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Executive Summary

The main objective of this deliverable D4.1. is to provide a detailed definition of the myAirCoach Patient modelling and representation framework (in order to build a structured, realistic and machine readable representation of the patient models) by taking into consideration existing knowledge of the consortium partners on virtual user modelling (VERITAS[1] project and the VUMS cluster).

In this direction, the identification and detailed conceptual definition of the basic entities/concepts of interest for the myAirCoach patients model (e.g. disease, symptom, diagnosis, risk factor, sensor input, treatment, action plans, interventions, patient, etc.) creation is analyzed and being investigated for life-long interoperable electronic health records.

More specifically, we initially provide a comprehensive insight of the heterogeneous Electronic Health Record (EHR) requirements from various domains involving different target stakeholders.

After the comparison of the available representation frameworks and the identification of the most appropriate one, we present the entities/concepts of interest that are included in the myAirCoach patients model including: monitored parameters, clinical data, diagnosis results, risk factor, action plans, interventions, patient, etc., in order to meet the requirements already defined in WP2. Thereafter, we provide a detailed description of the processing steps that we followed in order to include these entities to the patient models, using the most appropriate representation framework for the myAirCoach project.

[1] EU FP7 Veritas project: http://veritas-project.eu/

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List of abbreviations and acronyms

(*in alphabetic order*)

ADL	Archetype Description Language
AM	Archetype Model
AOM	Archetype Object Model
AQL	Archetype Query Language
CDS	Clinical Decision Support
EHR	Electronic Health Record
HL7	Health Level 7
RIM	Reference Information Model
RM	Reference Model
SM	Service Model
SOAP	Simple Object Access Protocol
UML	Unified Modeling Language
vMR	Virtual Medical Record
XML	Extensible Markup Language

1 Introduction

In the past 10 years different developments took place to specify data elements for clinical use and their re-use in health care information technology (HIT) to address several purposes. Clinicians, researchers, managers, institutions for quality control, regulatory agencies, health statistics developers, among others, have an increasing interest in data element standards for clinical data [1][5]. More specifically, they are particularly interested in the relationships among data elements that represent differential clinical concepts.

Currently, detailed patient models (provide the data elements specification and attributes for patients clinical knowledge) have been extensively used in several health care information and communication technologies as for example in Electronic Health Records, tele-health applications, medical devices, decision support tools, etc. Their purpose is to provide precisely, semantically consistent data and processing rules that are comparable and sharable between multiple healthcare providers, health enterprises and Healthcare systems.

However, the applicability of the patient models in a wide variety of clinical information applications have resulted in the design and implementation of diverse information models.

The focus of this deliverable is to select the most appropriate representation frameworks and use them for building a structured, realistic and machine readable representation format for the myAirCoach patient models. Relevant existing work from other projects like MobiGuide, UBIOPRED, etc. as well as existing models like the HL7 Reference Information Model (section 4 EHR profiles), IHE Patient Coordination Technical Framework and others will also be taken into account. After the selection of the most beneficial information representation model, the identification and detailed conceptual definition of the entities/concepts of interest for the myAirCoach patients model (e.g. disease, symptom, diagnosis, risk factor, sensor input, treatment, action plans, interventions, patient, etc.) will be analyzed and will be included in the detailed models, in order to meet the requirements defined in WP2.

The rest of this deliverable is organized as follows: Section 2 complements the review of the current practices in D1.1 by providing a more detailed description of the technical characteristics of existing Information models that can be used for building the myAirCoach patient models. Section 3 provides a more detailed description of the OpenEHR framework as it was selected as the initial framework to be integrated with the MyAirCoach project. In Section 4, we provide the definition of: i) the concepts of interest that need to be included in the developed models and ii) the technical requirements for integrating the models to myAirCoach overall system. Finally, Section 5 presents our proposal for the myAirCoach patient modelling framework by summarizing the related components of OpenEHR and describing the data representation within the project

2 Relevant Information Representation Standards

This section is divided into two parts. The first part is devoted to the description of the currently available, mainly non-functional quality requirements of the recent EHRs. The identified requirements are taken into account in order to build or modify existing machine readable representations of the MyAirCoach Patient Models. The second part presents a detailed comparison study of the available representation frameworks and giving emphasis to the most appropriate ones among those presented in the first part.

2.1 Electronic health record System Requirements

Keeping in mind that one of the primary targets of EHRs is to foster the quality of healthcare and support all stakeholders in the process of healthcare, it is crucial that EHRs themselves adhere to rigid systems of quality assurance and management. Such systems must be implemented along the whole life cycle of EHRs reaching from the design to the operation to the maintenance. The basis for systems that support and foster the quality of EHRs is – apart from the methodological, structural, and organizational aspects – the collection and definition of EHR-specific requirements. These requirement [12] are of a different nature and origin such as functional/non-functional, legal, organizational, etc. The heterogeneity renders an inter-organizational or even cross-country selection and coordination of such requirements difficult. Regardless of the specific selection of requirements in a certain context, it is necessary as a first step to be aware of scientifically and/or practically proven and relevant requirements for EHRs, which can be classified to the following categories:

- Data Security
    - Confidentiality
    - Integrity
    - Availability
    - Authenticity
    - Privacy and Data Protection
- Communication and Storage requirements
- Usability
- Content related requirements
- Interoperability
- General Functionalities
- Global Requirements

Table 1 summarizes the most important requirements that should be addressed by the MyAirCoach system and will be taken into account during the selection of the most appropriate representation framework.

Data security	Confidentiality	Integrity	Authenticity	Data Protection / Privacy	Performance and Efficiency	Reliability	Usability	Content	General functionalities	Global Requirements
Security must be guaranteed on different levels	Authorization and access control	All data should electronically be signed and encryption should	Each actor should unambiguously and persistently be identified.	Ability to change, correct, delete information included.	Access to data should be fast.	The system should support archiving of data.	The system should be user friendly, accessible for all kinds of users	Content should be complete, comprehensive. and linked to other relevant sources.	The system should offer possibilities to summarize information.	The system should follow an object/component oriented paradigm
The system should provide a login procedure requiring at least username and password.	Patient should know who accessed his/her data	The integrity of all data should be ensured at all time.	Authorship information available	A privacy policy should be stated.	The system should respond to any user input with acceptable performance	The system should be reliable.	Information should be understandable (for the intended audience).	Meta-information should be available	The system should offer data import/export functions.	The applicable laws should be followed
Different security services must be implemented and security policies must be explicitly defined.	Access control should be role-based.	IP-Sec and TLS/SSL should be used for transmission of data.	Authenticity of data should be assured.	The user should be informed about what his data is used for.	Data transmission and retrieval should be fast and adequate.	The system should support error recovery.	Alerts should be user specific.	Information/data sets should be standardized.	The system should offer the possibility to define reminders.	The system should be based on internet technology
The system should offer privilege , user and role management .	The access control must be able to deal with exceptional conditions.	The system should indicate when data is modified.	**Availability**	**Portability & maintainability**	Network speed should be fast and adequate.	Protected from technical break down.	Data entry templates should be customizable.	References to the source of information offered should be stated.	The patient should have the possibility to add self-reported health information.	Contact persons should be assigned
All security measures must be standardized.	Data integration should not create unauthorized disclosure of information.	The system should offer the possibility to validate data.	Availability of data/information should be ensured.	The system should ensure portability and backward compatibility.	The system should be scalable.	Ability to restore application data from a backup.	Data entry should support free text.	Versioning	A dictionary for terms should be available.	Training on the system should be offered
Application security should be maintained.	An information access policy should be stated	Modification of patient data should be avoided.	Ability to maintain readable archives	The system should provide documentation.	Records should instantly be updated.		There should be a search engine for data.	Last data update/change should be stated.	The system should offer print functions.	The system should be platform-independent
Firewalls should be used.	The patient should be able to designate someone else to control his data.	The integrity of data should be maintained during communication.	Deleted data should not be available in the system (e.g. .display, export, …)	All workflows that are support by the system should be documented.			The system should help users to avoid errors.	Data that is expired should be removed.		The system should be based on a distributed architecture

Table 1 : EHR Requirements

2.2 Relevant representation frameworks

There is a plethora of standards, clinical models based on standards, electronic health record systems and description languages. The purpose of this section is to focus on the current standards and EHR systems [4][6] available and distinguish the implementations that can cover the needs of the myAirCoach Program. Initially representation frameworks from completed projects were investigated. Specifically, from the MobiGuide project several health record related interoperability standards were investigated. These included the OpenEHR standard, the OpenEHR reference model, the relevant CEN/ISO 13606 and the HL7 set of standards. There were also investigated relevant representation format and terminology related standards. These included SNOMED CT and ICD 9 and 10. Additionally the VERITAS Virtual user modelling concept was also investigated. From the aforementioned standards and initiatives the OpenEHR (which was also briefly presented in D1.1) is presented to the following paragraphs in order to allow the reader to understand why we believe that it fits best of our needs in the myAirCoach project. In the following figure a categorization of the available existing frameworks is provided.

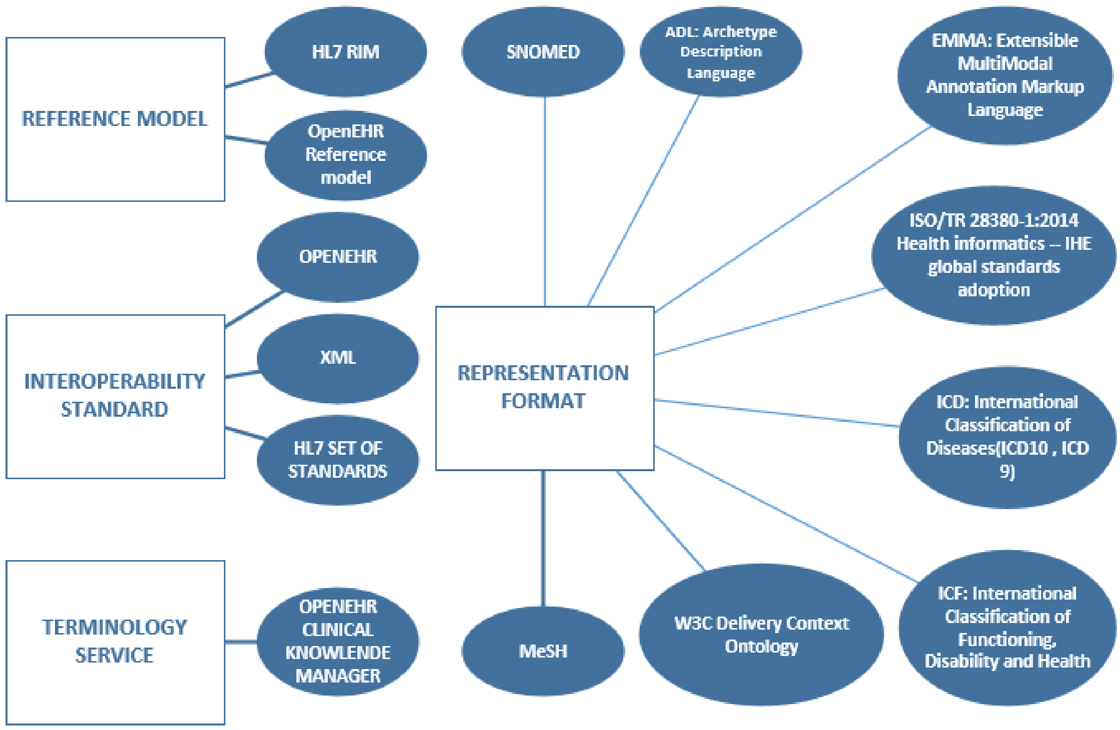


Figure 1 : Standards landscape

In the following part we provide more detailed information related to the aforementioned Interoperability standards and Representation formats.

2.2.1 Interoperability Standards

This section of the deliverable provides all the relevant representation frameworks that are characterized as interoperability standards, since they can be used as communication standards between different EHR systems. **CEN/ISO 13606:2008 Health informatics -- Electronic health record communication**

This standards has been thoroughly described in D1.1. The CEN/ISO EN13606 [28][59] is a European norm from the European Committee for Standardization (CEN) also approved as an international ISO standard. It is designed to achieve semantic interoperability in the electronic health record communication.

The overall goal of the CEN/ISO 13606 standard is to define a rigorous and stable information architecture for communicating part or all of the electronic health record (EHR) of a single subject of care (patient) between EHR systems, or between EHR systems and a centralized EHR data repository. It may also be used for EHR communication between an EHR system or repository and clinical applications or middleware components (such as decision support components) that need to access or provide EHR data, or as the representation of EHR data within a distributed (federated) record system.

To achieve this objective, CEN/ISO 13606 follows an innovative Dual Model architecture. The Dual Model architecture defines a clear separation between information and knowledge. The former is structured through a Reference Model that contains the basic entities for representing any information of the EHR. The latter is based on archetypes, which are formal definitions of clinical concepts, such as discharge report, clinical measurements or family history, in the form of structured and constrained combinations of the entities of a Reference Model. It provides a semantic meaning to a Reference Model structure.

The interaction of the Reference Model (to store data) and the Archetype Model (to semantically describe those data structures) provides an unseen capability of evolution to the information systems. Knowledge (archetypes) will change in the future, but data will remain untouched.

OpenEHR: Specification Program (CEN/ISO EN13606)

The main work of the OpenEHR Foundation[9] is performed by four 'programs' which respectively focus on specifications, clinical modelling, software, and localisation. The Specifications Program defines the formal models and languages defining OpenEHR data, OpenEHR content models (archetypes and templates) and OpenEHR services and APIs. These specifications are published and used in their own right and also underpin the Clinical Modelling Program (for which they provide the language of archetypes) and the Software Program (for which they provide schemas and interface definitions for software).

The goals of the Specification Program include:

- quality in health information: to enable data quality, validity, reliability, consistency and currency of clinical data across the data lifecycle from creation to archival, and across enterprises and sectors;
- support current technology: to actively support widely used ICT technologies e.g. major programming languages and frameworks;

- standards connections: to provide means for the specifications to be useful to users of related de jure standards, e.g. by providing additional transformation or mapping specifications and/or implementation guides;
- manage impact of change: to ensure the preservation of validity of clinical data created according to previous releases of the OpenEHR specifications.

The HL7 set of Standards

HL7 [46] is a non-for-profit standards organization founded in 1987 that was further accredited in 1994 by the American National Standards Institute (ANSI). It is directed to cope with the development of interoperability standards. It aims to provide standards for the exchange, integration, sharing and retrieval of electronic health information. HL7 v2.x, created in 1989, is the most used standard in the world’s healthcare organizations.

HL7 is responsible for some outstanding standards in the field, e.g.:

- the Arden Syntax [64] (a grammar for representing medical conditions and recommendations),
- the HL7 v3 RIM (Reference Information Model), a model for the representation of clinical data,
- the HL7 v2.x standard, a messaging standard for defining how to transmit information from one party to another,
- the CDA (Clinical Document Architecture), an exchange XML model for clinical documents,
- the HL7 vMR (virtual Medical Record), a subset information model designed for clinical decision support

In this section we will focus on HL7's data representation formats (RIM, CDA, VMR) and on service-oriented standards (HSSP and hData).

HL7 Reference Information Model

HL7 [46] is a non-for-profit standards organization founded in 1987. HL7 was further accredited in 1994 by the American National Standards Institute (ANSI). Its goal is to develop interoperability standards aiming to provide standards for the exchange, integration and sharing of electronic health information. HL7 v2.x, was created in 1989, It is the most used standard in the world’s healthcare organizations.

