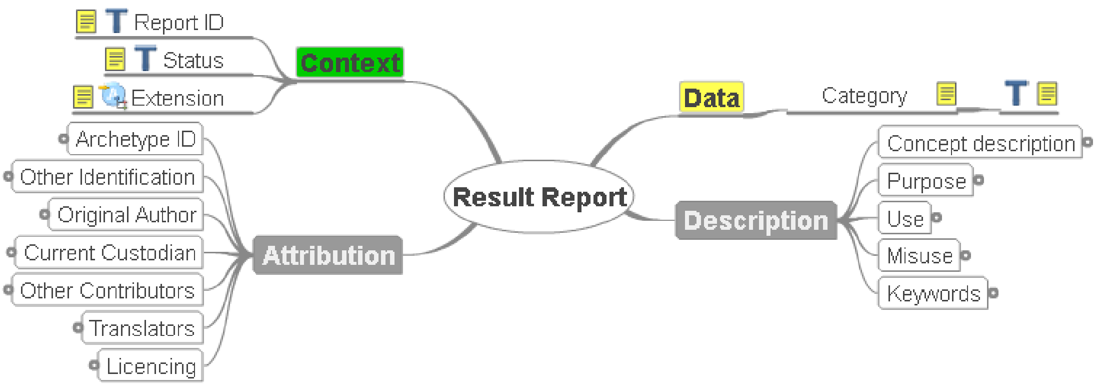


Figure 16: Telecom details archetype.

4.2.2 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 17). Furthermore, the ***openEHR-EHR-CLUSTER.level_of_exertion.v1*** archetype can be used for distinguishing between different activity actions performed by the older person (see Figure 17).



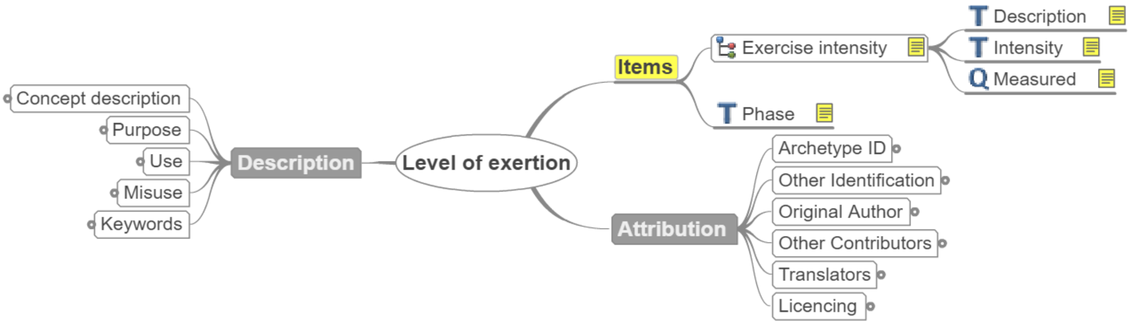


Figure 17: Result report and Level of exertion archetype archetypes.

4.2.2.1 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 18)
    - ***openEHR-EHR-CLUSTER.device.v1*** (see Figure 19)
- To record details about the rate and associated attributes for a *heartbeat*:
    - ***openEHR-EHR-OBSERVATION.pulse.v1*** (see Figure 20)
- To record the observed characteristics of spontaneous breathing (*respiration rate*):
    - ***openEHR-EHR-OBSERVATION.respiration.v1*** (see Figure 21)
- To record the systemic arterial *blood pressure*:
    - ***openEHR-EHR-OBSERVATION.blood_pressure.v1*** (see Figure 22)
- To record the *body weight* of an individual - both actual and approximate:
    - ***openEHR-EHR-OBSERVATION.body_weight.v1*** (see Figure 23)
- 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 24)
- 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 25)
- 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 26)

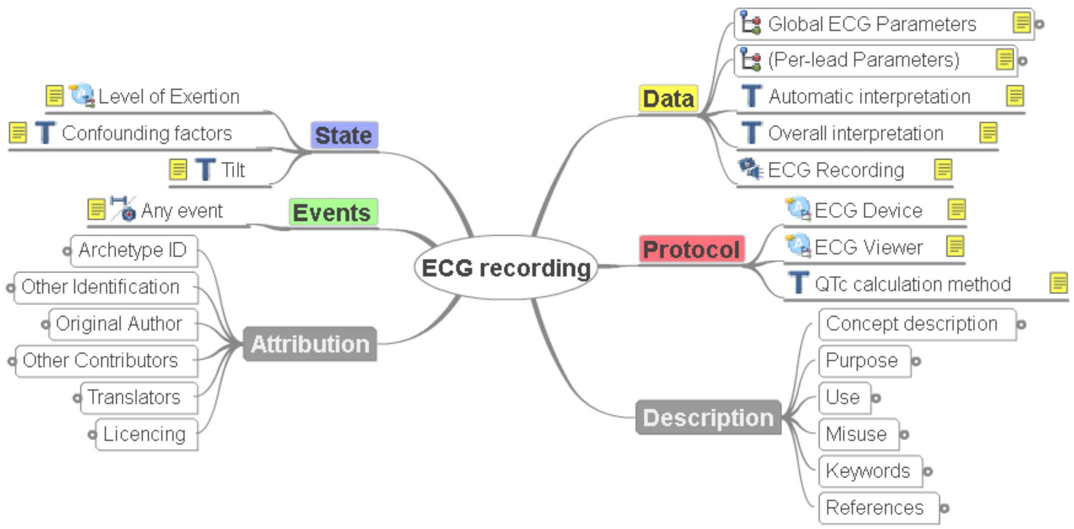


Figure 18: ECG recording archetype.

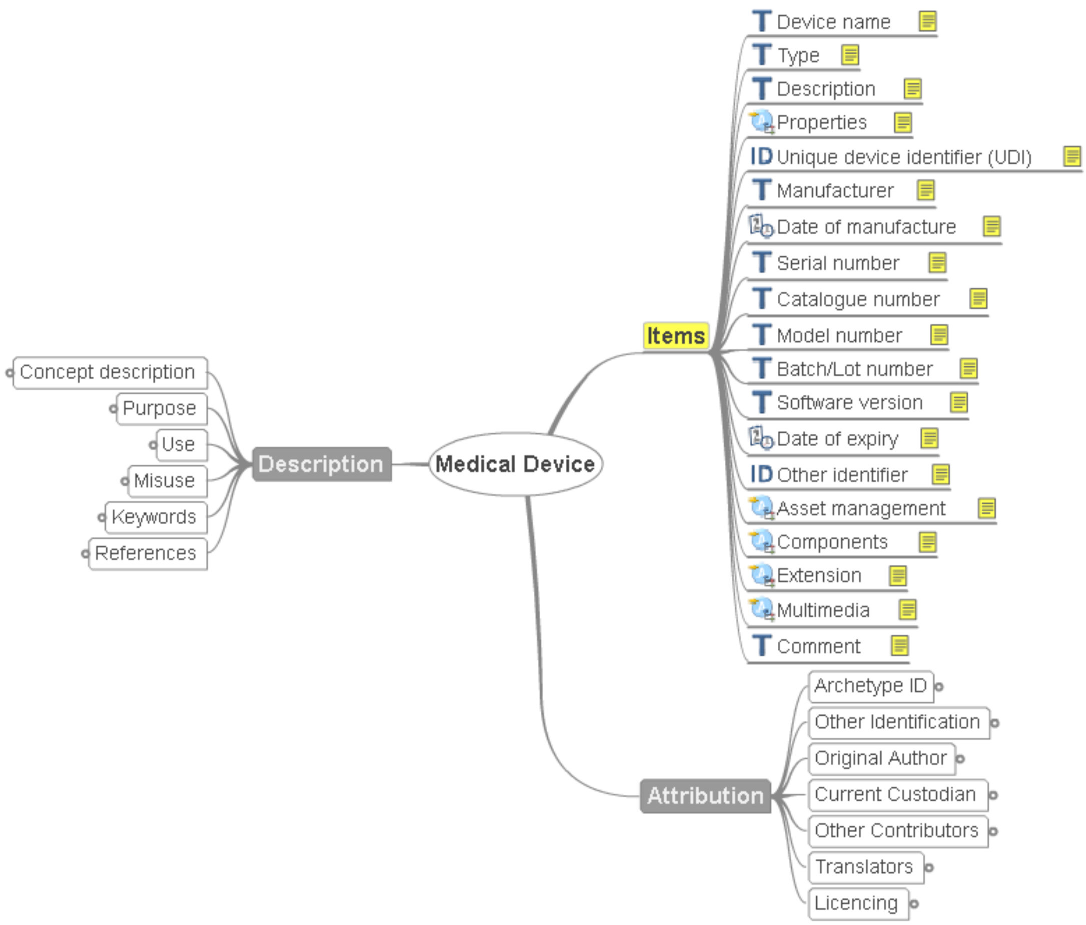


Figure 19: Medical device archetype.

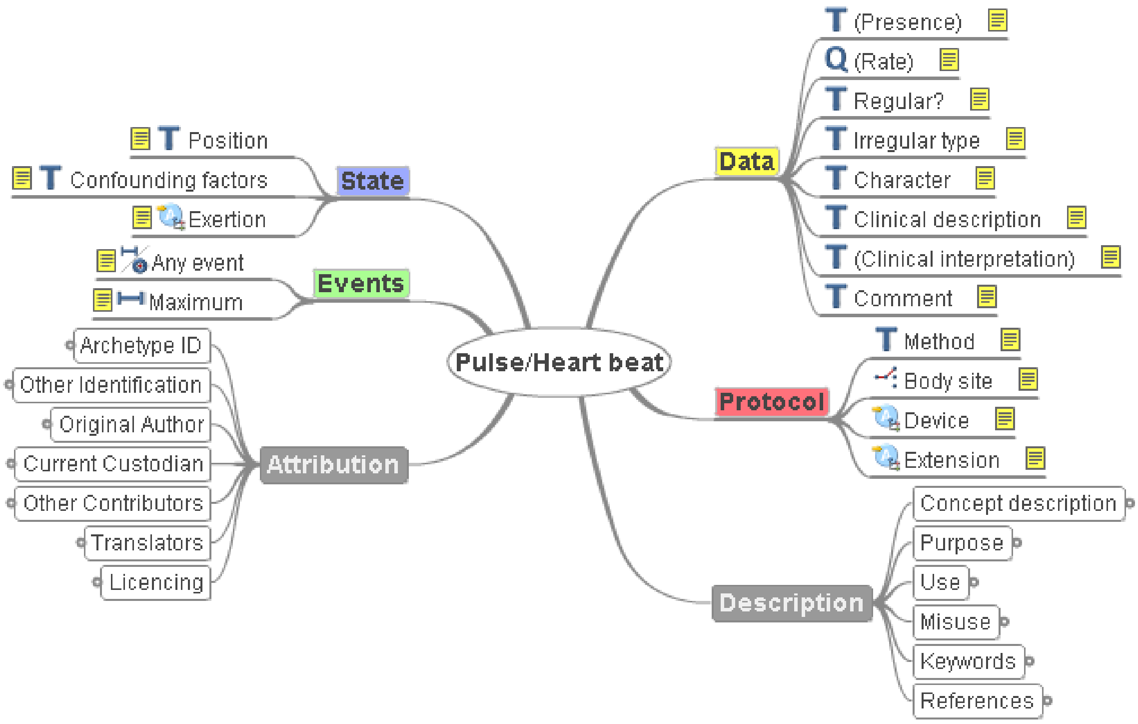


Figure 20: Heart beat archetype.

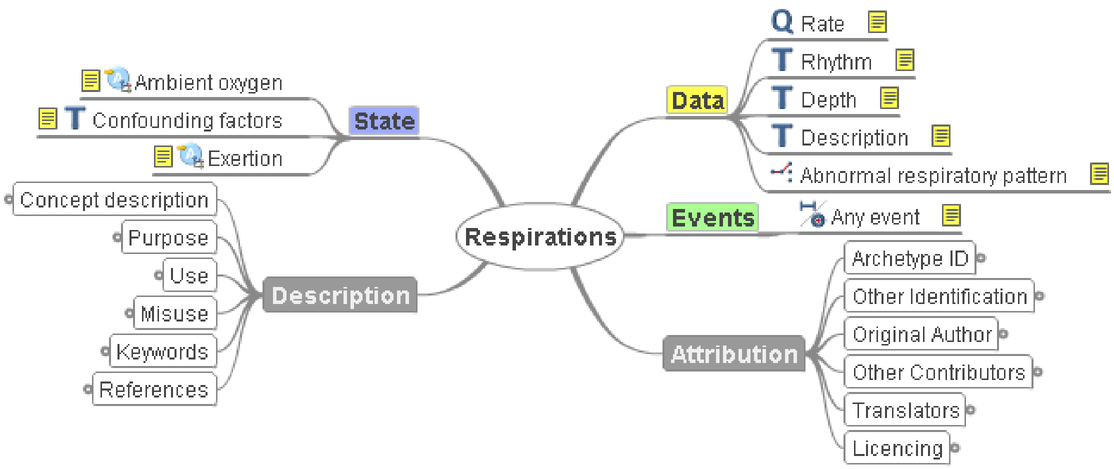


Figure 21: Respiration rate archetype.

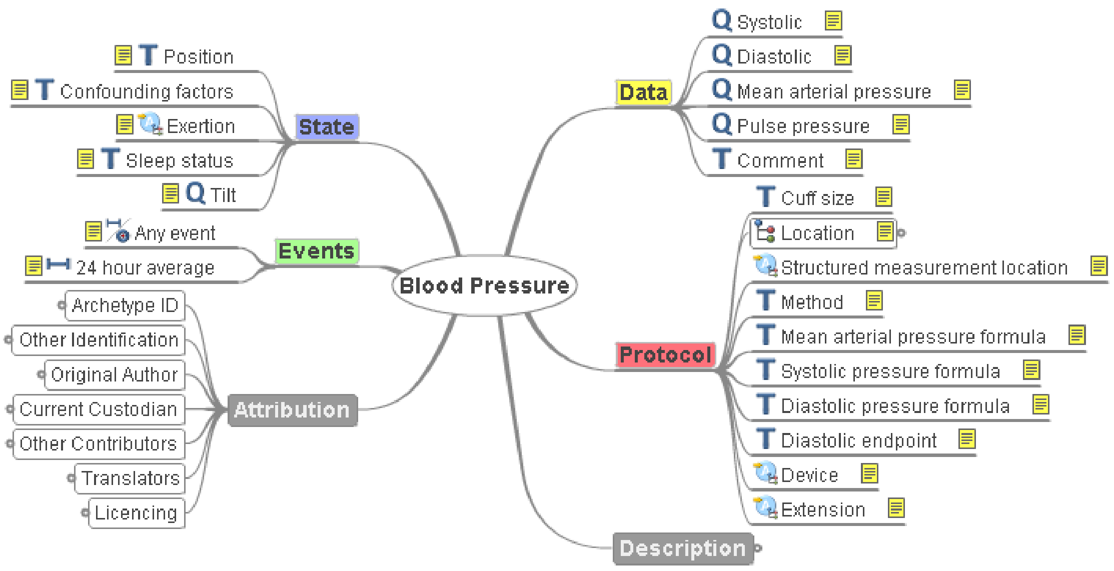


Figure 22: Blood pressure archetype.

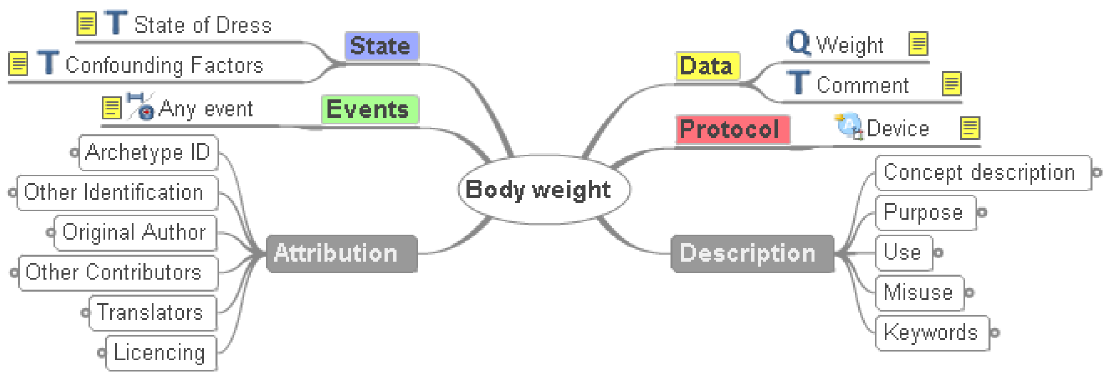


Figure 23: Body weight archetype.