HL7 has created the following standards : 1) the Arden Syntax [64] (a grammar for representing medical conditions and recommendations), 2) the HL7 v3 RIM (Reference Information Model), a model for the representation of clinical data, 3)the HL7 v2.x standard, a messaging standard for defining how to transmit information from one party to another, 4) the CDA (Clinical Document Architecture), an exchange XML model for clinical documents, and the HL7 vMR (virtual Medical Record), a subset information model designed for clinical decision support

HL7 Reference Information Model

The Reference Information Model (RIM)[21] is the base of the HL7 Version 3. An object model created as part of the Version 3 methodology, the RIM is a large, pictorial representation of the HL7 clinical data (domains) and identifies the life cycle that a message or groups of related messages will carry. It is a shared model between all domains and, as such, is the model from which all domains create their messages. The RIM is an ANSI approved standard. Additionally, the HL7 v3 Reference Information Model (HL7 RIM) is a standard adopted by the International Organization of Standardization (ISO/HL7 21731:2006).

ISO standards relevant to the HL7 Reference Information Model that can be found in the literature are:

- *ISO/HL7 21731:2014 ISO/HL7 21731:2006*
- *ISO/HL7 27932:2009 Data Exchange Standards -- HL7 Clinical Document Architecture, Release 2*
- *ISO/HL7 27931:2009 Data Exchange Standards -- Health Level Seven Version 2.5 -- An application protocol for electronic data exchange in healthcare environments*
- *ISO/HL7 27951:2009 Health informatics -- Common terminology services, release 1*
- *ISO/HL7 10781:2015 Health Informatics -- HL7 Electronic Health Records-System Functional Model, Release 2 (EHR FM)*

HL7 CDA (Clinical Document Architecture) standards

HL7 CDA [68] is a subset of HL7v3 for transferring health documents in XML that are both human-readable and machine interpretable . CDA documents are delivered as payloads (typically embedded in HL7v2.x or v3 messages) with messaging rules defining how they are managed. In this sense, they do not fully address needs for Shared EHR standards. However, like CEN13606, they can be used along with other interchange methods. HL7 CDA release 1 (CDA r1) is widely used in many parts of the world, although now superseded by CDA release 2 (CDA r2), which became a full ANSI standard in May 2005. The older CDA r1 cannot represent more complex Shared EHR content, is based on outdated XML constructs (DTDs) and is not recommended for uptake by NEHTA.CDA r2 is flexible but needs HL7 templates for defining complex Shared EHR content. CDA also needs extra functionality to manage EHR extracts containing multiple documents. Without issues such as these being resolved, CDA cannot be considered suitable as a Shared EHR architecture standard. Interoperability Framework. Other advantages are:

- CDA has growing international support and an IHE XDS profile, and

- It can capture less structured human readable EHR input today, while offering a seamless migration path to more fully structured data tomorrow, enabling more care providers to participate in Shared EHR.

However, there are also major issues, including:

- Design, implementation and cost implications of using HL7 CDA r2 for Shared EHR information interchange are unclear and need further investigation (as do its relationship to HL7v3 RIM and template classes), and

Standard and is recommended for further investigation in this role.

HL7v2 messaging standards

There is widespread acceptance of clinical messaging based on HL7v2. HL7v2 standards also continue to be developed including new features aimed at carrying Shared EHR content. HL7v2 messages have no underlying reference model that identifies their semantic content and the inter-relationships between content. Therefore, on their own, they cannot meet the requirements for a Shared EHR Architecture but they can be used to carry Shared EHR content specified using other Shared EHR architectures. This requires an explicit mapping between the Shared EHR content and a standardized set of HL7v2 messages. The advantages of this approach include:

• Speed of implementation, plus re-use of interfaces and mapping work

• In its native form, it has low demands on telecommunications services, and

• Some HL7v2 messages are supported by vendors and IHE profiles.

Initial provision of some support for HL7v2 messaging is considered essential for whatever architecture is adopted for sharing Shared EHR content and support for HL7 2.x messaging as an underlying Shared EHR transport protocol is needed until the marketplace is well advanced in its uptake of other approaches to e-health information interchange.

The HL7 vMR (Virtual Medical Record)

The vMR is a data model for representing the data that are analysed and/or produced by CDS engines. The term vMR has historically been used in the CDS community to refer to a simplified representation of the clinical record that is suitable and safe for a CDS knowledge engineer to directly manipulate in order to derive patient-specific assessments and recommendations. Historically, the challenge has been that different organizations used different vMRs. The purpose of the vMR effort is to define a standard vMR that can be used across clinical decision support implementations. Moreover, due to the intended use of the vMR, a primary goal is simple and intuitive representation of data that is easy and safe for a typical CDS knowledge engineer to understand, use, and implement.

This specification defines a logical model of the vMR using the Unified Modelling Language (UML). The vMR Logical Model can be further constrained through vMR templates. Furthermore, physical models derived from the logical model are defined through additional specifications such as the HL7 vMR XML Specification.

FHIR(HL7)

FHIR is a new draft standard based on emergent industry approaches [8][10]. FHIR claims to combine the best features of the previous HL7 standards while being fast and easy to implement. The FHIR standard [10] can be used as a stand-alone data exchange standard, but can also be used in partnership with existing widely used standards. The basic building block of a FHIR document is a resource. An example of a patient resource can be found in **Error! Reference source not found.**.

Resources have a wide range of uses, from clinical content such as care plans and diagnostic reports through infrastructure such as Message Header and conformance statements. Resources define all exchangeable content, despite the fact they are used in totally different fashions, they all share the following set of characteristics:

- A common way to define and represent them, building them from data types that define common reusable patterns of elements.
- A common set of metadata.
- A human-readable part.

FHIR's philosophy is to build documents from a set of resources that, either by themselves or when combined, satisfy the majority of common use cases. Extensions can be used to cover the remaining content as needed. Usually, specific use cases are implemented by combining resources through the use of resource references.

```xml
<Patient xmlns="http://hl7.org/fhir">
  <extension url="http://www.goodhealth.org/consent#trials">
    <valueCode value="renal"/>
  </extension>
  <text>
    <status value="generated"/>
    <div xmlns="http://www.w3.org/1999/xhtml">
      <p>Henry Levin the 7th</p>
      <p>MRN: 123456</p>
    </div>
  </text>
  <identifier>
    <use value="usual"/>
    <label value="MRN"/>
    <system value="http://www.goodhealth.org/identifiers/mrn"/>
    <value value="123456"/>
  </identifier>
  <name>
    <family value="Levin"/>
    <given value="Henry"/>
    <suffix value="The 7th"/>
  </name>
  <gender>
    <text value="Male"/>
  </gender>
  <birthDate value="1932-09-24"/>
  <managingOrganization>
    <reference value="Organization/2"/>
    <display value="Good Health Clinic"/>
  </managingOrganization>
  <active value="true"/>
</Patient>
```

Extension with URL to definition

Human Readable Summary

Standard Data:
- MRN
- Name
- Gender
- Birth Date
- Provider

Figure 2 : FHIR example [8]

ISO 13120:2013 Health informatics -- Syntax to represent the content of healthcare classification systems -- Classification Markup Language (ClaML)

At this point it should be mentioned that this standard has been also described in D1.1. thus in the rest part of this paragraph only a brief overview is provided for the sake of self-completeness. The goal of ISO 13120:2013 is to formally represent the content and hierarchical structure of healthcare classification systems in a markup language for the safe exchange and distribution of data and structure between organizations and dissimilar software products. It contains terminologies, and is constrained to traditional paper-based systems (like ICD-10) and systems built according to categorical structures and a cross thesaurus (like ICNP). ISO 13120:2013 is intended for representation of healthcare classification systems in which classes have textual definitions, hierarchical ordering, named hierarchical levels (such as "chapter", "section"), inclusion and exclusion criteria, and codes. The Classification Mark-up Language (ClaML) is an XML based format designed specifically for classifications. It was accepted in 2007 as European norm (CEN/TS 14463). Additional details on the specification and use can be found in the respective CEN document (www.cen.eu), it is indicative the WHO decided to use this format to share its classifications such as the ICD.

2.2.2 Representation formats

This subsection presents the most relevant representation formats that are essential for describing the content of the modelling standard. A short description for each one of the most representative representation formats is shortly presented below:

EMMA: Extensible MultiModal Annotation Markup Language

EMMA is part of a set of specifications for multimodal systems endorsed by the W3C through their recommendation in 2009; and proposed for the W3C Multimodal Interaction Framework [77]. An XML markup language is provided by EMMA in order to contain and annotate the semantic interpretation of user input gained from various input channels. Annotations and interpretations of user input are supported by a set of elements and attributes. This standard data interchange format is primarily to be used between the components of a multimodal system, especially those responsible for interpretation and integration of user's input.

SNOMED CT

Systematized Nomenclature of MEDicine Clinical Terms (SNOMED CT) is a set of medical terminology that covers most areas of clinical information. It includes terms for diseases, procedures, findings and microorganisms and so on. Using a shared dictionary where possible fits very well in the deterministic view and facilitates exchanging data [67]out of context.

ICD: International Classification of Diseases

Following the successful and wide use of ICD-9, ICD-10 [60] was endorsed by the Forty-third World Health Assembly in May 1990 and came into use in WHO Member States as from 1994. The classification is the latest in a series which has its origins in the 1850s. The first edition, known as the International List of Causes of Death, was adopted by the International Statistical Institute in 1893. WHO took over the responsibility for the ICD at its creation in 1948 when the Sixth Revision, which included causes of morbidity for the first time, was published. The World Health Assembly adopted in 1967 the WHO Nomenclature Regulations that stipulate use of ICD in its most current revision for mortality and morbidity statistics by all Member States.

The ICD is the international standard diagnostic classification for all general epidemiological, many health management purposes and clinical use. These include the analysis of the general health situation of population groups and monitoring of the incidence and prevalence of diseases and other health problems in relation to other variables such as the characteristics and circumstances of the individuals affected, reimbursement, resource allocation, quality and guidelines.

It is used to classify diseases and other health problems recorded on many types of health and vital records including death certificates and health records. In addition to enabling the storage and retrieval of diagnostic information for clinical, epidemiological and quality purposes, these records also provide the basis for the compilation of national mortality and morbidity statistics by WHO Member States.

ICF: International Classification of Functioning, Disability and Health

The International Classification of Functioning, Disability and Health, known more commonly as ICF [78], is a classification of health and health-related domains. These domains are classified from body, individual and societal perspectives by means of two lists: a list of body functions and structure, and a list of domains of activity and participation. Since an individual's functioning and disability occurs in a context, the ICF also includes a list of environmental factors. ICF assumes that every human being can experience a decrement in health and thereby experience some degree of disability. Furthermore, ICF takes into account the social aspects of disability and does not see disability only as a 'medical' or 'biological' dysfunction. By including Contextual Factors, in which environmental factors are listed ICF allows to records the impact of the environment on the person's functioning.

W3C Delivery Context Ontology

The Delivery Context Ontology provides a formal model of the characteristics of the environment in which devices interact with the Web or other services. The Delivery Context includes the characteristics of the Device, the software used to access the service and the Network providing the connection among others. The Delivery Context is an important source of information that can be exploited to create context-aware applications, thus providing a compelling user experience. The ontology is formally specified in the Web Ontology Language (OWL). The normative definition of the ontology terms is generated automatically from the OWL file. A more detailed description has been provided in D1.1.

ISO/TR 28380-1:2014 Health informatics -- IHE global standards adoption

The Integrating the Healthcare Enterprise (IHE) initiative aims to define a framework for integrating information systems in a healthcare environment [66]. This initiative began in 1998 as an effort to more clearly define how existing standards, notably and HL7, should be used to resolve common information system communication tasks in radiology. Medical Information System vendors have rapidly become strong supporters and architects of the IHE effort to check the conformance of their systems with IHE standards. It is also important to note that, while this initiative began as a joint effort of American Medical Societies (RSNA and HIMMS), its relevance in the field has also reached Europe19 as well as other regions and countries. Therefore, IHE has actually become a global non-profit initiative with regional/national branches.

2.3 Comparison of available representation frameworks

The comparative review of the afore-mentioned standards allow us to understand their similarities and differences and also to examine their potential use in the user modelling procedures of the cluster projects. The following Table presents a comparison of the most common standards, according to the following dimensions:

- ISO standardized
- Allowing deviations from reference model
- Implementation
- Dual level architecture: Full separation of health domain knowledge and the IT domain
- Use of data type specification
- Coding present?
- One or many terminology systems
- Unique code per data element
- Reference model required?
- Authorship
- Assigning keywords in the clinical model
- Unique id for the clinical model
- Versioning
- Status (e.g. final versus draft)
- Purpose
- Evidence base explicit
- Guidance for documentation
- Interpretation
- Deploy once technology
- Available in repository
- Use of keywords in repository
- Language of the content

The comparative study presented in Table 2, clearly shows the benefits of the OpenEHR representation framework as compared to HL7. Therefore, it was decided that the representation of the myAirCoach patient models will be based on the OpenEHR architecture.

Table 2: Comparison of different representation frameworks

Criteria	Archetypes 13606 /OpenEHR	Health Level (HL) 7
ISO standardized	⍰	⍰
Allowing deviations from reference model	⍰	⍰
Implementation	Different implementation in 13606 or OpenEHR based EHR	HL7 messages, CDA and services around the world
Dual level architecture	⍰	⍰
Use of data type specification	⍰	⍰
Coding present?	⍰	⍰
One or many terminology systems	One : SNOMED-CT	Many
Unique code per data element	⍰	⍰
Reference model required?	⍰	⍰
Authorship	⍰	⍰
Assigning keywords in the clinical model	⍰	⍰
Unique id for the clinical model	⍰	⍰
Versioning	⍰	⍰
Status : final versus draft	⍰	⍰
Purpose	Explicitly stated	Derived from name
Evidence base explicit	⍰	⍰
Guidance for documentation	⍰	⍰
Interpretation	⍰	⍰
Deploy once technology	⍰	⍰
Available in repository	⍰	⍰
Use of keywords in repository	⍰	⍰
Language of the content	Multi-language	Multi-language

3 The OpenEHR Framework

The current section serves as an introduction to the structure and interfaces of the openEHR framework as it will be adopted within the final MyAirCoach system. More specifically the archetype based structure of open HER is presented together with some important characteristics of the Archetype Query Language and online Clinical Knowledge manager system of OpenEHR.

Figure 3 illustrate the basic components that form the OpenEHR specification project. The relationship between the parts of the computing platform are indicated on the diagram. The abstract specifications consist of the reference model (RM), the service model (SM) and archetype model (AM). The first two correspond to the ISO RM/ODP information and computational viewpoints respectively. The latter formalises the bridge between information models and knowledge resources.

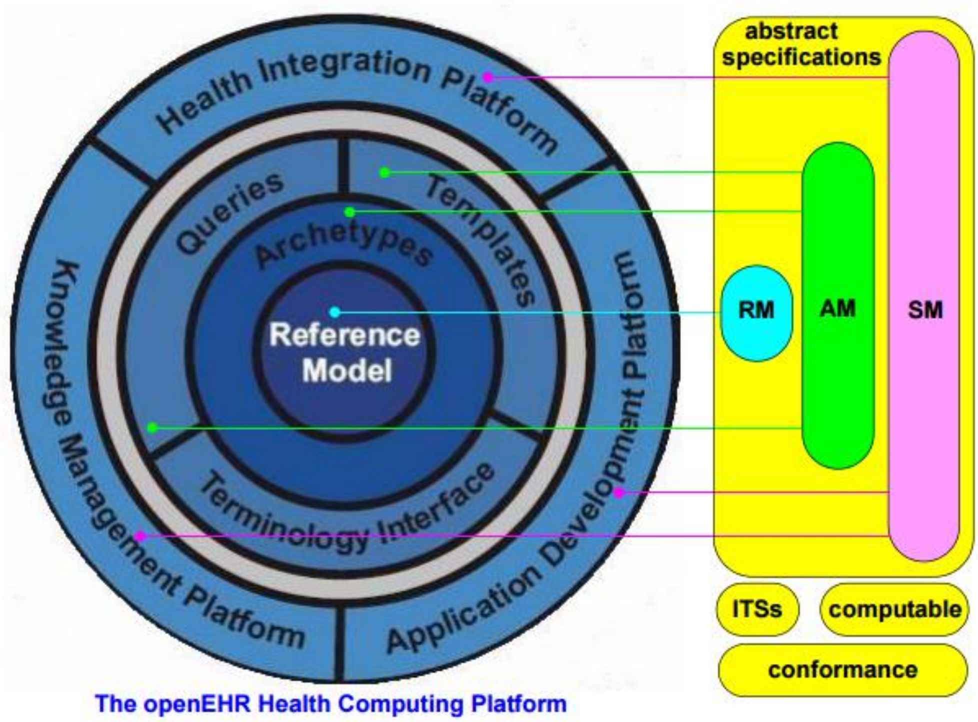


Figure 3: OpenEHR specification [9]

One of the important design aims of OpenEHR is to provide a coherent, consistent and re-usable type system for scientific and health computing. Accordingly, the 'core' of the RM (bottom-most layers) provides identifiers, data types, data structures and various common design patterns that can be reused ubiquitously in the upper layers of the RM, and equally in the AM and SM packages. Figure 4 illustrates the relationships between the packages. Dependencies only exist from higher packages to lower packages. While the following part of this subsection is devoted to the description of the RM, SM and AM packages.