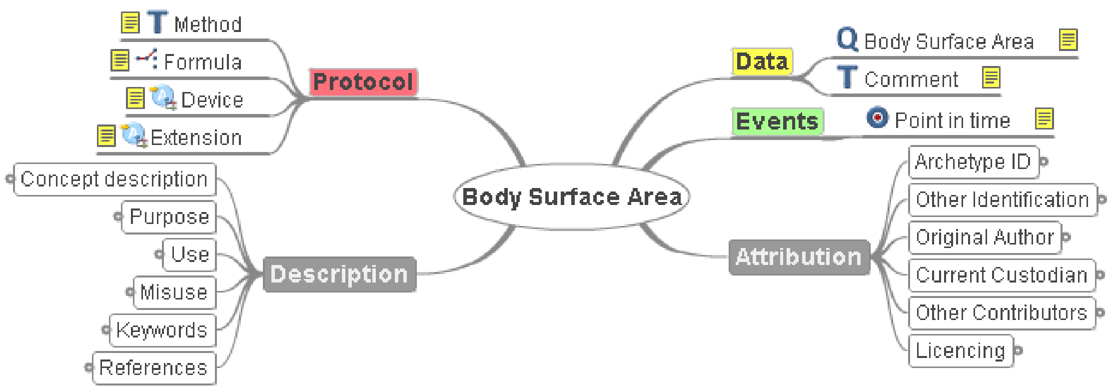


Figure 24: Body surface area archetype.

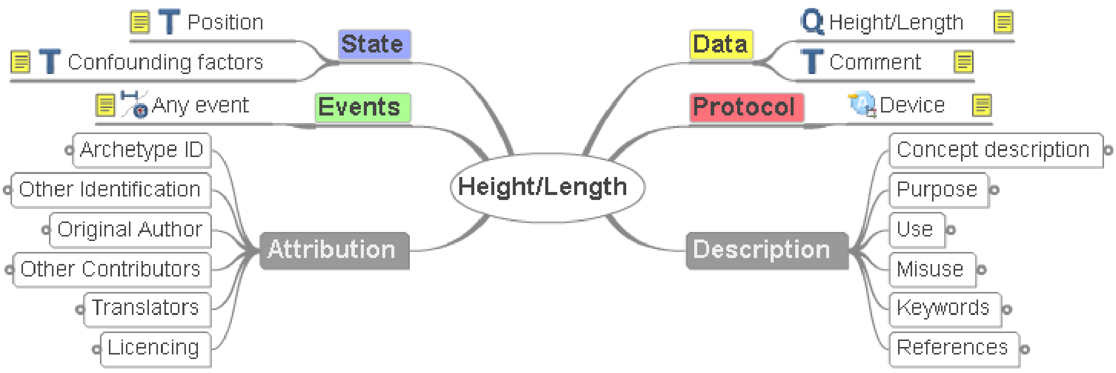


Figure 25: Height/Length archetype.

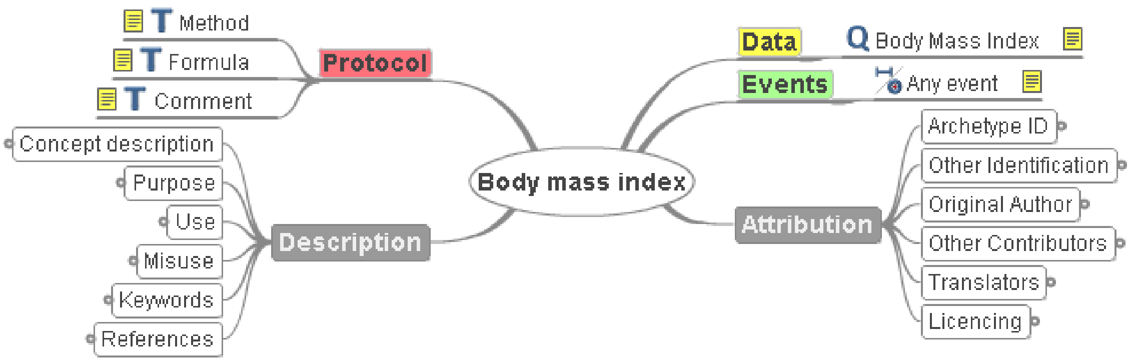


Figure 26: Body mass index archetype.

4.2.2.2 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 27)

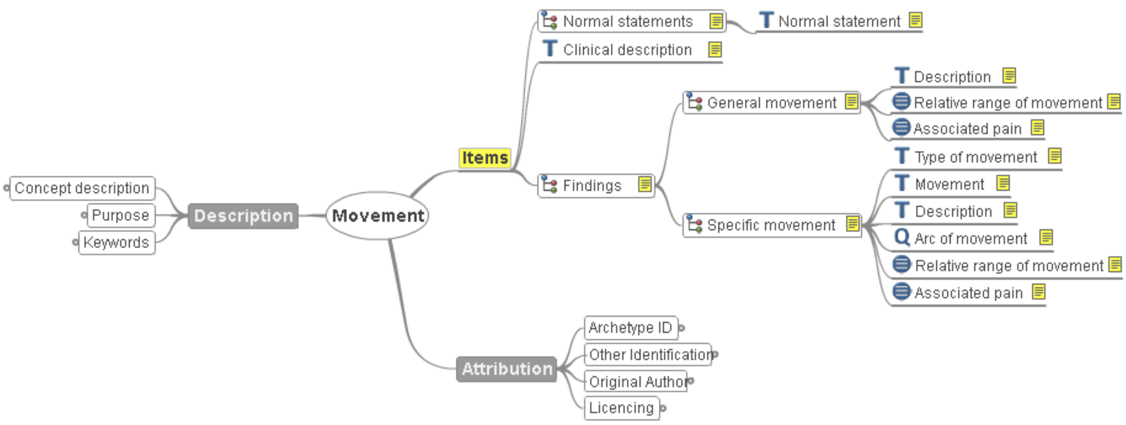


Figure 27: Movement archetype.

4.2.2.3 Lifestyle related data

The lifestyle relevant archetype needs to include nutrition summary and activities levels details of the older people. 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 include, 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 28 and Figure 29.

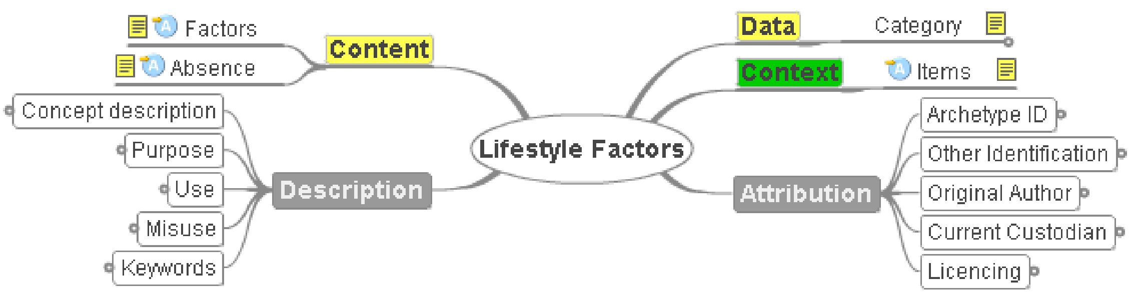


Figure 28: Lifestyle factors archetype.

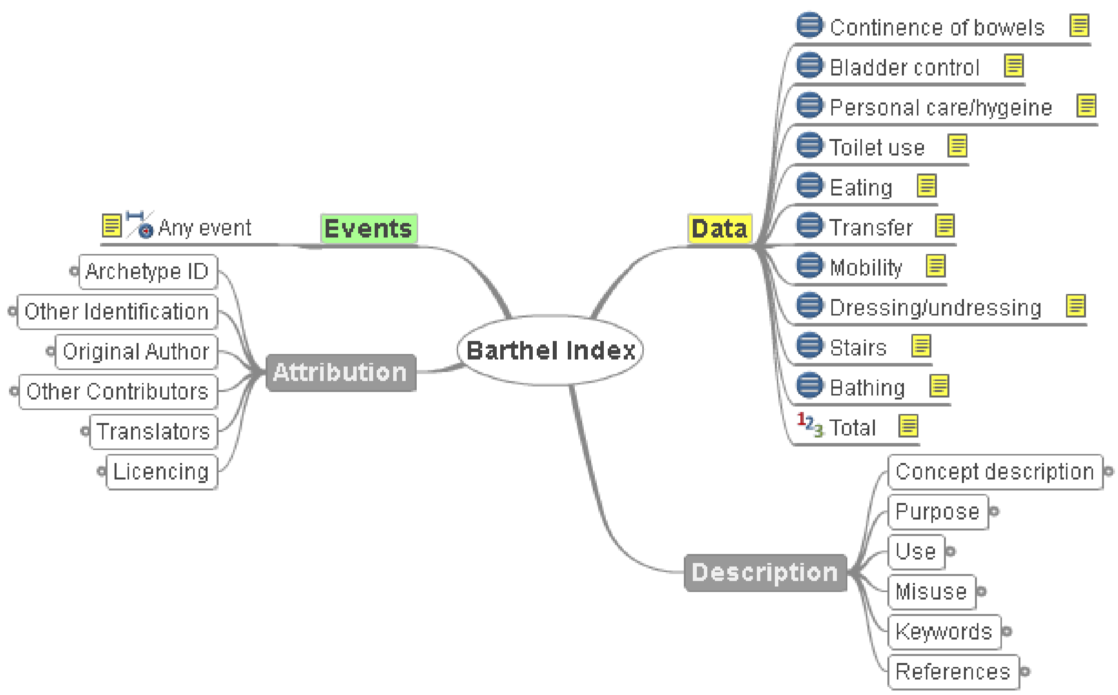


Figure 29: IADL Barthel index archetype.

4.2.3 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 30 and Figure 31.

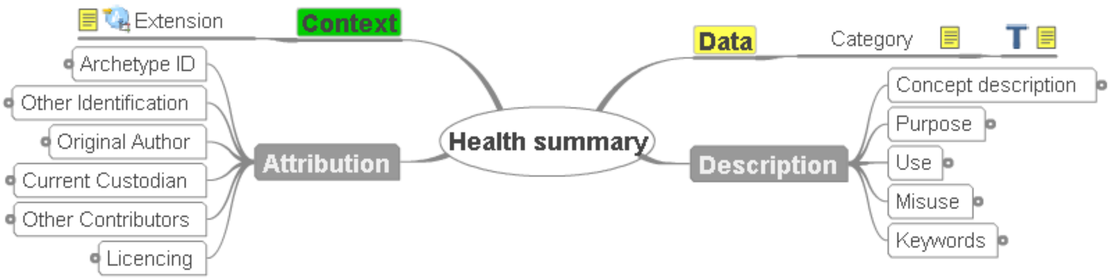


Figure 30: *Health summary archetype.*

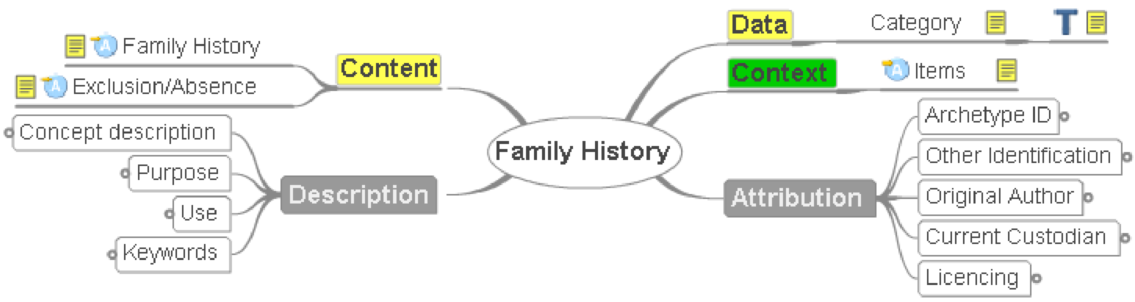


Figure 31: *Family history archetype.*

4.2.4 Clinician Input

4.2.4.1 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 32, Figure 33, Figure 34, Figure 35 and Figure 36.

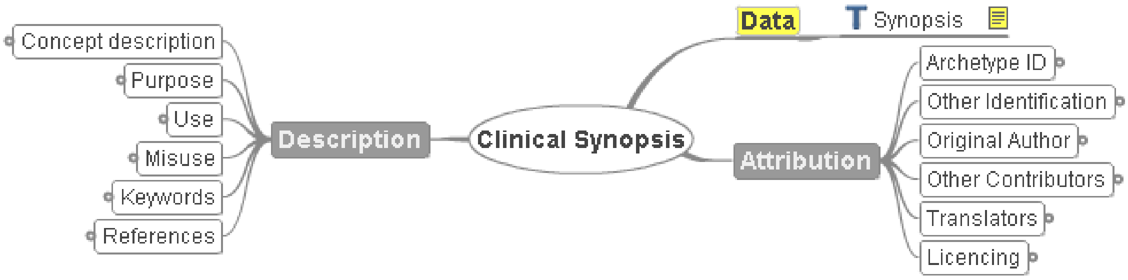


Figure 32: Clinical synopsis archetype.

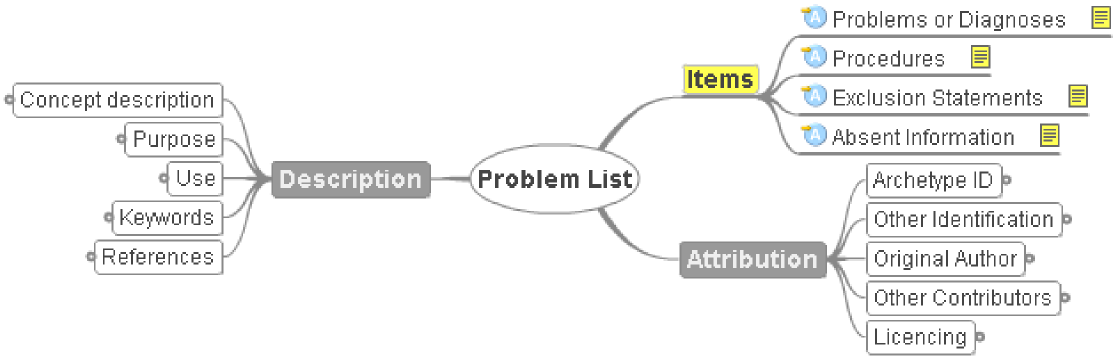


Figure 33: Problem list archetype.

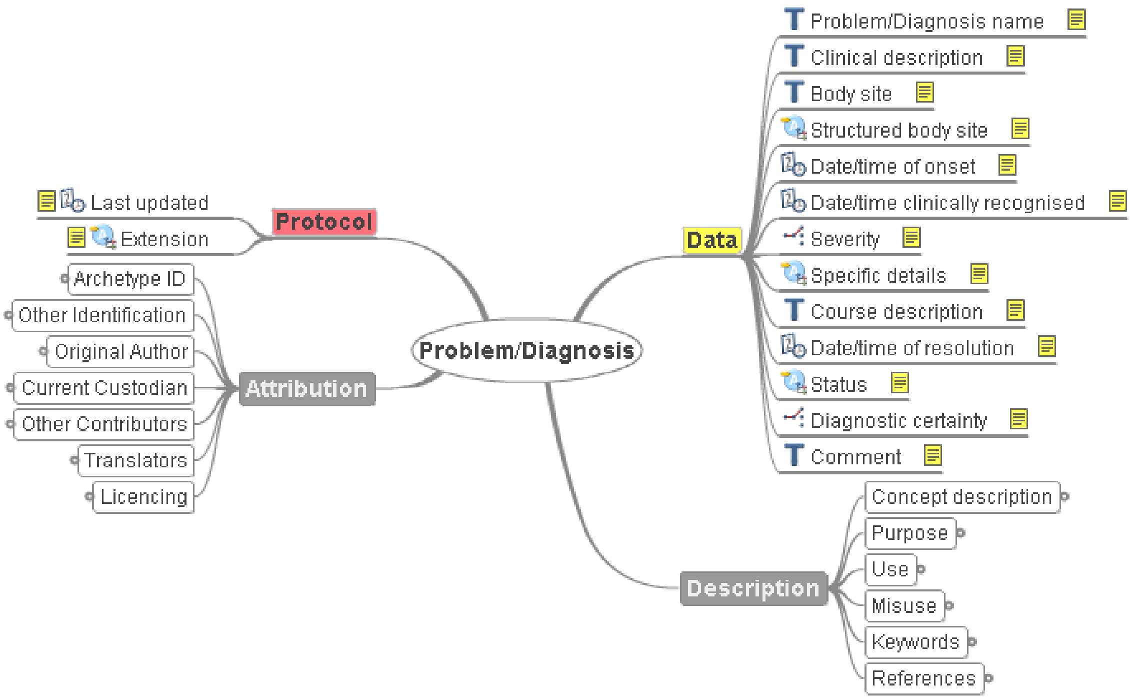


Figure 34: Problem/Diagnosis archetype.

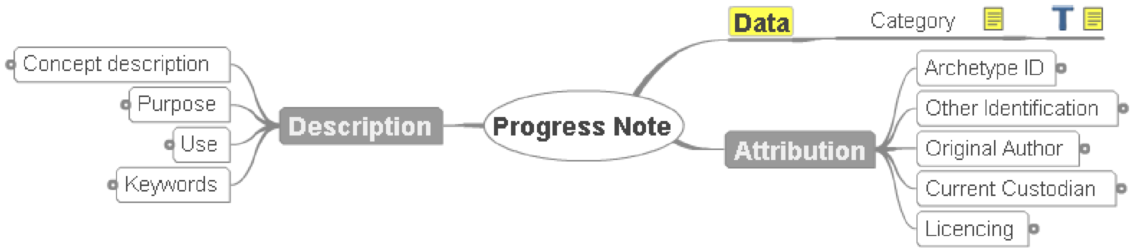


Figure 35: Progress note archetype.