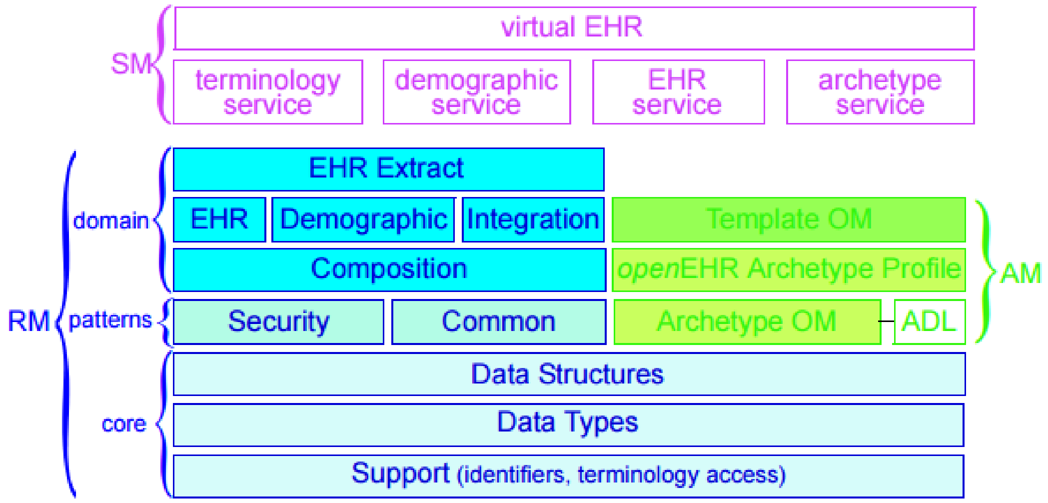


Figure 4: OpenEHR packages [9]

3.1.1 Design principles

Based on the two-level approach, a stable reference information model constitutes the first level of modelling, while formal definitions of clinical content in the form of archetypes and templates constitute the second Only the first level (the Reference Model) is implemented in software, significantly reducing the dependency of deployed systems and data on variable content definitions. The only other parts of the model universe implemented in software are highly stable languages/models of representation 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 computerized clinical guidelines The use of archetyping in OpenEHR is shown in next figure.

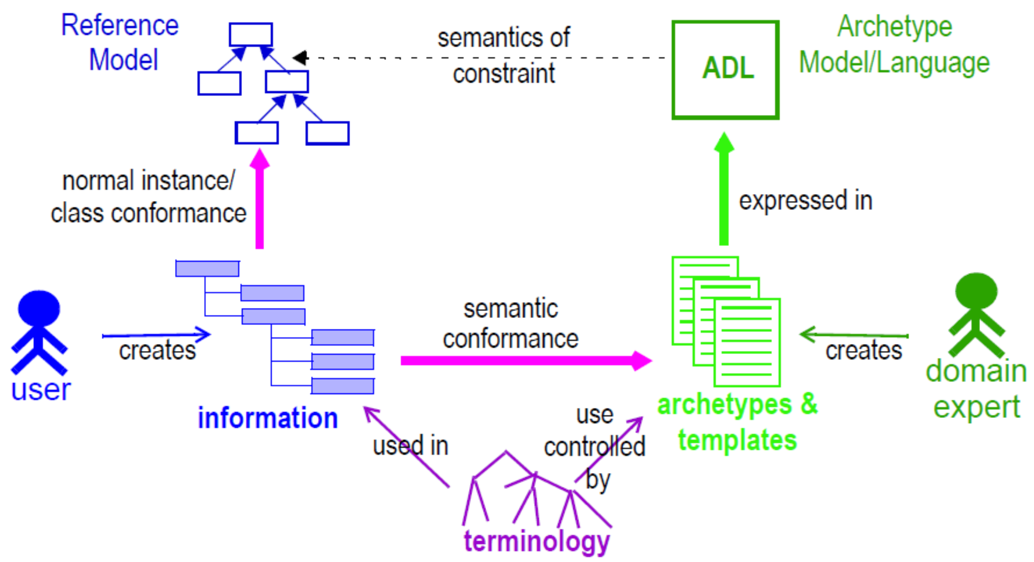


Figure 5: Two level modelling [9]

3.2 OpenEHR Package Structure

This section provides a short description of the basic OpenEHR models which are: i) the OpenEHR reference model, ii) the OpenEHR archetype model and the iii) OpenEHR service model.

OpenEHR Reference Model (RM)

Reference model includes packages with each package defining a local context of definition of classes. The RM includes the following packages 1) support information model package 2) data types information model package 3)data structure information model package 4) common information model packages 5) security information model packages 6)EHR information model packages 7)EHR extract information model packages 8)integration information model packages 9)Demographics Information model packages.

Support information model describes the most basic concepts, required by all other packages, and is comprised of the Definitions, Identification, Terminology and Measurement packages. The semantics defined in these packages allow all other models to use identifiers and to have access to knowledge services like terminology and other reference data.

Data types information model includes a set of clearly defined data types and provides a number of general and clinically specific types required for all kinds of health information. The following categories of data types are defined in the data types reference model: Text, Quantities, date/ times, encapsulated data, basic types.

Data Structures Information Model includes generic data structures are used for expressing content whose particular structure will be defined by archetypes. The generic structures are as follows: single, list, table, tree, history.

Common Information Model includes concepts that recur in higher level packages. These include the classes LOCATABLE and ARCHETYPED that provide the link between information and archetype models and the classes ATTESTATION and PARTICIPATION are generic domain concepts that appear in various reference models

The Security Information Model defines the semantics of access control and privacy setting for information in the EHR.

The EHR IM defines the containment and context semantics of the concepts EHR, COMPOSITION, SECTION, and ENTRY

The EHR Extract IM defines how an EHR extract is built from COMPOSITIONs, demographic, and access control information from the EHR.

The Integration model defines the class GENERIC_ENTRY, a subtype of ENTRY used to represent freeform legacy or external data as a tree. This Entry type has its own archetypes, known as “integration archetypes”, which can be used in concert with clinical archetypes as the basis for a tool-based data integration system.

The demographic model defines generic concepts of PARTY, ROLE and related details such as contact addresses. The archetype model defines the semantics of constraint on PARTYs, allowing archetypes for any type of person, organisation, role and role relationship to be described. This approach provides a flexible way of including the arbitrary demographic attributes allowed in the OMG HDTF PIDS standard.

Figure 6:Structure of the reference model package [9]

OpenEHR Archetype Model (AM)

The OpenEHR archetype model package contains the models necessary to describe the semantics of archetypes and templates, and their use within OpenEHR. These include ADL, the Archetype Definition Language (expressed in the form of a syntax specification), the archetype and template packages, defining the object-oriented semantics of archetypes and templates, and the openehr_profile package, which defines a profile of the generic archetype model defined in the archetype package, for use in OpenEHR (and other health computing endeavours). The internal structure of the am package is shown the following figure

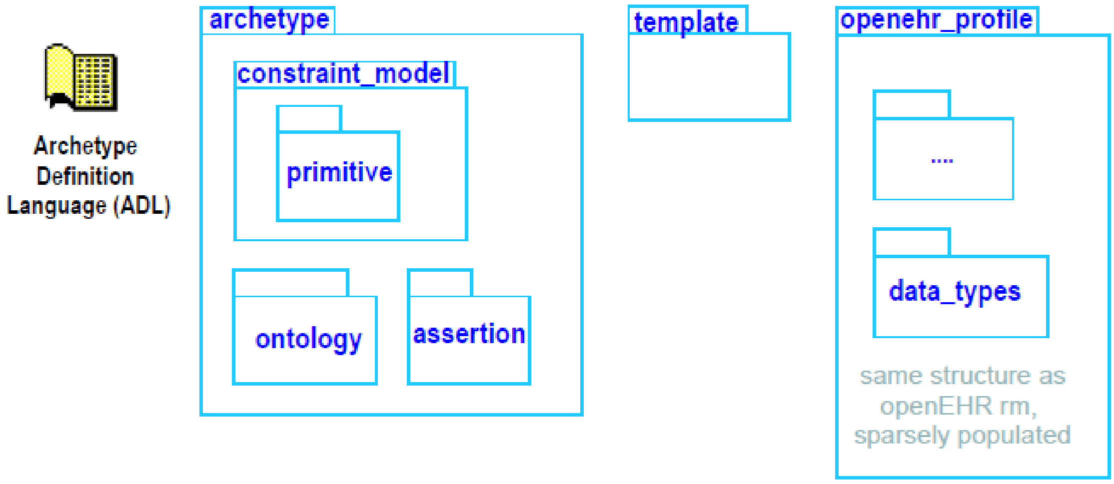


Figure 7: Structure of the archetype model package [9]

OpenEHR Service Model (SM)

The OpenEHR service model includes definitions of basic services in the health information environment, centred around the EHR. It includes the Virtual EHR API model, the EHR service model , the archetype service model , the terminology interface model .

The virtual EHR API defines the fine-grained interface to EHR data, at the level of Compositions and below. It allows an application to create new EHR information, and to request parts of an existing EHR and modify them. This API enables fine-grained archetype-mediated data manipulation. Changes to the EHR are committed via the EHR service.

The EHR service model defines the coarse-grained interface to electronic health record service. The level of granularity is OpenEHR Contributions and Compositions, i.e. a version-control / change-set interface. Part of the model defines the semantics of server-side querying, i.e. queries which cause large amounts of data to be processed, generally returning small aggregated answers, such as averages, or sets of ids of patients matching a particular criterion.

The archetype service model defines the interface to online repositories of archetypes, and can be used both by GUI applications designed for human browsing as well as access by other software services such as the EHR.

The terminology interface service provides the means for all other services to access any terminology available in the health information environment, including basic classification vocabularies such as ICDx and ICPC, as well as more advanced ontology-based terminologies.

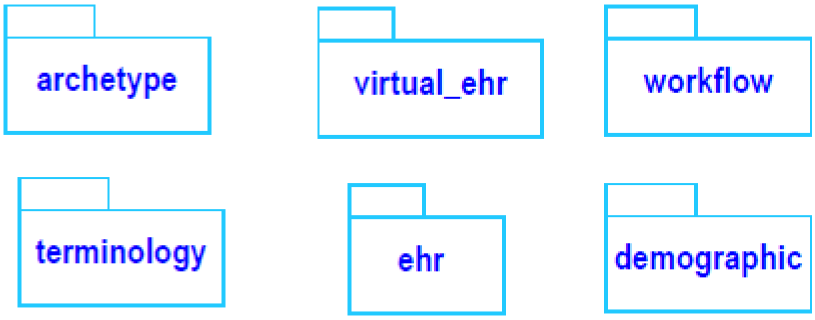


Figure 8 : Structure of the service model package [9]

3.3 OpenEHR Archetypes

Under the two-level modelling approach, the formal definition of information structuring occurs at two levels. The lower level is that of the reference model, a stable object model from which software and data can be built. Concepts in the OpenEHR reference model are invariant, and include things like Composition, Section, Observation, and various data types such as Quantity and Coded text. The upper level consists of domain-level definitions in the form of archetypes and templates. Concepts defined at this level include things such as “blood pressure measurement”, “SOAP headings”, and “HbA1c Result”

All information conforming to the OpenEHR Reference Model (RM) - i.e. the collection of Information Models (IMs) - is “archetypable”, meaning that the creation and modification of the content, and subsequent querying of data is controllable by archetypes. Archetypes are themselves separate from the data, and are stored in their own repository. The archetype repository at any particular location will usually include archetypes from well-known online archetype libraries. Archetypes are deployed at runtime via templates that specify particular groups of archetypes to use for a particular purpose, often corresponding to a screen form.

Archetypes are themselves instances of an archetype model, which defines a language in which to write archetypes; the syntax equivalent of the model is the Archetype Definition Language, ADL. These formalisms are specified in the OpenEHR Archetype Object Model (AOM) and ADL documents respectively. Each archetype is a set of constraints on the reference model, defining a subset of instances that are considered to conform to the subject of the archetype, e.g. “laboratory result”. An archetype can thus be thought of as being similar to a LEGO® instruction sheet (e.g. for a tractor) that defines the configuration of LEGO® bricks making up a tractor. Archetypes are flexible; one archetype includes many variations, in the same way that a LEGO® instruction might include a number of options for the same basic object. Mathematically, an archetype is equivalent to a query in F-logic [5]. In terms of scope, archetypes are general-purpose, re-usable, and composable. For data capture and validation purposes, they are usually used at runtime by templates.

An archetype is composed of four main parts: a header section, a description section, a definition section, and an ontology section. The description section includes metadata information, such as audit information, life cycle status, or purpose. The definition section is a basic formal definition of the archetype, containing restrictions arranged in a tree-like structure created from the reference information model. The ontology section includes the terminological definitions and bindings that link the data structures and content to the knowledge resources.

3.4 OpenEHR Templates

An OpenEHR Template is a specification that defines a tree of one or more archetypes, each constraining instances of various reference model types, such as Composition, Section, Entry subtypes and so on. Thus, while there are likely to be archetypes for such things as “biochemistry results” (an Observation archetype) and “SOAP headings” (a Section archetype), templates are used to put archetypes together to form whole Compositions in the EHR, e.g. for “discharge summary”, “antenatal exam” and so on. Templates usually correspond closely to screen forms, printed reports, and in general, complete application-level lumps of information to be captured or sent; they may therefore be used to define message content. They are generally developed and used locally, while archetypes are usually widely used.

A template is used at runtime to create default data structures and to validate data input, ensuring that all data in the EHR conform to the constraints defined in the archetypes referenced by the template. In particular, it conforms to the path structure of the archetypes, as well as their terminological constraints. Which archetypes were used at data creation time is written into the data, in the form of both archetype identifiers at the relevant root nodes, and archetype node identifiers (the [atnnnn] codes), which act as normative node names, and which are in turn the basis for paths. When it comes time to modify the same data, these archetype node identifiers enable applications to retrieve and use the original archetypes, ensuring modifications respect the original constraints.

3.5 OpenEHR Archetype Description Language

In OpenEHR, archetypes are formalised by the Archetype Object Model (AOM). This is an object model of the semantics of archetypes. When an archetype is represented in memory (for example in an archetype-enabled EHR “kernel”), the archetype will exist as instances of the classes of this model. The AOM is thus the definitive statement of the semantics of archetypes. In serialised form, archetypes can be represented in various ways. The normative, abstract serialisation in OpenEHR is Archetype Definition Language (ADL). This is an abstract language based on Frame Logic queries (also known as F-logic) with the addition of terminology. An ADL archetype is a guaranteed 100% lossless rendering of the semantics of any archetype, and is designed to be a syntactic analogue of the AOM. Nevertheless, other lossless and lossy serialisations are possible and some already exist. For practical purposes, XML-based serialisations are used in some situations.