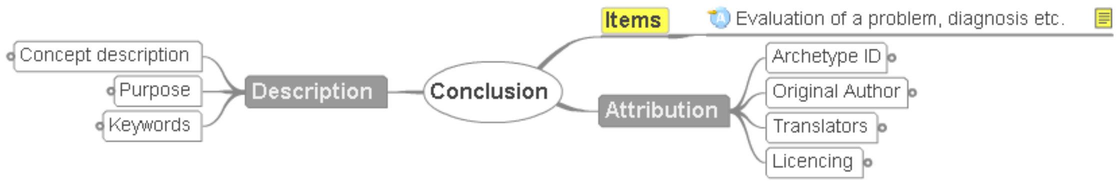


Figure 36: Conclusion archetype.

4.2.4.2 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 37, Figure 38 and Figure 39.

Figure 37: Recommendation archetype.

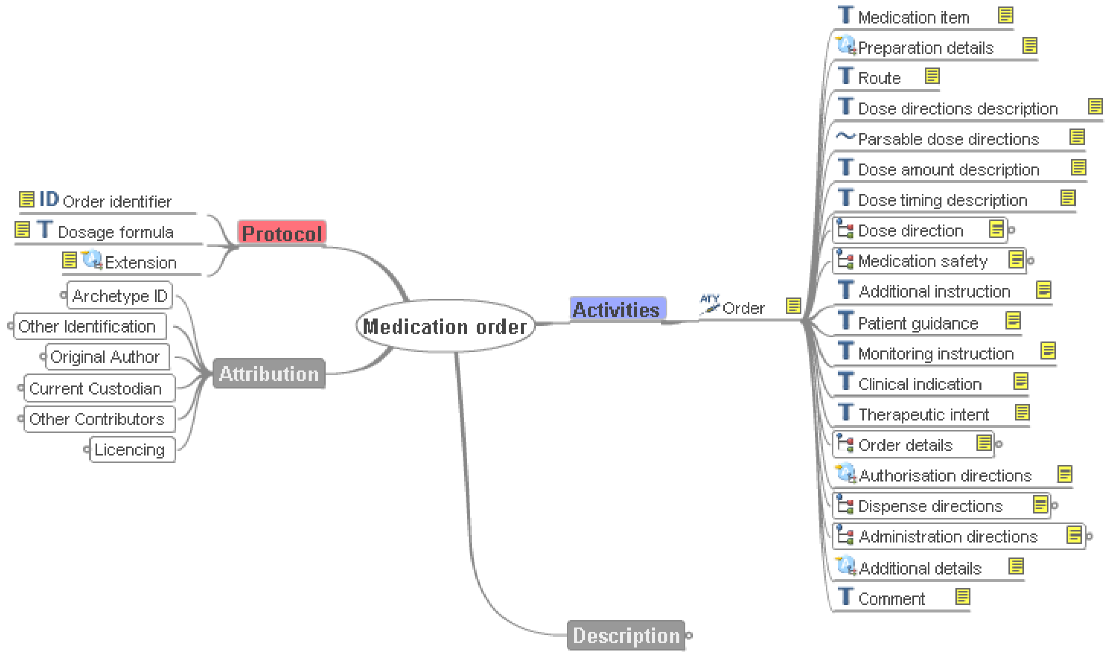


Figure 38: Medication order archetype.

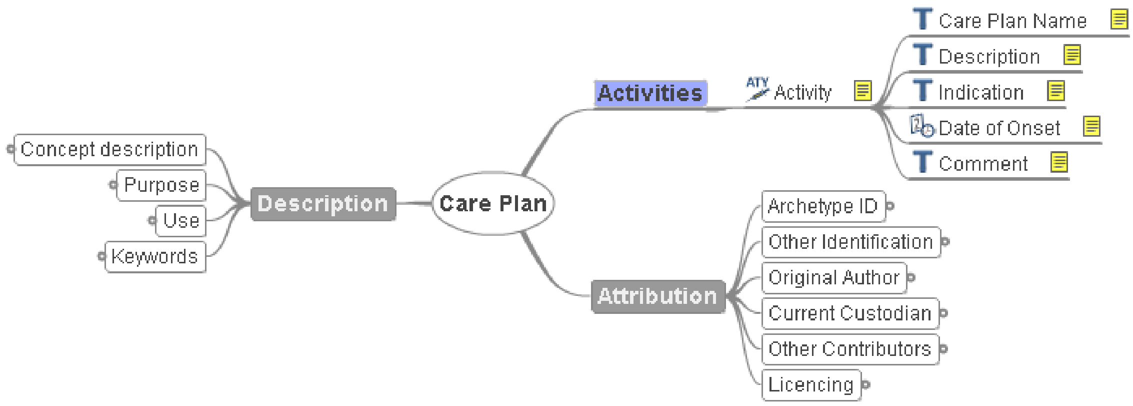


Figure 39: Care plan archetype.

4.2.5 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 40.

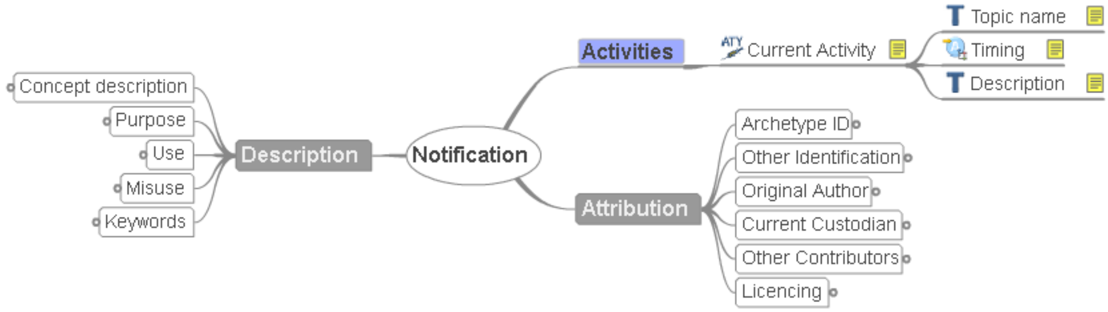


Figure 40: Notification archetype.

4.3 VPM semi-automatic creation and maintenance

As soon as a new user is enrolled in the FrailSafe system, a virtual patient model is created for this user. The initial parameters for this model are retrieved from the using both manual parameters setup by the clinician, based on initial examinations and measurements, as well by the parameters of all already enrolled users, which themselves evolve through time. After this initial model is created, it can be used to represent the user, perform analyses and facilitate decisions and interventions. As soon as new data become available for this user, the virtual patient model is automatically updated. However, the operator (e.g. clinician) will be able to manually adjust specific parameters that cannot be fully described automatically. In order to facilitate the initial creation and the manual maintenance of an older person's Virtual Patient Model, a VPM generation and maintenance tool is used. This tool is described in this section, while the automatic adaptation mechanisms are described in the next section. Furthermore, the generic models will be periodically updated and enriched with new representative models based on the analysis of representative newly enrolled patients.

4.3.1 VPM semi-automatic generation

The FrailSafe VPM generation and maintenance tool builds on the VERITAS Virtual User Model generator, allowing for the manual definition of all clinical, physical, cognitive, etc. parameters included in the VPM. Upon the enrolment of a new user, the clinician manually inserts values for the new user's parameters, through a dedicated Graphical User Interface (GUI), similar to the one depicted in Figure 41. This interface will ultimately be integrated in the clinical Web platform, to be delivered along with the DSS UI, in future deliverables D6.4 and D6.5.

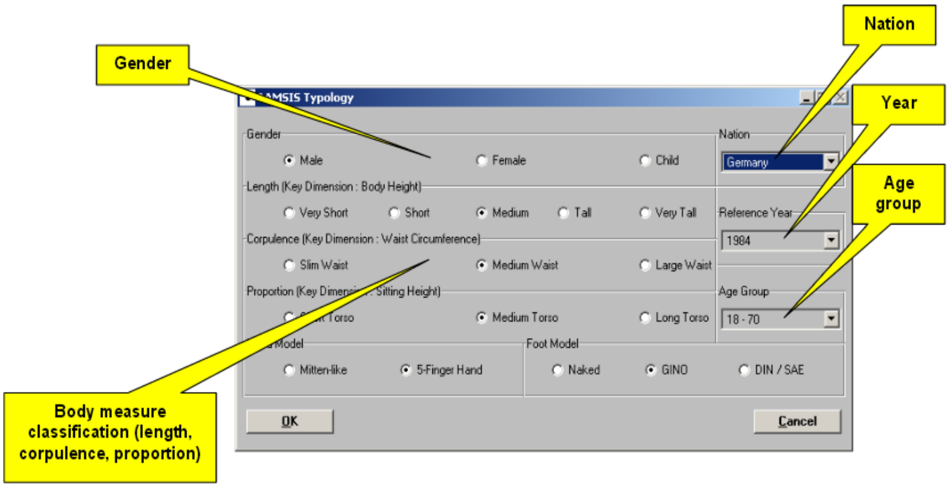


Figure 41: Graphical user interface for definition of parameters for the generic models.

Upon enrolment of a new user, the clinician fills in the user's parameters, by directly measuring them or through performing a number of questions, dictated by the clinical study methodologies of WP2. However, not all parameters are available at the time of the enrolment. For instance, measurements produced by the WWBS or by games are not available until the user starts wearing the WWBS or starts playing the games. The purpose of semi-automatic VPM generation is to use those parameters that are available in order to fill in the rest parameters, so that they best describe the user, and provide a good starting point for the intervention mechanisms of the DSS. Later on, when new data become available for this user, this initial model will be updated with more accurate values, following the dynamic adaptation mechanisms described in Section 4.4 , below.

The procedure followed to fill in the missing values for the new user is inspired by the user generation methods of VERITAS, in that the missing values are inferred from the distribution of the parameter values of the population of already enrolled users. However, hereby the generation is not based upon specifying percentiles for the distributions, but instead considering the distribution of users in the high-dimensional parameter space and performing a nearest-neighbour search.

Specifically, at first, the population of already enrolled users is considered, along with their offline data collected so far. Each user is represented by a VPM, containing representative values for clinical, cognitive, social, etc. parameters (the long-term model parameters are used; details of how the long-term model is computed are included in Section 4.4.2). The VPM for a user contains numerical parameters, e.g. the systolic blood pressure or the average pulse rate, as well as categorical parameters, e.g. the user's co-morbidities. All parameters are converted to numerical parameters, using appropriate scales, and normalized based on their means and standard deviations, in order to convert a complete VPM to a numerical vector, describing each user. This procedure is depicted in Figure 42. The vectors computed in this manner for all already enrolled users can be considered as the coordinates of the users in a high-dimensional parameter space.

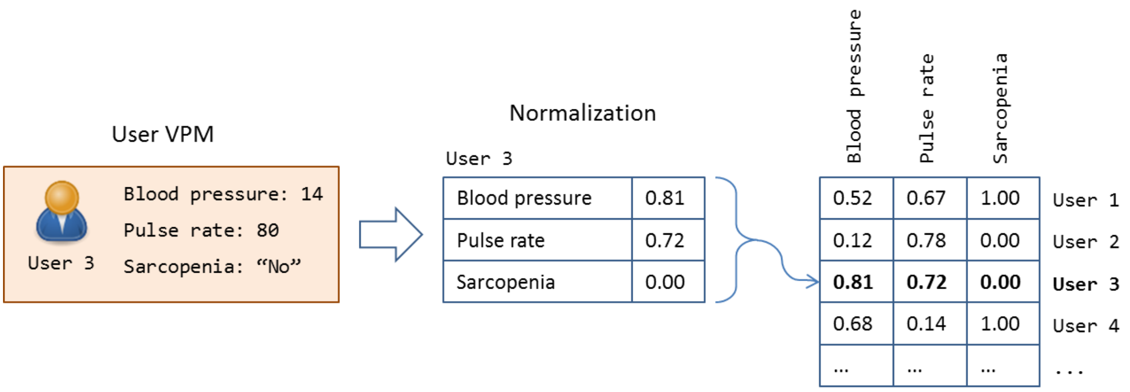


Figure 42: Conversion of an existing VPM to a vectorial form.

When a new user is enrolled, a vectorial form for the user's parameters is also produced, as described above. However, now not all parameters will be available, so that the vector will have missing values. The missing parameters are filled by setting them to the average values of the already enrolled users that are most similar to the new user, with respect to those parameters that are available.

The set of available parameters for the new user defines a subspace of the full parameter space, on which the enrolled users are mapped. In order to compare the new user to the enrolled ones, the enrolled ones are first projected to the subspace of available parameters, so that the comparison is possible. Then, both the enrolled users and the new user are considered as points in the same space. This procedure is illustrated in Figure 43.

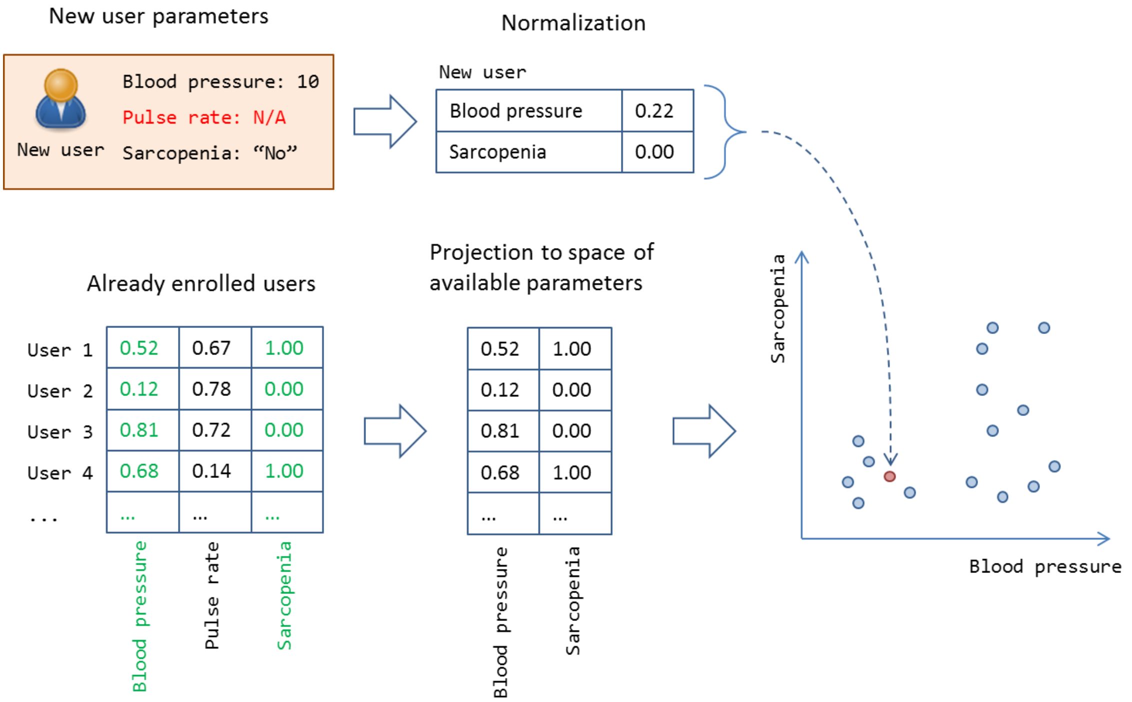


Figure 43: Mapping a new user to the same space as the already enrolled users. The already enrolled users are first projected in the subspace of available parameters for the new user.

The last step is to consider the nearest neighbours of the new user on this subspace. The number of nearest neighbours to consider is determined as a fraction, e.g. 5%, of the number of all enrolled users, so that a representative set of neighbours is always used. The exact value of this fraction is susceptible to change during evaluation trials, in order to select the most appropriate value. The missing values for the non-available parameters of the new user are computed as the average values of the corresponding parameters of the nearest neighbours. This procedure is illustrated in Figure 44.

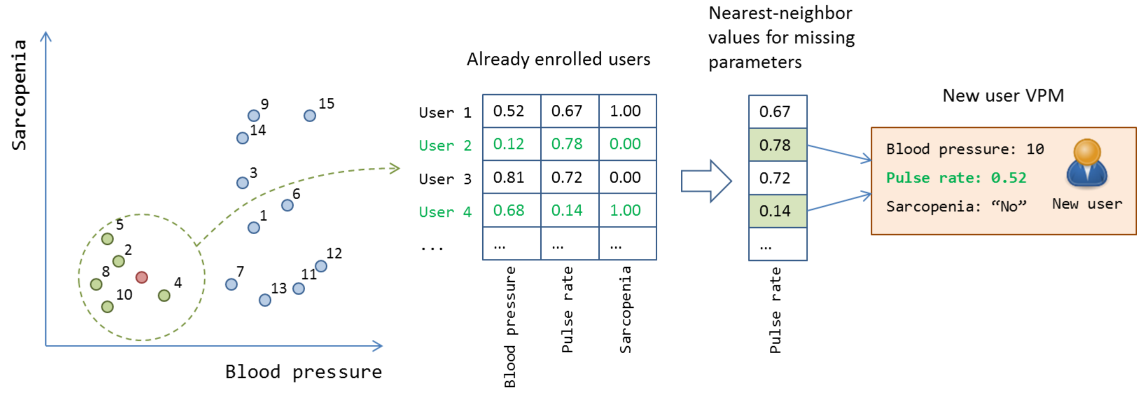


Figure 44: Computation of missing values for the new user, based on the values of the nearest neighbours.