ADL is also composed of four parts, corresponding to the structure of an archetype, and uses two main types of syntax (cADL and dADL). cADL is used to express archetype definitions, and it enables constraints on data defined by object oriented information models to be expressed in archetypes or other knowledge definition formalisms [9]. On the other hand, dADL is used to express data appearing in the language, description, ontology, and revised history sections. It provides a formal means of expressing instance data based on an underlying information model.

3.6 OpenEHR Archetype Query Language (AQL)

The second major computational function of archetypes is to support querying. Currently, the available query languages, such as SQL, XQuery, or Object-Oriented Query Language, have dependencies on particular system data structure and working environment. Users must know the persistence data structure of an EHR in order to write an appropriate query. The query statement cannot be used by other systems which have different data store. Consequently, none of these languages meet the aforementioned requirements and none of these can be used directly as the query language required by integrated care EHRs

Archetype Query Language (AQL) is a declarative query language developed specifically for expressing queries used for searching and retrieving the clinical data found in archetype-based EHRs. It is applied to the OpenEHR EHR Reference Model (RM) and the OpenEHR clinical archetypes, but the syntax is independent of applications, programming languages, system environment, and storage models. The minimum requirement for data to be querying with AQL (including with archetype structures and terminology) is for the data to be marked at a fine granularity with the appropriate archetype codes and terminology codes. This may be native OpenEHR-structured data, or legacy system data to which the relevant data markers (mainly archetype paths and terminology codes) have been added. Unlike other query languages, such as SQL or XQuery, AQL expresses the queries at the archetype level, i.e. semantic level, other than at the data instance level. This is the key in achieving sharing queries across system boundaries or enterprise boundaries.

AQL has the following distinctive features:

- the utilization of OpenEHR archetype path syntax in AQL. OpenEHR path syntax is used to locate clinical statements and data values within them using Archetypes. This path syntax is used to represent the query criteria and returned results. It allows setting query criteria using archetype and node identifiers, data values within the archetypes, and class attributes defined within the OpenEHR RM. It also allows the returned results to be top-level archetyped RM objects, data items within the archetypes or RM attribute values.

- the utilization of containment mechanisms to indicate the data hierarchy and constrain the source data to which the query is applied.

- the utilization of ADL-like operator syntaxes, such as matches, exists, in, negation.

- neutral expression syntax. AQL does not have any dependencies on the underlying RM of the archetypes. It is neutral to system implementation and environment.
- supporting queries with logical time-based data rollback.

AQL has some other features which can be found from other query languages: Supporting naming returned results. Supporting query criteria parameters. Supporting arithmetic operations (such as count, addition, subtraction, multiplication, and division), relational operations (>, >=, =, !=, ⇐, <) and Boolean operations (or, and, xor, not). . Supporting some functions that are supported in XQuery, such as current-date (). . Users can specify their preference on the retrieved data, such as ordering preferences, or total number of retrieved results. Supporting queries for individual clinical subjects at the point of care, administrative purposes and clinical research purposes.

Structure & Example

Like SQL, AQL has five clauses: SELECT, FROM, WHERE, ORDER BY, and TIMEWINDOW. The SELECT clause specifies the data elements to be returned. The FROM clause specifies the result source and the corresponding containment criteria. The WHERE clause specifies data value criteria within the result source. The ORDER BY clause indicates the data items used to order the returned result set. TIMEWINDOW clause is to constrain the query to data that was available in the system within the specified time criteria. The following is an example AQL query meaning “Get the BMI values which are more than 30 kg/m2 for a specific patient”:

AQL Example: “Get the BMI values which are more than 30 kg/m2 for a specific patient”
SELECT o/[at0000]/data[at0001]/events[at0002]/data[at0003]/item[0004]/value FROM EHR [uid=@ehrUid] CONTAINS COMPOSITION c [openEHR-EHR-COMPOSITION.report.v1] CONTAINS OBSERVATION o[openEHR-EHR-OBSERVATION.body_mass_index.v1] WHERE o/[at0000]/data[at0001]/events[at0002]/data[at0003]/item[0004]/value > 30

Table 3 : AQL Example

3.7 OpenEHR Clinical Knowledge Manager

The OpenEHR Clinical Knowledge Manager instance is an online international clinical knowledge resource (**Error! Reference source not found.**), where registration is open to all – no matter what geographical domain, professional training or expertise [11] . No matter whether a clinician, informatics experts, software engineer, terminologist, administrator, consumer or student, involvement is provided on a voluntary basis. It is effectively an active Web 2.0 collaborative community of interested and motivated individuals, harnessing the collective clinical informatics intelligence. The initial focus of CKM development has been on the creation of an archetype library, the development of a formalized review process to achieve content consensus and archetype publication, and governance of archetypes. A community template library is a recent addition to CKM.

Archetypes within CKM have been developed by a broad range of domain experts - largely clinicians and informatics experts. They are created outside the CKM space and offered to the community for international review and refinement. Registered users can make comments about any aspect of each archetype at any time. A formal content review process can be initiated on each archetype and once consensus is reached on the clinical content and design, the archetype can be published. After ensuring that the content is stable and published, translations and terminology binding can be added to the archetype specification, and similar team review processes for archetype translations and terminology binding are planned.

All registrants, including clinicians, can participate in CKM archetype publication through a number of designated roles – Editor; Reviewer; Translator; & Terminology binder. Inputs from all experts are welcomed as each can potentially enrich the content of each archetype with domain expertise. Clearly clinicians need to drive the clinical content of the clinical archetypes, but others contribute further aspects to the quality of the archetype – for example, ensuring that the design of the archetype is technically optimized, has correct terminology binding, is translated correctly etc.

Archetype development requirements have emerged from a number of sources: such as the OpenEHR community priorities, common clinical activities, international or national priorities, and local vendor or organisation requirements, which have universal applicability, e.g. wound care related archetypes. Archetype review priorities have been largely driven by the OpenEHR community. The most prominent methods to determine these priorities have been the common clinical activities, agreement and consensus on 10 key archetypes that would support healthcare provision in a typical crisis situation, and adoption of archetypes by registered users, indicating a willingness to participate in the formal review of an archetype.

The need for shared clinical artefacts supporting common clinical activities is one mechanism driving setting of priorities for archetype review. The need for shared clinical artefacts supporting common clinical activities is one mechanism driving setting of priorities for archetype review. In addition, we are increasingly seeing interest by national eHealth programs to actively support archetype review.

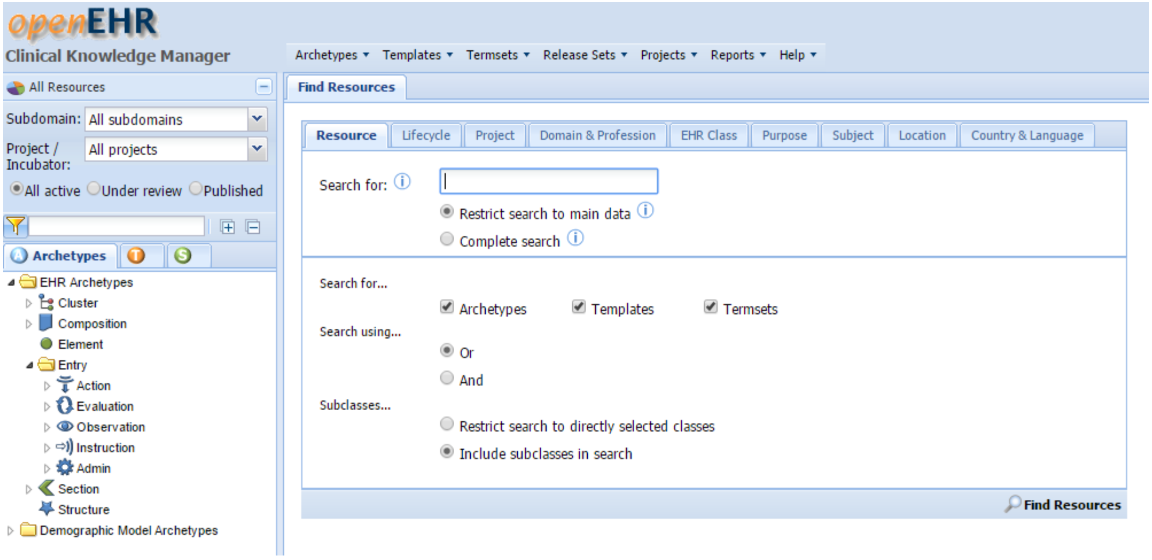
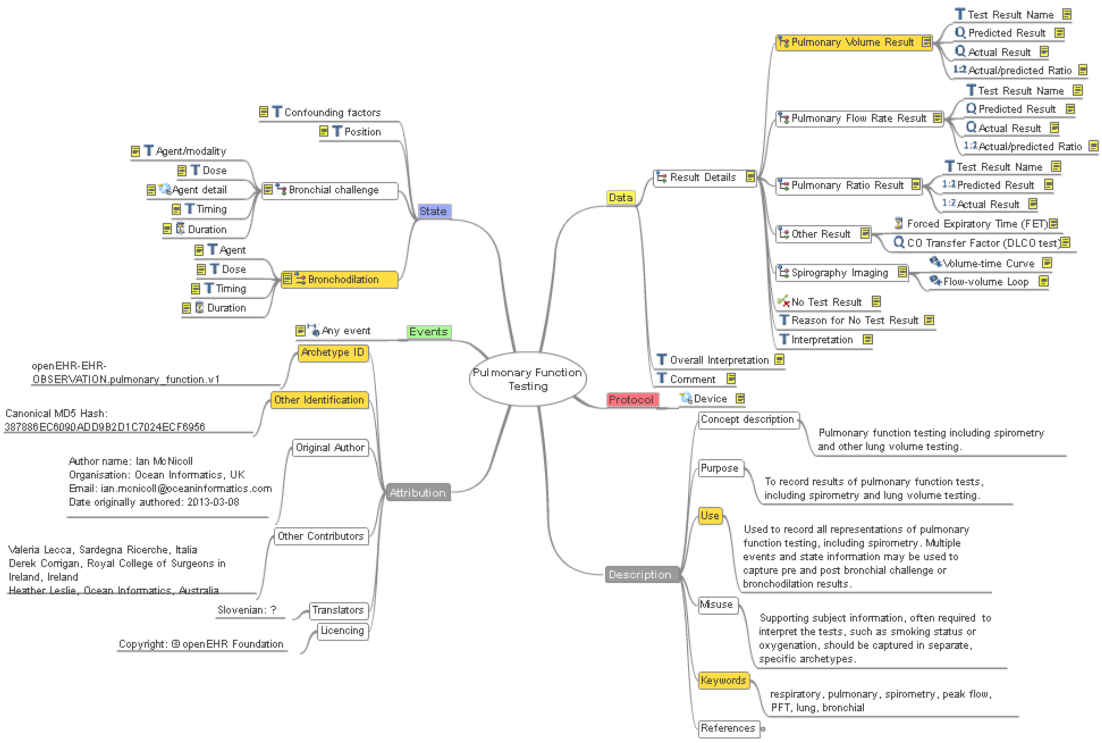


Figure 9: OpenEHR Clinical Knowledge Manager

3.8 Archetype Example

In order to understand the opeEHR archetypes and how this could be used in the myAirCoach, in this section an archetype example for the pulmonary function has been created and is presented below.



The ADL version of the archetype is presented in the following **Error! Reference source not found.**.

Table 4 : Pulmonary function archetype example[11]

```
archetype (adl_version=2.0.5; rm_release=1.0.2; generated)
	openEHR-EHR-OBSERVATION.pulmonary_function.v1.0.0

language
	original_language = <[ISO_639-1::en]>
	translations = <
		["sl"] = <
			language = <[ISO_639-1::sl]>
			author = <
				["name"] = <"?">
			>
		>
	>
description
	lifecycle_state = <"unmanaged">
	original_author = <
		["name"] = <"Ian McNicoll">
		["organisation"] = <"Ocean Informatics, UK">
		["email"] = <"ian.mcnicoll@oceaninformatics.com">
		["date"] = <"2013-03-08">
	>
copyright = <"© openEHR Foundation">
	details = <
		["en"] = <
			language = <[ISO_639-1::en]>
			purpose = <"To record results of pulmonary function tests, including spirometry and lung volume testing.">
			use = <"Used to record all representations of pulmonary function testing, including spirometry. Multiple events and state information may be used to capture pre and post bronchial challenge or bronchodilation results.">
			keywords = <"respiratory", "pulmonary", "spirometry", "peak flow", "PFT", "lung", "bronchial">
			misuse = <"Supporting subject information, often required to interpret the tests, such as smoking status or oxygenation, should be captured in separate, specific archetypes.">
		>
		...
	>

other_contributors = <"Valeria Lecca, Sardegna Ricerche, Italia", "Derek Corrigan, Royal College of Surgeons in Ireland, Ireland", "Heather Leslie, Ocean Informatics, Australia">

other_details = <
		["references"] = <"Lung volumes [Internet]. [date unknown];[cited 2010 Aug 25 ] Available from: http://en.wikipedia.org/wiki/Lung_volumes
```

```
Spirometry [Internet]. [date unknown];[cited 2010 Aug 25 ] Available from: http://en.wikipedia.org/wiki/Spirometry
Johns DP, Pierce R. Pocket guide to spirometry.  McGraw-Hill Medical; 2007.
Pingul EM, de Guia TS, Ayuyao FG. FEV1/FEV6 VS FEV1/FVC IN THE SPIROMETRIC DIAGNOSIS OF AIRWAYS OBSTRUCTION AMONG ASIANS.  In: Chest Meeting Abstracts. 2007 p. 491c.
Tiffeneau R, Pirelli A. Air circulant et air captif dans l'exploration de la fonction ventilatrice pulmonary. Paris Med 1947;133:624-8.">
		["MD5-CAM-1.0.1"] = <"387886EC6090ADD9B2D1C7024ECF6956">
	>
-- Definition part

definition
	OBSERVATION[id1] occurrences matches {0..1} matches {	--	Pulmonary Function Testing
		data matches {
			HISTORY[id2] matches {
				events cardinality matches {1..*; unordered} matches {
					EVENT[id3] occurrences matches {0..1} matches {	-- Any event
						data matches {
							ITEM_TREE[id4] matches {
								items matches {
									CLUSTER[id128] matches {	-- Result Details
										items matches {

	CLUSTER[id53] occurrences matches {0..1} matches {	-- Pulmonary Volume Result

	items matches {

		ELEMENT[id88] occurrences matches {0..1} matches {	-- Test Result Name

			value matches {

				DV_CODED_TEXT[id132] matches {

					defining_code matches {[ac1]}		-- Test Result Name (synthesised)

				}

			}
```

```
                    }

                    ELEMENT[id55] occurrences matches {0..1} matches {        --    Predicted
Result

                              value matches {

                                        DV_QUANTITY[id133] matches {

                                                  property matches {[at131]}

                                                  [magnitude, units] matches {

                                                            [{|>=0.0|}, {"l"}],

                                                            [{|>=0.0|}, {"ml"}]

                                                  }
                                        }
                              }
                    }

-- Terminology part

terminology
          term_definitions = <
                    ["en"] = <
                              ["id1"] = <
                                        text = <"Pulmonary Function Testing">
                                        description  =  <"Pulmonary  function  testing  including
spirometry and other lung volume testing.">
                              >
                              ["id3"] = <
                                        text = <"Any event">
                                        description = <"Any event.">
                              >
                              ["id9"] = <
                                        text = <"Predicted Result">
                                        description = <"Predicted pulmonary flow rate result.">
                              >
                              ["id14"] = <
                                        text = <"Forced Expiratory Time (FET)">
                                        description  =  <"The  time  taken  to  complete  a  forced
expiration.">
                              >
                              .
                              .
```

4 MyAirCoach Patient Modelling and Representation Methodology

Asthma is a heterogeneous condition. Its natural history includes acute episodic deterioration (exacerbations) against a background of chronic persistent inflammation and/or structural changes that may be associated with persistent symptoms and reduced lung function. Trigger factor exposure combines with the underlying phenotype, the degree of hyper-responsiveness and of airflow obstruction, and the severity of airway inflammation to cause wide variability in the manifestations of asthma in individual patients. Its assessment in clinical studies and in clinical practice should include components relevant to both of the goals of asthma treatment, namely achievement of best possible clinical control and reduction of future risk of adverse outcomes. Therefore, in this section we describe the different entities/concept of interests (e.g., devices, procedures and data sources) that are really important for the myAirCoach definition representation format.