Filling in the missing values for a new user completes the semi-automatic VPM generation for the new user. The generated VPM is now available to be used by the DSS, in order to provide interventions. The above procedure ensures that the generated VPM is representative for the new user, utilizing collective information from all users enrolled so far. The more users are enrolled, the more characteristic the mapping of users to vectorial spaces will be, with respect to the monitored parameters and the clusters that older persons may form in these spaces. Furthermore, the generated VPM is just the starting point. As new data become available for a user, the VPM will be dynamically adapted, as described in Section 4.4 , so that it becomes closer to the actual profile of the user and his/her variations with regard to the other users. This will also ensure that the model is up-to-date when it will be mapped, along with the other enrolled users, for determining the missing parameters of another new user.

4.3.2 Manual adjustment and maintenance of VPM parameters

The FrailSafe Virtual Patient Model representation is a multilevel schema of entities, as presented in Section 3.2 , covering both functional and non-functional requirements established through the use cases (Deliverable D1.2 and D1.3). Certain parameters of the VPM are static and can only manually be filled by the clinician. These include the following:

- patient identification,
- demographic information,
- contact details,
- health history record, including co-morbidities (e.g. gait disorders, sarcopenia, cardiovascular diseases, etc.).

The parameters belonging to the monitoring parameters class, representing data collected by the continuously monitoring devices (see section 3.2) are only automatically updated, and include:

- physiology-related parameters,
- physical condition-related parameters,
- psychological parameters,
- behavioural parameters
- social activity-related parameters,
- cognitive parameters, and
- frailty metric.

However, for these parameters, the clinicians are manually setting up intervention rules (Interventions subclass of the Clinician Input class), which take into account thresholds for various context-dependent cases. These intervention rules are guiding the Decision Support System with respect to the guidance and notifications to be sent to the patients. Parameter thresholds in the rules differentiate with respect to short-term and long-term patient models, thus different notifications are triggered. These rules are edited by the clinicians through the model editor. Details about the construction of the rules of the Decision Support System are presented in the DSS-related deliverables D4.16 and D4.17.

4.4 VPM dynamic adaptation

When new data become available for a specific user, through the FrailSafe sensors, clinical measurements and games, the Virtual Patient Model will be automatically updated, in order to consist a most accurate and up-to-date representation of the user. At each time, the VPM for a specific user will contain an aggregation of all the information collected so far for this user. The user VPMs will be updated in regular intervals, at different granularities, in order to capture various transitions and trends. In this section, the aggregated information stored in the VPM is described, followed by the adaptation mechanisms used.

Depending on the scale of information needed from the VPM, the dynamic adaptation process is separated into the following granularities:

- **short-term adaptation** (per event): sensitive to in-person fluctuations that occur on a daily basis
- **long-term adaptation** (per week): responsive to significant changes in older people's behaviour

These adaptation types are described in more detail in the following sections.

4.4.1 Short-term adaptation

The short-term model contains the most up-to-date information about all aspects of the older person’s physical and cognitive status. It captures short-term variations of the older person’s condition and can be used to provide the older person and the clinician with a detailed picture of the older person’ progress through time. Combined with the information stored in the long-term model, the information of the short-term model can be used for the detection of unusual situations and alarming conditions (e.g. when a certain value far exceeds the expected value for a particular older person).

For each parameter describing the physical and cognitive aspects of an older person, the short-term model maintains the measurements collected in the most recent measurement day. In case there are more measurements for the same parameter on the same day, the short-term model contains an aggregated value. However, the separate multiple measurements are still stored in the VPM database, in order to be available to the clinician or the user, if requested. If measurements for a specific parameter are not available for the current day, the most recent measurements are used. In this way, the model always contains the most recent information collected for a specific user.

The information contained in the short-term model are used both for decision making, in order to provide recommendations and guidance to the older person or in order to produce alerts, and for information visualization, allowing the older person and the clinician to have an overview of the person’s status through a mobile or Web interface.

4.4.2 Long-term adaptation

The long-term model contains information about the overall physical and cognitive status of the older person, throughout a large period of time. The long-term model captures large-scale variations in the older person's conditions and can be used to define thresholds for the decision making procedure, or to display expected values in information visualization components.

For the purposes of long-term adaptation, each of the parameters of the virtual patient model, e.g. the older person's systolic blood pressure, is considered as following a mixture of Gaussian distributions, with an unknown mean. The purpose of the long-term adaptation is to compute this unknown mean values, which characterize the specific older person.

Formally, let μ_p be the unknown mean of parameter p. Before any data are acquired for the specific user, μ_p is considered to follow a prior Gaussian distribution

$$\mu_p \sim N(\mu_{p,0}, \sigma_p).$$

The parameters of this prior distribution, i.e. $\mu_{p,0}$ and σ_p, are the initial parameter values computed during the VPM generation procedure, described in section 4.3 . The prior distribution encodes the general characteristics of the population in which the older person best fits (e.g. the frail, pre-frail or healthy groups).

The purpose of dynamic adaptation is to incrementally update the estimate of μ_p, when new measurements for parameter p are acquired. Specifically, let $(x_{p,1}, x_{p,2}, \dots, x_{p,n})$ be a set of off-line measurements collected for parameter p. For instance, they could be the consecutive measurements of blood pressure, conducted each day for a week. These measurements are considered as drawn from the true distribution of the person's parameter value, with mean μ_p and standard deviation σ_p. However, only an estimate $\overline{\mu_p}$ of the true mean and an estimate $\overline{\sigma_p}$ of the true standard deviation are available, which are computed from the collected data:

$$\bar{\mu} = \frac{1}{n}\sum_{i=1}^{n} x_i$$

$$\overline{\sigma_p} = \sqrt{\frac{1}{n}\sum_{i=1}^{n}(x_i - \bar{\mu})^2}$$

Using maximum a posteriori (MAP) inference, the update of the current estimate of μ_p ensuring the optimal likelihood given the collected data, is as follows:

$$\mu_{p,post} = \frac{1}{n\overline{\sigma_p}^2 + \sigma_p^2}\left(n\overline{\sigma_p}^2\bar{\mu} + \sigma_p^2\mu_{p,0}\right)$$

This a posteriori estimate can then be used as the current model parameter, and also as the a priori estimate for the next update, when a new set of data become available. A schematic description of the update process is depicted in Figure 45.

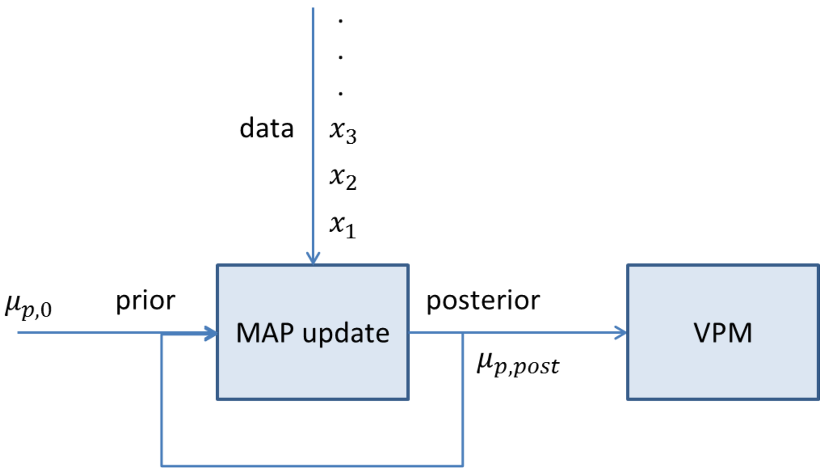


Figure 45: Dynamic maximum a posteriori estimation of VPM parameters.

4.4.3 Modification of the adaptation granularity

In general, the long-term model will be updated weekly. A week is selected as a balanced period of time, filtering out any short-term variations that do not correspond to significant changes of the overall older person's condition. However, there are cases where this time interval needs to be smaller. High-risk participants, e.g. ones with frequent hospitalizations, need a closer examination of their condition. A weekly interval for the update of the long-term model may fail to capture significant alterations of the older person's condition. For such cases, a shorter interval will be used for the dynamic adaptation. This interval will be manually set by the clinician, during the generation and maintenance of the older person's Virtual Patient Model.

4.5 Database schema

To integrate the defined specifications, requirements and archetypes into the architecture of the FrailSafe system, the database structure of the VPM should be carefully defined so as to cover all the above and allow relatively easy modifications or extensions in the following phases of the project as it is going to form the fundamental basis of the framework (see Figure 1).