4.1 Entities/concepts of interest for the myAirCoach patient models\

In **Error! Reference source not found.**, we provide the list of parameters which might have significant predictive value for asthma from those already known and should be included in the myAirCoach patient modelling framework in order to be processed by the intelligent information processing system (WP4).

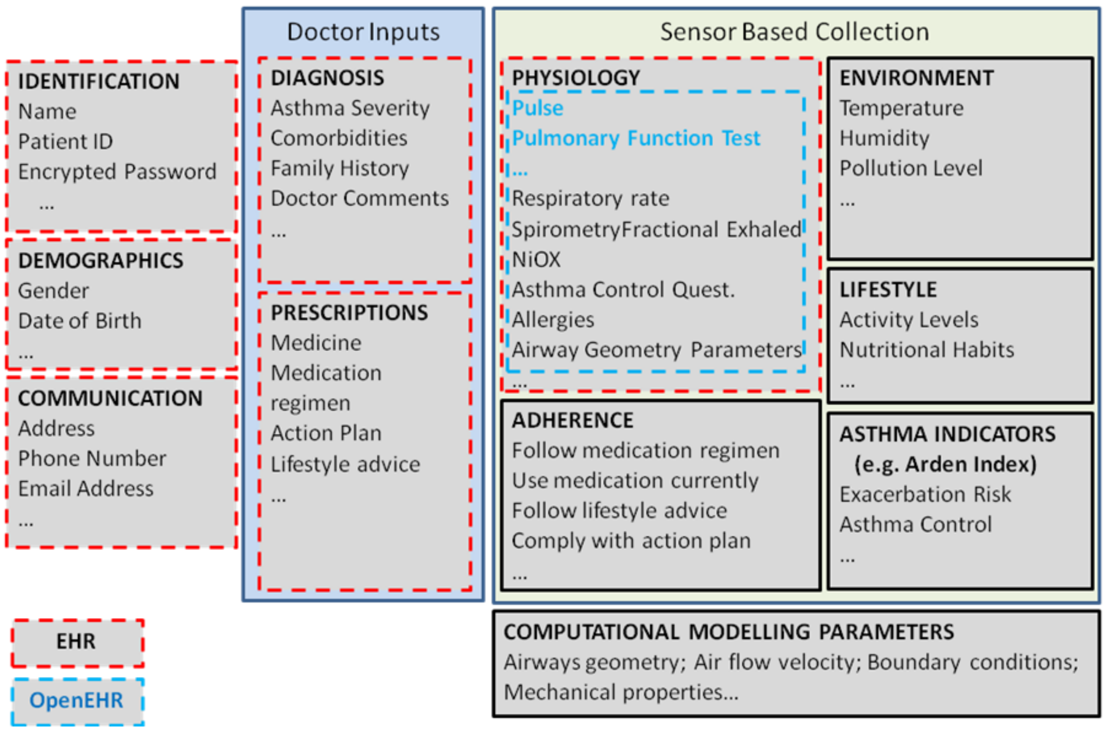


Figure 10: Overview of Entities/Concepts of interest that will be included in the MyAirCoach patient models

The ultimate goal is to use effectively those data in order to recognise threats and predict episodes of controlled and uncontrolled asthma. Additionally, more generic information related to the patient identification and demographic details is also presented.

In this context, the Patient data includes personal details for the patient (e.g., contact information, demographic information or identification details), the Doctor inputs includes clinical data like Family history, Previous hospital admittance for asthma, severe asthma exacerbation in the previous year, Nutritional information, related information such as Medication, smoking status, action plans. Finally, the sensor data are sub classified into 6 sub categories: i) physiological measurements ii) environmental measurements iii) asthma biomarkers iv) lifestyle parameters v) medication usage and action plan scores and final pre-process parameters that will be essential to the statistical and computational models that will be described in T4.2. etc.,

The aforementioned data are classified according to the sampling frequency into continuous measurements, weekly/daily measurements, offline data and questionnaires. The continuous measurements include the following parameters:

- Ozone (O3)
- Air pollution (PM10, PM2.5)
- Ambient temperature
- Nitrous oxide (NO2)
- Sulphur dioxide (SO2)
- PM10 and Ozone forecast
- Weather conditions and forecast
- Mean temperature
- WBAN (Heart rare, Breath rate)

The weekly/daily measurements are composed by:

- Spirometry (FEV1) values
- Exhaled Nitric Oxide (FeNO) values [2][3]
- Exhaled Breath Temperature values

The offline data are listed below:

- Name
- Age
- Gender
- Country
- Weight
- Height
- Body mass index

- Body surface area
- Atopic status
- Allergic rhinosinusitis
- Lung function test & spirometry
- Fractional exhaled nitric oxide
- Previous hospital admittance for asthma
- Severe asthma exacerbation in the previous year

and finally the questionnaires that need to be stored for further processing according to the analysis performed in T1.2. are the following ones:

- Smoking status (YES or NO)
- Socio-economic status (SES) (Level of Status ?)
- Asthma Control Questionnaire (ACQ)
- Asthma Quality of Life Questionnaire (AQLQ)
- Nutritional/diet questionnaire
- Online hospital anxiety and depression score (HADS)

In addition to the aforementioned parameters, a list of pre-processed parameters that will be essential for providing more timely and accurately prediction of potential upcoming dangerous events is provided in the subsection that follows.

4.1.1 Pre-processed output for statistical analysis

The intelligent information processing unit that will be implemented in T4.2 will use as input all the aforementioned parameters. From the information processing perspective these parameters can be categorized into time series datasets and Questionnaire dataset.

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 averaging. That way, a single attribute is extracted from the questionnaire data, that is the sum or average of the subject responses. While such a type of data manipulation is useful in a dimensionality reduction way, much of the original information is lost. A more sophisticated method for dimensionality reduction in questionnaire datasets is factor analysis. Factor analysis aims to group the items (attributes) of the questionnaire by means of their correlation, given the individuals' answers. If n is the number of items, then factor analysis aims to create a set of p<<n groups of items, with each group having its own group (factor) score. Therefore, a set of only p attributes is considered for meta-analysis of the questionnaire, which include almost all the information of the original data. These attributes are also part of the MyAirCoach Patient Models.

There are two types of factor analysis. When no a priori assumption is made on the structure of the questionnaire in terms of its items, exploratory factor analysis is utilized. Otherwise, confirmatory factor analysis is performed. In either case, a metric has to be computed that specifies how valid is the factor identification of the questionnaire items. That is, how robust or consistent each constructed or identified factor is. This is usually done with the Cronbach's alpha coefficient. Big alpha (usually >0.7) implies an internally consistent subgroup of items. Of course, Cronbach's analysis can be applied to the whole questionnaire as well. The Cronbach alpha coefficient for each one of the questionnaire will be extracted and added to the patient model after the end of the quantification campaign.

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. The reason is twofold. First, such algorithms receive as input static instead of temporal data. Second, the number of attributes of a time series may be large, while extracting characteristic values can reduce significantly this number, in a dimensionality reduction fashion, and maintain almost all of the original information. In the literature, there have been proposed numerous means for processing time series data and extracting characteristic values from them. We intend to perform the following types of manipulation: a) discrete Fourier transform (DFT), b) principal component analysis (PCA), and c) trivial and more sophisticated statistical calculations. That is, we intend to utilize three totally different approaches that originate from the worlds of a) signal processing, b) machine learning, and c) statistics. While the two former methods seem straightforward, the latter is not. We will attempt to generate from time series subjects the following global characteristic measurements: mean, standard deviation, skewness, kurtosis, periodicity, trend, seasonality, autocorrelation, nonlinearity, self-similarity, and chaoticity. This characteristic values will be also part of the MyAirCoach patient models and will be further analysed in D4.2.

4.1.2 Pre-processed data essential for the computational models

The development of computational models in T4.3, that take into account details related to i) the lung geometry alterations, ii) different lung mechanical features and iii) the changes of the airflow inside the lung airways could increase the knowledge and understanding of the pathophysiology behind these diseases leading to improved diagnosis and assessment of asthma.

The lung geometry is traditionally reconstructed from CT/MRI scans. However, these scans are not always available and even when they are, the reconstruction outcome is a static representation of the lung geometry, that does not provide any information related to the dynamic deformations that characterize the severity of the obstructive diseases. To this end novel geometry processing schemes[16][17] need to be included in computational models of T4.3, in order create patient specific 3d models, that will correspond to different levels of airway narrowing related to different levels of inflammation, from existing 3D models that have been constructed from available CT/MRI scans[18]. In addition, they could be also applied in cases that these scans do not exist. This can be achieved by performing iteratively the aforementioned geometry deformations in the context of an optimization approach in order to match specific metrics that assess and quantify airflow limitation. These metrics include forced vital capacity (FVC), meaning the amount of air a person can exhale with force after inhaling as deeply as possible and forced expiratory volume (FEV) meaning the amount of air a person can exhale with force in one breath.

The deformed geometric models will be finally used to perform realistic airflow simulation using computational fluid dynamics for predicting particle deposition[20] upon the inner part of the airway walls, allowing: i) the clinician to study the way the drug or other harmful particles that cause inflammation are dispersed inside the lungs for different stages of a crisis and for different levels of inflammation ii) the user to determine the effectiveness of a delivery system upon inflamed airways and use the results as input for assessing which parts of the patient's lung are more easily affected and predicting an obstruction of a specific airway. Further details related to the developments of the computational models will be provided in D 4.3.

The aforementioned schemes lead us to include in the MyAirCoach patient models the following parameters that are related to the geometry and the mechanical properties of the lung:

- Dense 3d meshes corresponding to the patient specific lung geometry 3D representation
- Patient specific lung 1D representation corresponding to the skeleton of the 3D model
- Pressure distribution inside the lung for different levels of narrowing (pressure contour)(historical values)
- Velocity distribution inside the lung (velocity colour-map) (historical values)
- Particle deposition for different levels of narrowing and different types of particle size
- Airways inflammation level index,
- Level of airways narrowing for each generation

The inclusion of the aforementioned parameters will be further investigated in D 4.3.

At this point we would like to mention that in order to be able to store efficiently and securely the dense 3d Models corresponding to the lung geometry, we have developed in [79] novel compression/reconstruction schemes with appealing properties, such as low encoding complexity, universality and privacy preservation. They allow the processing of dense meshes in parts and the reconstruction of the Cartesian coordinates of each part from a small number of random linear combinations, providing a flexible framework in mesh geometry compression design to trade efficiency for reconstruction quality. Extensive evaluation studies, carried out using a large collection of different 3D lung models, show that the proposed schemes, as compared to the state of the art approaches, achieve competitive Compression Ratios (CRs), offering at the same time significantly lower encoding complexity, which is essential for Mobile Cloud Computing platforms.

4.2 MyAirCoach Requirements for EHR and Model Representation

A significant number of requirements specification methodologies have been proposed over the past that focus on specific types of applications and utilize different methodological approaches. Unfortunately, there is no specific method for the collection of requirements related to model representation, despite the increasing number of systems that include user modelling components and the gradual adoption of electronic records in health care systems. In order to formulate and standardize the collection of such requirements within the MyAirCoach project and towards the definition of the foreseen modelling and EHR framework the Volere method was adapted on the basis of the collection methodology used in D1.3 “MyAirCoach technical specifications and end-to-end architecture”.

The first version of the Volere Requirements Specifications template was released in 1995 as a highly detailed structure that was intended to integrate the widest possible spectrum of requirement categories. Since its first introduction the Volere method has been continuously updating based on the feedback from users and affiliated organizations. The most recent updates are characterized by an increased level of specificity in order to cover all the proposed schemes and therefore allow a highly detailed specification of requirements. Volere also offers a formal template for the collection of the requirements in tabular format through its “requirements shell” (also called a “snow card”) as presented in **Error! Reference source not found.**.

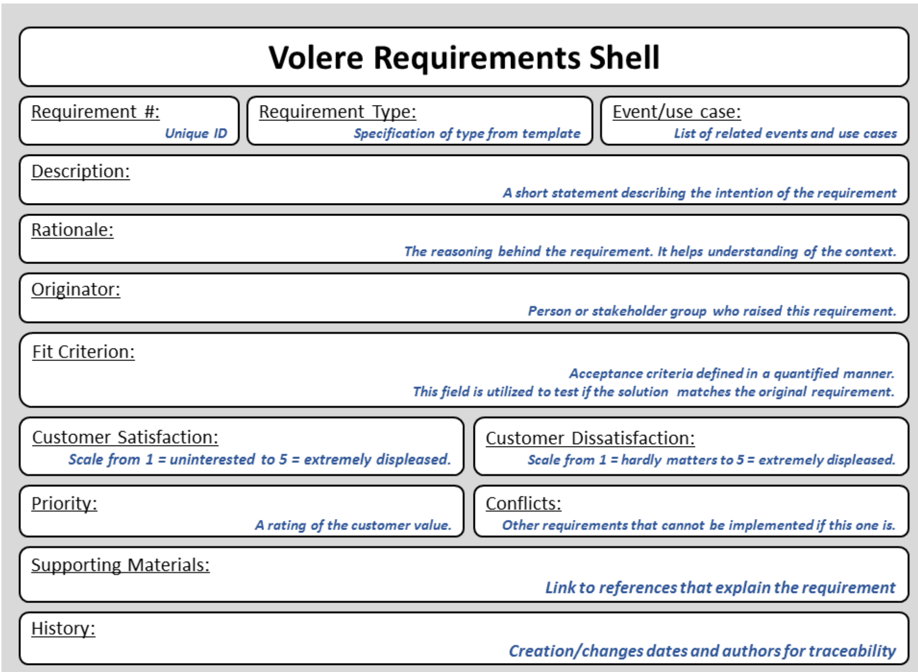

Volere Requirements Shell
Requirement #: *Unique ID*
Requirement Type: *Specification of type from template*
Event/use case: *List of related events and use cases*
Description: *A short statement describing the intention of the requirement*
Rationale: *The reasoning behind the requirement. It helps understanding of the context.*
Originator: *Person or stakeholder group who raised this requirement.*
Fit Criterion: *Acceptance criteria defined in a quantified manner. This field is utilized to test if the solution matches the original requirement.*
Customer Satisfaction: *Scale from 1 = uninterested to 5 = extremely displeased.*
Customer Dissatisfaction: *Scale from 1 = hardly matters to 5 = extremely displeased.*
Priority: *A rating of the customer value.*
Conflicts: *Other requirements that cannot be implemented if this one is.*
Supporting Materials: *Link to references that explain the requirement*
History: *Creation/changes dates and authors for traceability*

Figure 11: Volere Requirements shell as a guide to writing each atomic requirement

In order to formulate the development of the model representation scheme, a taxonomy of requirements was proposed that covers the objectives of the project and forms the foundations for the MyAirCoach model representation scheme.**Error! Reference source not found.** illustrates the underlining structure of the taxonomy and illustrates the positioning of Electronic Health Records in the overall model representation framework.

More specifically the taxonomy of model representation requirements includes:

1. **Patient identification requirements:** This category should include all the requirements that are related with the identification of patients and how they are represented in the modelling framework of the MyAirCoach project
2. **Patient demographics requirements**: Requirements related to the representation of demographic information such as the age, gender, should be included in the current category
3. **Requirements related to communication and contact details**: This category should include all the requirements related to the documentation of contact details of patients.
4. **Requirements for doctor inputs representation**: This category includes all the information that is provided by doctors and is based on their opinion and experience rather than the use of medical devices of the execution of exams. This category can be further separated into the following two types of information.
    a. **Diagnosis representation requirements**: This category includes the requirements for the representation of the diagnosis of doctors in the framework of the EHR
    b. **Prescriptions documentation requirements**: This category includes the requirements for the documentation of medicines and medications plans prescribed by doctors for their patients
5. **Requirements for the representation of sensor measurements and doctor assessments**: The current category should include the requirements for the representation of the collected data from sensing devices; either they are used by doctors in the clinical environment of by patients in their everyday living environment.
    a. **Physiology oriented data representation**: This category focuses on the requirements of the physiological measurements such as blood pressure or respiratory rate.
    b. **Representation of medication adherence**: This category of requirements should cover any parameter that is connected with the adherence of medication by patients.
    c. **Representation of the conditions in the patient's environment**: This category should focus on the requirements that will allow the representation of environmental data for the specific patient.
    d. **Requirements for the representation of the patient's lifestyle**: This category should requirements that are related to parameters that allow the understanding of the patients lifestyle such as activity levels and nutritional habits.

   e. **Requirements for Asthma indicators**: This type of requirements should allow the representation of asthma indicators that have a proven clinical significance together with the methodology for their assessment or calculation.
6. **Computational Modelling parameters**: Finally, the requirements of computational modelling parameters should cover all the issues that are related to the representation such parameters and their use for the foreseen simulations.

Table 5: Notation and Naming of Requirements

Taxonomy of Model Representation Requirements	Notation
General requirements for model representation	GEN-RE
Patient identification requirements	ID-RE
Patient demographics requirements	DEM-RE
Requirements related to communication and contact details	CONT-RE
Requirements for doctor inputs representation	DOC-RE
Diagnosis representation requirements	DIAGN-RE
Prescriptions documentation requirements	PRES-RE
Requirements for the representation of sensor measurements and doctor assessments	MEAS-RE
Physiology oriented data representation	PHYS-RE
Representation of medication adherence	ADH-RE
Representation of the conditions in the patient's environment	ENV-RE
Requirements for the representation of the patient's lifestyle	LIFE-RE
Requirements for Asthma indicators	IND-RE
Computational Modelling parameters	MPAR-RE

Table 6 illustrates the template for the gathering of model representation requirements. As mentioned above, and in order to allow the use of these requirements for the definition of the system's architecture and the development when necessary, the basic components of the "MyAirCoach Specific Requirements Template" were used as they are presented in D1.3 "MyAirCoach technical specifications and end-to-end architecture".

Table 6: MyAirCoach Gathering Template of Model Representation Requirements

ID	*A unique identifier.*
Name	*Title of the requirement.*
Description	*A requirement must be described with as much detail as possible.*
Rationale	*A justification of the model representation requirement*
Fit Criterion	*Describe the ability to identify if the requirement is met by a representation framework. This means the tests which must be performed in order to verify whether the requirement has been*

	addressed.
Priority	*The requirement is ranked according to the value that different categories of users attach to it (patients/doctors/researchers). (Scale from 1=low priority to 5=highest priority).*
Conflicts/Relations	*Description of any relation of the current requirement with previously described ones. Special attention to conflict with other requirements whose implementation is blocked by this one.*
Author	*The owner of each requirement that was recorded.*
Revision	*This section lists when a version of the requirement was created.*

5 MyAirCoach Patient Modelling and Representation Framework

Since the selected representation framework for creating the MyAirCoach patient models is based on openEHR, we initially present the archetypes that were created or modified for including the entities/ concepts of interest, presented in Section 3.1. The second part of this section, describes the database structure behing the representation framework that integrates the developed archetypes to the MyAirCoach system. At this point it should be mentioned that the proposed structure adresses succesfully the defined specifications and requirements presented in Section 3.2.

5.1 MyAirCoach Developed/Modified Archetypes

Based on the entities /concepts of interest needed to be taken into account as described in Section 3.1, they can be separated in several categories : a) offline features including identification , demographics and communication features, offline physiology characteristics b) clinical personnel inputs including diagnosis and prescriptions and c) sensor based input including physiology characteristics , adherence to medical plan , environmental conditions, lifestyle factors , asthma indicators and computational modelling parameters. In order to build a patient representation framework based on the OpenEHR platform the most relevant archetypes need to be retrieved from the OpenEHR clinical knowledge manager[11] . If an entity cannot be described by any of the existing archetypes new archetypes can be created using the Archetype Editor.

Identification and demographics offline characteristics

Regarding the patient identification input relevant archetypes need to include the name of the patient while the patient id or the password are system relevant characteristics and are included in the integration. For the name input the archetype openEHR-*EHR-CLUSTER.person_name.v1 and openEHR-EHR-CLUSTER.individual_personal.v1* can be used . The first is used to record the personal name of a patient, relative, healthcare provider or other third party. The latter can be used to record details of external parties e.g. family members who cannot be referenced uniquely within the electronic health record. Additionally, in includes date of birth fields and sex fields. A relevant structure of the aforementioned archetypes is shown in the figures below

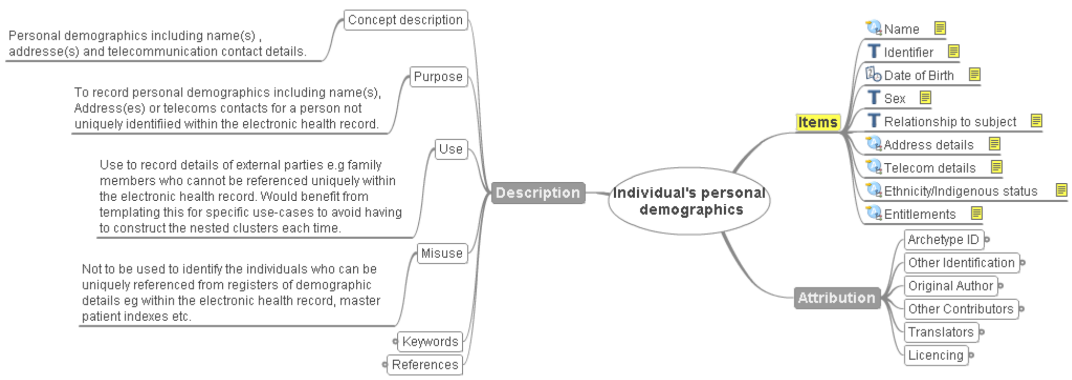


Figure 12 : Individual's personal demographics archetype

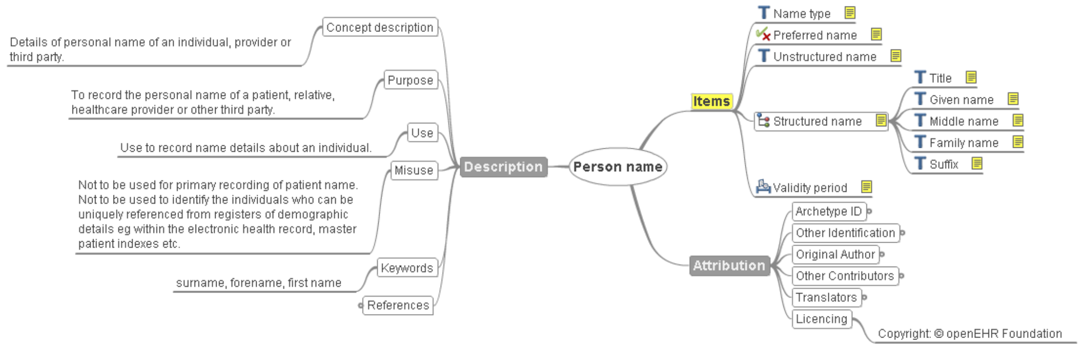


Figure 13:Person name archetype

Contact information related offline entities

For the communication and contact information relevant fields the archetypes that can be used are *openEHR-DEMOGRAPHIC-ADDRESS.address.v1* based on ISO22220 standard.

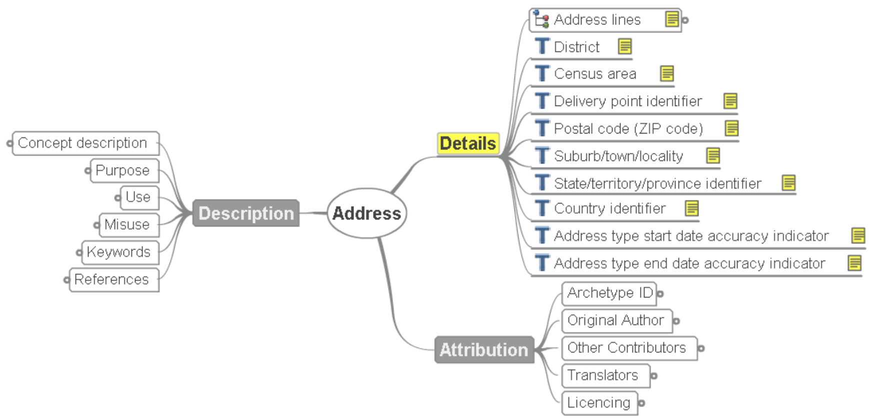


Figure 14:Address archetype

Physiology related offline inputs

The offline physiology related features are related to body mass index, body surface area, height, body weight and atopic status, allergic rhinosinusitis, lung function test and spirometry, previous admittance for asthma entities. The relevant archetypes include *openEHR-EHR-OBSERVATION.body_mass_index.v1* featuring the body mass, *openEHR-EHR-OBSERVATION.body_surface_area.v1* featuring the body surface , *openEHR-EHR-OBSERVATION.body_weight.v1* related to the body weight *openEHR-EHR-OBSERVATION.height.v1* related to patient's height , openEHR-EHR-OBSERVATION.atopic_status.v1 featuring the patient's atopic status , *openEHR-EHR-OBSERVATION.pulmonary_function.v1* related to lung function test and spirometry . Body mass index related archetype is used to record the Body Mass Index (BMI) of a person. Body Mass Index is 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. A schematic of body mass index archetype is shown below:

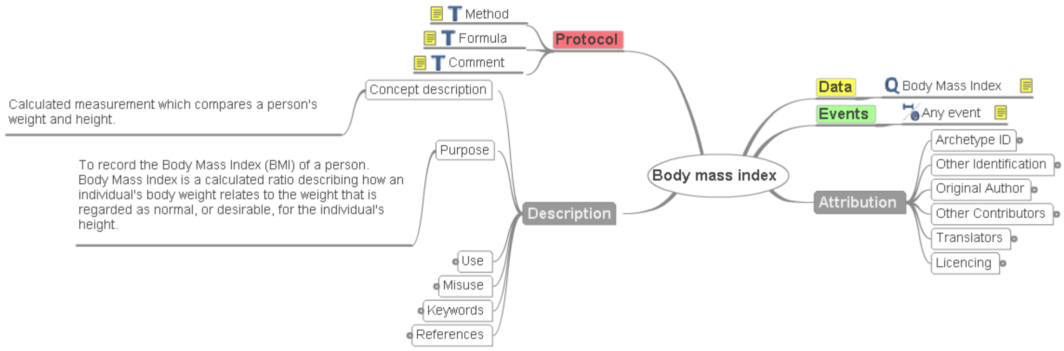


Figure 15: Body mass index archetype

Body surface area is the measured or calculated surface area of a human body. A schematic of this archetype is shown in Figure 16

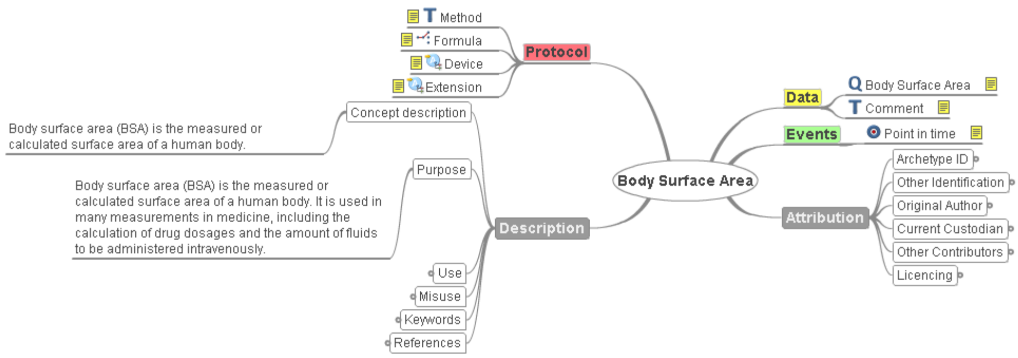


Figure 16:Body surface area archetype

Height, or body length, is measured from crown of head to sole of foot. Height is measured with the individual in a standing position and body length in a recumbent position. The structure of this archetype appears below

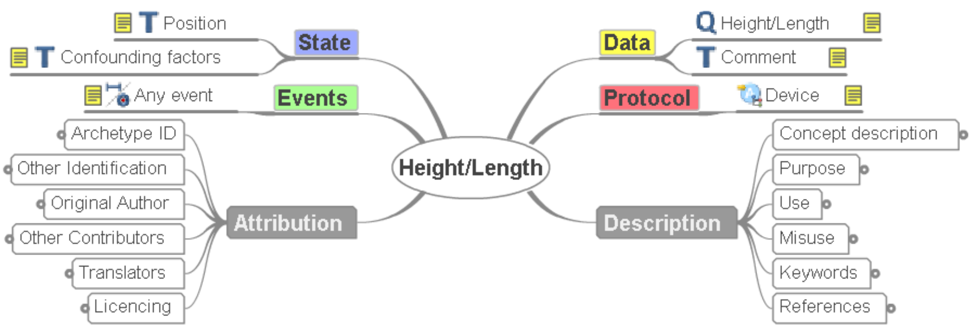


Figure 17:Height archetype

Body weight archetype describes the measurement of the body weight of an individual. The structure of this archetype is shown in Figure 18

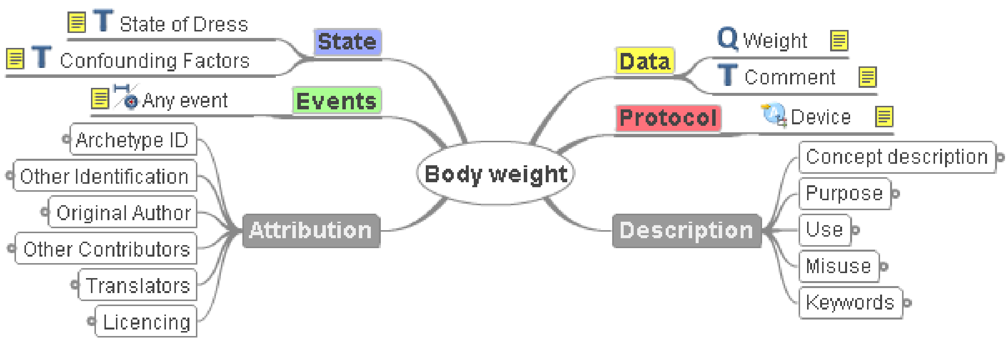


Figure 18:Body weight archetype

Lung function test and spirometry is concluded by the *openEHR-EHR-OBSERVATION.pulmonary_function.v1* archetype as it appears below.