At the early stages of the FrailSafe project, a relational database was designed and developed for the storage of the acquired data. However, taking into consideration the existing literature related to archetype-based maintenance solutions, we reached the conclusion that a NoSQL (Not-only-SQL) database would be more appropriate for the storage of Failsafe's data. NoSQL databases provide a mechanism for storage and retrieval of data which are modelled by means other than the tabular relations used in relational databases. Some of their basic characteristics are that they are schema-free, distributed, open-source, low-cost, horizontally scalable and can store a huge amount of data [28].

A further advantage of using a schema-free database for the storage of the FrailSafe VPM is that it also allows the easy extension and adaptation of the VPM, when new types of data and measurements become available.

All the related works reach a common observation: the NoSQL databases outperform the relational and the XML models in terms of characteristics, that are crucial also for Failsafe's Database Management System (DBMS) [29] [30] [31] [32]. More specifically, their main advantages are that they are faster, they have better response times, they especially target large sets of distributed data and they seem to be a promising solution for retrieving results from population-based queries in openEHR-based systems.

Comparing the best known NoSQL Databases, we selected Apache HBase for the storage of the data of our project, as it is a column-family database and this type of databases is the most suitable for the nature of our case study. More specifically, in FrailSafe project except for the abstract medical information, sensor raw data is also collected in a real-time scenario. The frequency of the measurements is very high (e.g. 25Hz), hence the DBMS has to be capable of managing hundreds of gigabytes of data efficiently in real-time. HBase is considered as the most suitable option as: (1) It is a distributed, scalable, big data store, (2) it is suitable for random, real-time read/write access to Big Data, (3) it is capable of hosting very large tables with billions of rows × millions of columns, (4) it is optimized for queries over large datasets [33].

4.5.1 Methodology for the integration of archetypes into a NoSQL Database System

In this subsection the methodology developed and adapted for a one-to-one mapping between openEHR archetypes and a column-family NoSQL schema is described.

In HBase, only column families are defined by the table schema. A table can have multiple column families, each of which can have any number of columns. In general, the table design logic in HBase is the following: (1) A table is a group of rows, (2) A Row is a group of column families, (3) A column family is a group of columns, (4) A column is a group of key value pairs [34] [35].

Row key	Column Family 1				Column Family 2				Column Family 3			
	Col1	Col2	Col3	......	Col1	Col2	Col3	......	Col1	Col2	Col3	......
1												
2												
3												
...												

Figure 46: Structure of an HBase Table.

The idea behind the design of an archetype-based Database schema was to incorporate the openEHR archetypes' structure into a table schema with respect to HBase table-design logic. Thus the mapping between the archetypes and an HBase table could be performed by following the next steps:

(1) Definition of a table schema in which the column families are mapped to the labels contained into the archetype categories while at the same time being used for the representation of concepts in a particular use-case scenario. If for example no archetype of a specific category is used, it is not required to comprise column families mapped to the labels of this archetype category in our table schema.

The term "labels" can be better understood through an example: Figure 47 illustrates the structure of the archetypes "**EHR-OBSERVATION.body weight.v1**" and "**EHR-EVALUATION.clinical synopsis.v1**" which are typical examples of the categories "Observations" and "Evaluations" respectively. These figures are called mindmaps and are generated by the openEHR CKM online tool. The concepts described by each archetype are divided into specific categories based on the archetype class thee archetype belongs to. These categories can be considered as labels for the contents of the archetype. For instance, the labels of the objects in the archetype "EHROBSERVATION. body weight.v1" as in every Observation archetype are: State, Events, Data, Protocol, Description, Attribution.

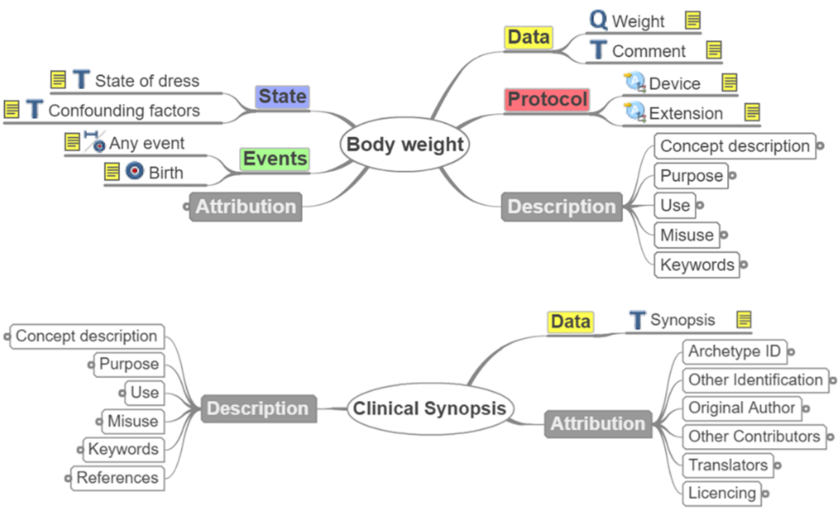


Figure 47: Typical examples of openEHR archetypes structure.

The labels ”Description” and ”Attribution” are excluded, as they contain common details related to the archetype and not to the concept they represent, such as original author, translators, purpose, use etc., and there is no point in storing such information for every record in the database. Hence, this information is stored in a separate table.

(2) Population of the column families with columns for storage of the information, represented by the archetype in a particular use-case scenario. Since usually the archetypes contain more fields than required for the representation of the corresponding concepts, columns have to be created only for the storage of data related to the used fields of the Archetypes. Table 6 shows an example. Only the fields ”Weight”, ”Comment” and ”Any Event” from the ”**EHROBSERVATION.body weight.v1**” archetype and ”Synopsis” from ”**EHR-EVALUATION.clinical synopsis.v1**” archetype were needed for the representation of the required concepts. Hence, only these fields are represented by columns in the corresponding HBase table.

Table 6: Example: Result of the archetypes - Hbase table schema mapping.

Rowkey	Data			Events
	Weight	Comment	Synopsis	Any Event
XXXX_YYYYMMDD_weight_EHR-OBSERVATION.body_weight.v1	+	+		+
XXXX_YYYYMMDD_clinical_EHR-EVALUATION.clinical_synopsis.v1			+	
XXXX_YYYYMMDD_weight_EHR-OBSERVATION.body_weight.v1	+	+		+
.....				

(3) Determination of the row key form which will be common for all column families. The name of the archetype has to be included in the row key to avoid a possible overlap of data in cases where the fields of the used archetypes have common names; the represented data have to be stored in columns with the same name, accordingly. Including the archetype name into the row key, data related to different archetypes are stored in different rows.

4.5.2 Produced NoSQL Database

In this subsection, the NoSQL schema resulted from the methodology described in the previous subsection is discussed. As mentioned before, the column families of the table in which the VPM data are stored are mapped to the labels of the (reused, modified or developed) archetypes, as shown in Table 5. For example, the required labels for the representation of "Blood Pressure" are: Data, State, Protocol, Events. These labels include all the required items of the incorporated archetypes, which in this case are: Systolic, Diastolic, Pulse, Position, Device, Any event. Following the same procedure for every parameter of Table 5, the final column-family NoSQL schema of the produced Database is generated. Two different HBase tables are used for the storage of the data based on the nature of the stored information (subject-specific or temporal parameters), which consequently necessitates the use of corresponding tables for updates.

More specifically:

- The first table is used for storing the personal details of the participants/patients, which are static and hence, rarely altered.

Table 7: HBase Table used for the storage of personal details.

Rowkey	Items		Data		Details	
	...Columns...					

- The second table stores all the dynamically changing parameters, which are aggregated daily or at regular intervals.

Table 8: HBase Table used for the storage of dynamically changing parameters.

Rowkey	Data		Events		State		Protocol			Items		Activities		
	...Columns...													

5 CONCLUSIONS

In this deliverable, a description of the Virtual Patient Model (VPM) used in the FrailSafe project has been provided. The VPM is a central part of the FrailSafe architecture, as it encodes all information collected for a specific older person registered in FrailSafe.

We have presented how virtual user modelling research has attempted to address critical issues of FrailSafe's human-computer interaction through a large number of analytic, usability-oriented approaches by providing older people 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. Archetype modelling has then been utilized either to select and expand existing archetypes from the public archetype repository or to define new ones in order to meet all data requirements.

Each time a new user enrols in the FrailSafe system, a VPM is created for him/her. The generation of the VPM is semi-automatic, in the sense that the clinician manually provides initial information about the older person, while the rest of the VPM parameters are automatically filled, based on information from all already enrolled users. As more data become available for a particular user, through the use of FrailSafe sensors, wearables, games, clinical studies, etc., the VPM is automatically and dynamically updated, in order to be up-to-date and most representative of the person's condition. Both short-term and long-term variations of the user's condition are considered during this dynamic adaptation.

The physical implementation of the VPM involves an HBase schema-less database, which has been designed in order to best represent the VPM archetypes.

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