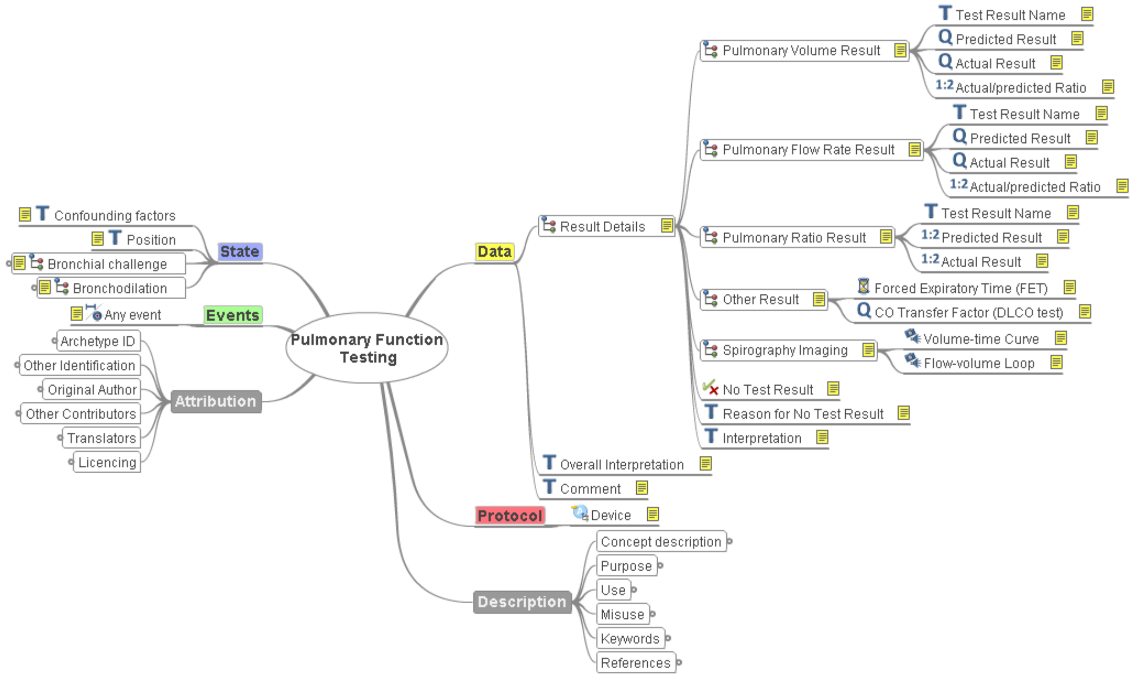


Figure 19:Pulmonary function archetype

The atopic status archetype was created using the OpenEHR archetype editor and uses a boolean field to state patient's atopic status.

Clinical personnel diagnosis and medication related inputs

Clinical personnel inputs include, asthma severity, co-morbidities , doctor comments , prescription related data such as medication plan , action plans related advices and family history. The relevant archetypes of the aforementioned inputs are *openEHR-EHR-EVALUATION.family_history.v1* concluding the patient's family history openEHR-*EHR-EVALUATION.clinical_synopsis.v1* used to provide narrative summary or overview about a patient, specifically from the perspective of a healthcare provider, and with or without associated interpretations.

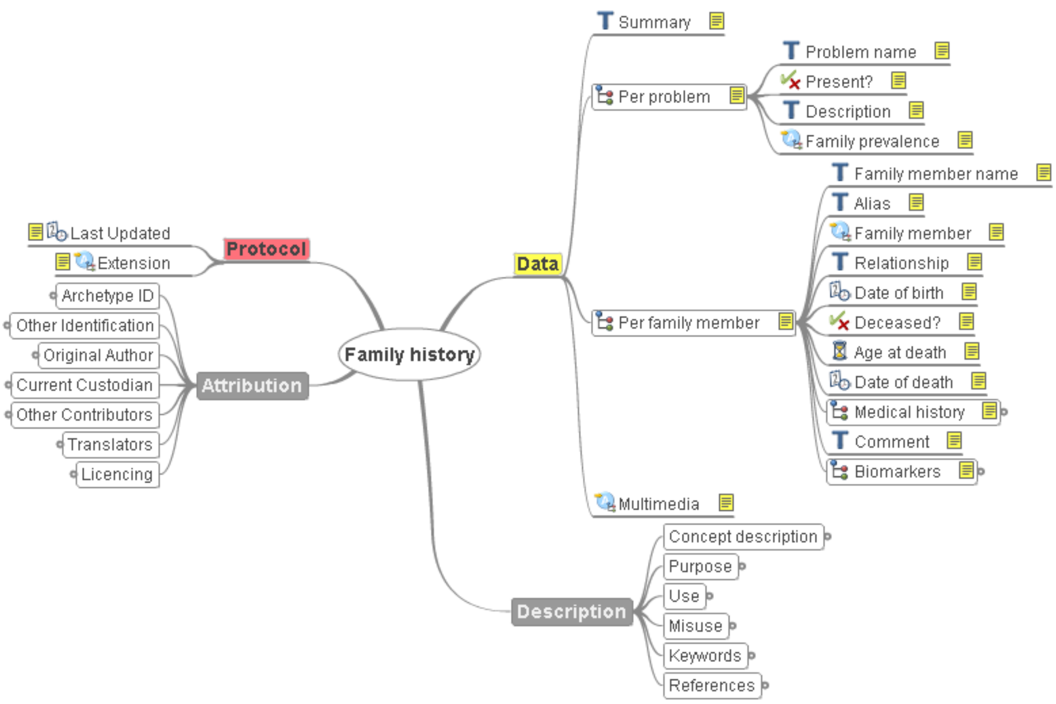


Figure 20:Family history archetype

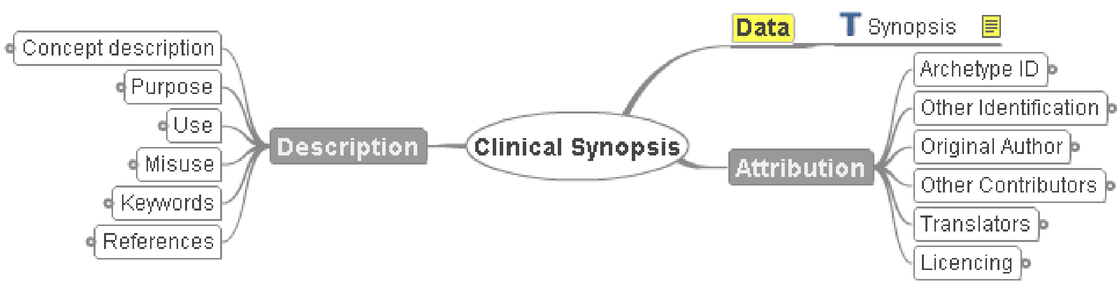


Figure 21:Clinical synopsis archetype

Sensor based physiology related data

This category of inputs includes pulse, pulmonary function test, respiratory rate. For the pulmonary test function the aforementioned archetype *openEHR-EHR-OBSERVATION.pulmonary_function.v1* can be used**.** For respiratory rate the *openEHR-EHR-OBSERVATION.respiration.v1* can be used.

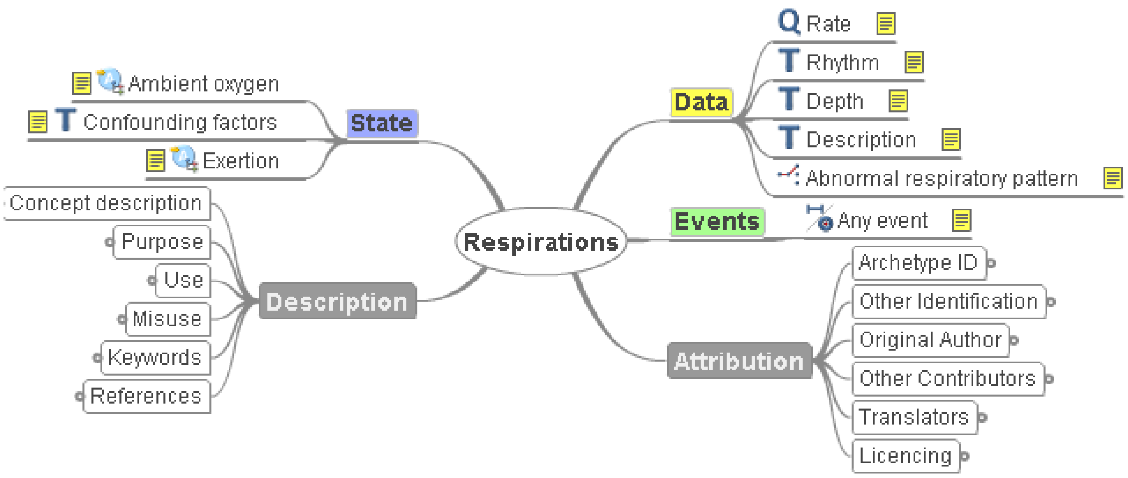


Figure 22:Respirations archetype

Sensor based environmental conditions input

Environmental conditions include the set of environmental parameters affecting the patient. They can be modeled using a relevant archetype named *openEHR-EHR-CLUSTER.environmental_conditions.v1*. The archetype schematic is shown in Figure 23.

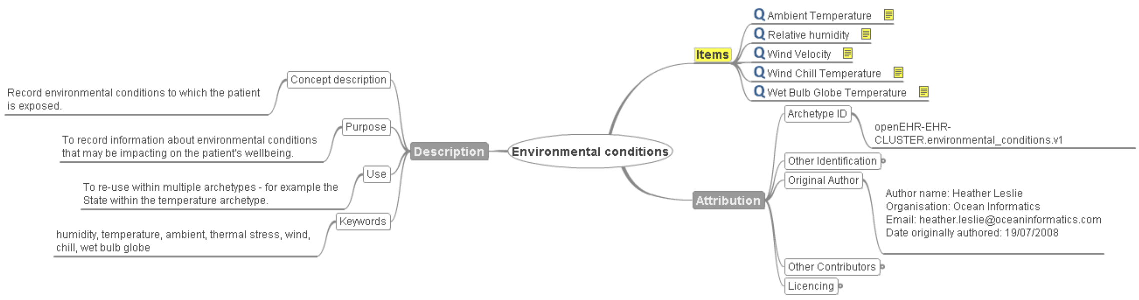


Figure 23:Environmental conditions archetype

This archetype was modified to include measurements such as air pollution (PM10), air pollution (PM2.5) nitric oxide(NO2) , sulphur dioxide (SO2), PM10 forecast , ozone forecast and mean temperature.

Sensor based adherence to medication or action plan related input

This section includes the archetypes *openEHR-EHR-ACTION.medication.v0* and *openEHR-EHR-INSTRUCTION.care_plan.v1.* The first can be used for recording the planning, issuing of a prescription, dispensing, administration, cessation, suspension, completion of a medicine, vaccine or other therapeutic good . This will usually be in response to a medication order but may be administered immediately without an order at times, thus requiring recording of the administration alone (e.g. in an emergency situation).A schematic of medication archetype is shown in Figure 24

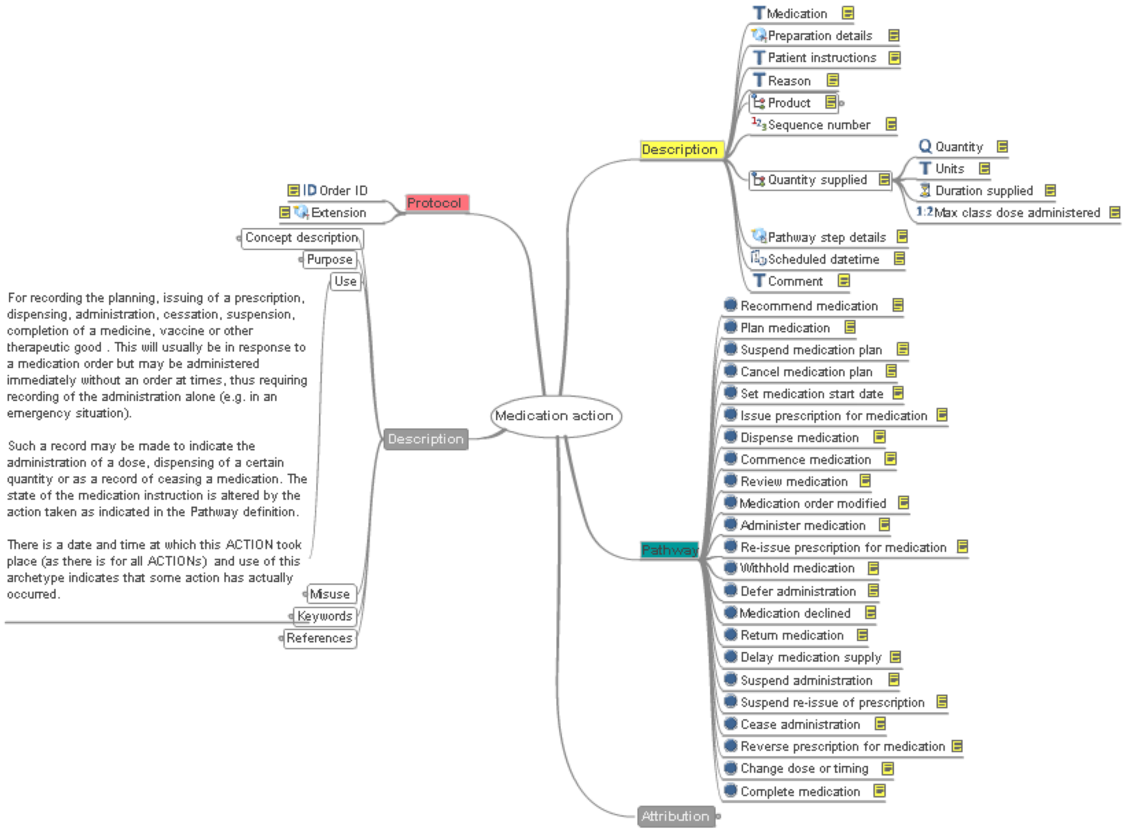


Figure 24:Medication action archetype

The care plan archetype describes the order or instruction for the creation and sequence of activities to achieve a specified management goal or treatment outcome, carried out by health professionals and/or the subject. Its schematic appears in Figure 25

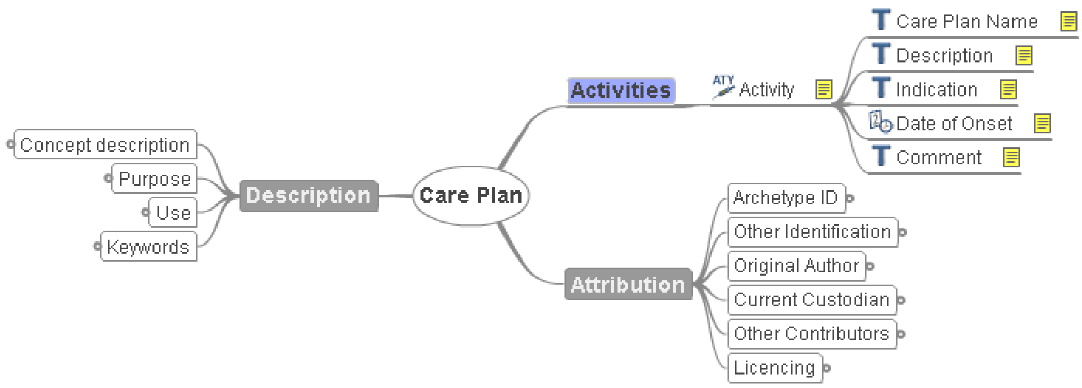


Figure 25:Care plan

Lifestyle related data

This section deals with lifestyle factors. These can be modelled using *the openEHR-EHR-COMPOSITION.lifestyle_factors.v1* archetype describing a persistent and evolving summary record of information about lifestyle factors that may influence clinical decision-making and care provision. A schematic of lifestyle factors archetype is shown below.

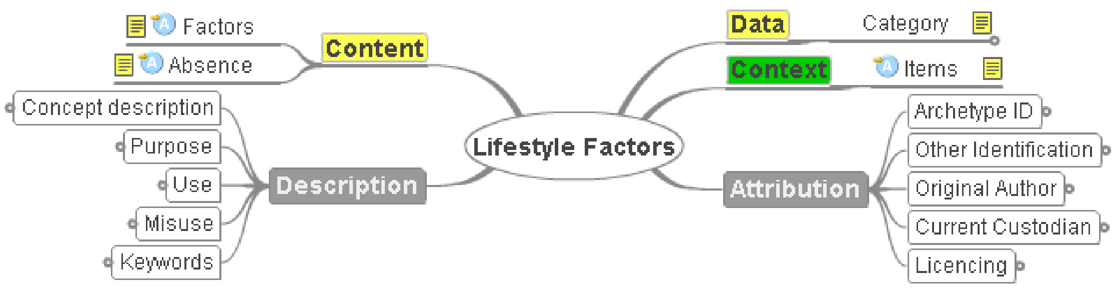


Figure 26:Lifestyle factors

5.2 MyAirCoach Database structure

In order to integrate the defined specifications and requirements into the architecture of the MyAirCoach system, the database structure should be carefully defined so as 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 MyAirCoach system. The following figure provides an initial version of the MyAirCoach system database that can be considered as the myAirCoach backbone for storing all the identified patient data and collecting measurements during the deployment of test campaigns and measurements (WP2 "Test campaigns, measurements, clinical analysis").

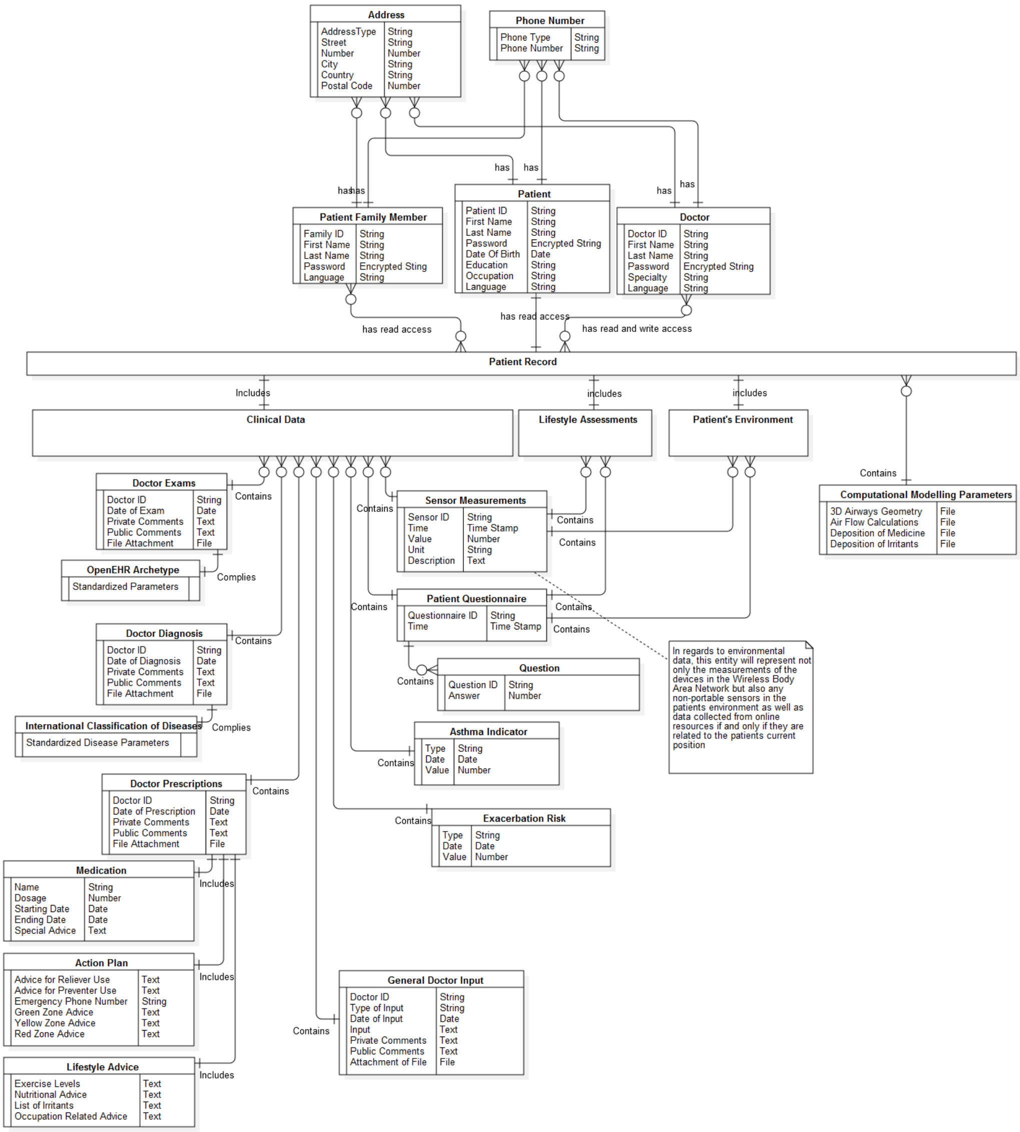


Figure 27: Entity Relationship Diagram of the MyAirCoach Database[2]

[2] A higher resolution image of the proposed database structure can be found in Appendix

5.3 Addressing the model representation requirements

The following tables are directly connected with the model representation requirements of the myAirCoach while it provides a concise description of their characteristics and how they were addressed in the above database structure.

5.3.1 Addressing general requirements for patient model representations

ID	GEN-RE01
Name	Representation of Text
Description	The modelling framework should allow the representation of text in different languages
Rationale	A variety of inputs by patients and doctors in the EHR 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 MyAirCoach users
Priority	High
Conflicts/Relations	No conflicts currently identified
Author	CERTH
Revision	Initial Version V1.0
Proposed solution	The selected development framework allow the representation of text as well as scalar and discrete types of information

ID	GEN-RE02
Name	Representation of Scalar Mutli-dimensional Values
Description	The modelling framework should allow the representation of scalar values of single and multiple dimension
Rationale	The patient model as a whole will mainly comprise from numerical data of singly or multiple dimensions. This data may represent clinical assessments, environmental conditions, activity levels or any other parameter foreseen in the framework of the project.
Fit Criterion	Ability to define a two dimensional parameter for all MyAirCoach users
Priority	High
Conflicts/Relations	No conflicts currently identified

Author	CERTH
Revision	Initial Version V1.0
Proposed solution	The selected development framework allows 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.

ID	GEN-RE03
Name	Representation of responses to a Questionnaire
Description	The modelling framework 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 educational level. The objectives of MyAirCoach are related the deployment of such questionnaire and therefore they should be represented in the model representation framework.
Fit Criterion	Questionnaires can be integrated to the MyAirCoach model representation framework.
Priority	High
Conflicts/Relations	No conflicts currently identified
Author	CERTH
Revision	Initial Version V1.0
Proposed solution	The combination of text and discrete scalar values can cover the representation of questionnaires. The entity of “Patient Questionnaire” will aggregate the patient responses.

5.3.2 Addressing patient identification requirements

ID	ID-RE01
Name	Creation of a unique system ID
Description	The proposed MyAirCoach framework should be based on a unique ID that will be generated for all users
Rationale	The unique ID of users will be the basis for the discrimination of users
Fit Criterion	An automatically generated unique ID is assigned to every new user of the system

Priority	High
Conflicts/Relations	No conflicts currently identified
Author	CERTH
Revision	Initial Version V1.0
Proposed solution	A unique ID is generated for each user, not confined to patients but also extended to their family members and doctors.

ID	ID-RE02
Name	Anonymization of patient model
Description	The proposed modelling framework should allow the exclusion of nulling of all identification parameters
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 asthma disease
Fit Criterion	An anonymized model should be compatible with all system components and allow the processing by all modules of MyAirCoach system
Priority	High
Conflicts/Relations	No conflicts currently identified
Author	CERTH
Revision	Initial Version V1.0
Proposed solution	The user identifying information are stored in separate entities and not within the main modelling framework (Patient Record)

5.3.3 Addressing patient demographics requirements

ID	DEM-RE
Name	Inclusion of important demographics information
Description	The proposed modelling framework should include an extendable list of demographic information including but not confined to: Age, Gender, Educational level, Main occupation, Language and Ethnicity
Rationale	The collected demographic data can be used for the personalization of MyAirCoach functionalities. Some examples include the use of age and gender for the understanding of clinical status of patients. Furthermore the educational level

	can reveal important parameters of medication adherence. The occupation may reveal important components regarding the risks and allergens in the patient's environment. Finally Language and ethnicity will allow the customization of user interfaces
Fit Criterion	The myAirCoach framework allows the representation of demographic information.
Priority	High
Conflicts/Relations	No conflicts currently identified
Author	CERTH
Revision	Initial Version V1.0
Description	The proposed modelling framework should include an extendable list of demographic information including but not confined to: Age, Gender, Educational level, Main occupation, Language and Ethnicity

5.3.4 Addressing requirements related to communication and contact details

ID	CONT-RE01
Name	Multiple contact details
Description	The patient representation framework should allow the definition of more than on contact details for one system user
Rationale	In modern environment patients 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 MyAirCoach user can define any number of details for a specific type communication, e.g phone number
Priority	Low
Conflicts/Relations	No conflicts currently identified
Author	CERTH
Revision	Initial Version V1.0
Proposed solution	The separation of contact details in separate matrices allows the definition of more than one record for each type of contact. Additional contact types can be added when required. The email address was chosen to be unique for each user and define his/her username for the login process.

5.3.5 Addressing requirements for doctor inputs representation

ID	DOC-RE01
Name	General field of doctor inputs not related to diagnosis or prescriptions
Description	The MyAirCoach patient representation framework should allow the creation of custom types of doctor inputs based on their needs.
Rationale	Clinical practice is highly complicated and dynamic. Therefore doctors 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
Priority	Medium
Conflicts/Relations	No conflicts currently identified
Author	CERTH
Revision	Initial Version V1.0
Proposed solution	New archetypes of data can be created and integrated with the main modelling structure of the database under the entity of “Doctor Exams”. Furthermore, the separate entity of “General Doctor Inputs” is intended to cover any specific needs of practitioners before gradual adoption of the proposed archetype.

5.3.6 Addressing diagnosis representation requirements

ID	DIAGN-RE01
Name	Compatibility with terminology standards
Description	The doctor 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 doctor cannot diagnose a condition that is not included in standardized terminology
Priority	Medium
Conflicts/Relations	No conflicts currently identified
Author	ICL

Revision	Initial Version V1.0
Proposed solution	An archetype can be created for the expression of diagnosis that will get values from standardized clinical terminology. The entity of "Doctor Diagnosis" is intended to cover this type of data.

ID	DIAGN-RE02
Name	Personalization of diagnosis
Description	The representation framework of doctor diagnosis should allow the addition of comments or the specification of parameters related to the severity of the condition in the specific patient
Rationale	The diagnosis of many conditions is not a direct yes/no parameter and the comments of the doctor regarding the indicators of the severity offer a crucial insight to the accurate understanding of the patient's condition
Fit Criterion	
Priority	Medium
Conflicts/Relations	No conflicts currently identified
Author	CERTH
Revision	Initial Version V1.0
Proposed solution	The diagnosis archetypes and data structures can be extended with any type of required information, including comments (text) and severity (definition of scalar representation).

5.3.7 Addressing prescriptions documentation requirements

ID	PRES-RE01
Name	Documentation of asthma related prescriptions
Description	The MyAirCoach patient representation framework should be able to include doctor prescriptions (type of medication and dosage)
Rationale	Medication is a crucial component of the medical record of a patient and as such should be included in the patient modelling framework.
Fit Criterion	Doctors have the capability document their prescription in the MyAirCoach system (Type of medicine and dosage)
Priority	High

Conflicts/Relations	No conflicts currently identified
Author	ICL
Revision	Initial Version V1.0
Proposed solution	An archetype can be created for the expression of prescriptions based on accurate medication naming and scalar representation of dosage. The "Doctor Prescription" entity will aggregate this type of data covering: medications, action plans and lifestyle advice.

5.3.8 Addressing requirements for the representation of sensor measurements and doctor assessments

ID	MEAS-RE01
Name	Representation of 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 MyAirCoach
Rationale	A fundamental components of the project is the collection of measurements in the everyday environment of patients in order to support the better management of asthma disease
Fit Criterion	The data collected by the MyAirCoach inhaler based sensor can be stored in the record of the respective patient.
Priority	High
Conflicts/Relations	No conflicts currently identified
Author	CERTH
Revision	Initial Version V1.0
Proposed solution	The solution of GEN-RE02 covers the current requirement as any type of collected measurements can be represented in the MyAirCoach framework. The entity "Sensor Measurements" covers this type of data and is used across the three main categories of data within the patient record, namely: clinical data, lifestyle assessments and patient's environment.

ID	MEAS-RE02
Name	Representation of doctor assessments
Description	Doctors 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 doctors should be district and separated from their diagnosis and prescriptions as defined in the previous section
Fit Criterion	A doctor can add an clinical assessment (e.g measurement of Forced Exhaled Volume) in the record of one patient
Priority	High
Conflicts/Relations	No conflicts currently identified
Author	CERTH
Revision	Initial Version V1.0
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. The entity “Doctor exams” together with the “General Doctor Input” and “Sensor Measurements” cover this area of information.

5.3.9 Addressing physiology oriented data representation

ID	PHYS-RE
Name	Standardized representation of physiological parameters
Description	The MyAirCoach system should be able to represent physiological parameters of patients on the basis of standardized electronic health record frameworks
Rationale	The basis of MyAirCoach is the collection of physiological parameters of patients which will be used for the personalized understanding of asthma disease. It is therefore of fundamental importance to represent the data of this category in the patient modelling framework of the project.
Fit Criterion	MyAirCoach patient model covers different types of physiological parameters related to asthma disease.
Priority	High
Conflicts/Relations	No conflicts currently identified
Author	CERTH
Revision	Initial Version V1.0
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. The entity “Doctor Exams” form the main aggregator of such

	data, whereas “General Doctor Inputs” will allow the draft representation of new types of information before their adoption by the MyAirCoach system.

5.3.10 Addressing representation of medication adherence

ID	ADH-RE01
Name	Representation of timing of medication use
Description	The model representation framework should cover the documentation of the time of medication use by patients
Rationale	Medication adherence is one of the most important difficulties towards the effective treatment of asthma. Therefore the MyAirCoach system should allow the representation of related parameters in the patient’s model.
Fit Criterion	MyAirCoach patient model covers the timing of medication usage
Priority	High
Conflicts/Relations	No conflicts currently identified
Author	CERTH
Revision	Initial Version V1.0
Proposed solution	New types of archetypes will be created to cover the medication adherence of patients; either it is assessed automatically by sensing devices or through questionnaires. Depending on their nature the current data can be represented under the entities of “Asthma Indicators” or “Sensor Measurements”

ID	ADH-RE02
Name	Representation of inhaler technique
Description	The patient model of MyAirCoach should include parameters related to the proper use of inhaled medication (Patient Competence)
Rationale	A significant percentage of asthma patients are not using their inhalers correctly, a fact that reduces the desired effects of medication. One of the research objectives of the MyAirCoach project is to study this problem of asthma management and suggest novel approaches for its mitigation.
Fit Criterion	MyAirCoach patient model covers the evaluation of inhaler technique.

Priority	High
Conflicts/Relations	No conflicts currently identified
Author	CERTH
Revision	Initial Version V1.0
Proposed solution	New types of archetypes will be created to cover the technique of inhaler use; either it is assessed automatically by sensing devices or through questionnaires. Depending on their nature the current data can be represented under the entities of “Asthma Indicators” or “Sensor Measurements”

5.3.11 Addressing representation of the conditions in the patient’s environment

ID	ENV-RE01
Name	Representation of environmental data
Description	The MyAirCoach model representation scheme should be able to include environmental measurements as they are found the patient’s environment
Rationale	The understanding of the effects of environmental conditions on asthmas disease is a crucial components of the MyAirCoach objectives
Fit Criterion	Data related to the temperature, humidity and pollution in the environment of patients should be allowed in the model representation framework
Priority	High
Conflicts/Relations	No conflicts currently identified
Author	CERTH
Revision	Initial Version V1.0
Proposed solution	New types of archetypes will be created to cover the environmental parameters; either they assessed via sensors in the patients’ body area network or from online resources. The environmental condition are represented through the entities of “Sensor Measurements” and “Patient Questionnaires” depending on their assessment methodology.

5.3.12 Addressing requirements for the representation of the patient’s lifestyle

ID	LIFE-RE01

Name	Representation of lifestyle data
Description	The MyAirCoach model representation scheme should be able to include lifestyle parameters such as activity levels and nutritional habits
Rationale	The understanding of the patient's lifestyle on asthmas disease is a crucial components of the MyAirCoach objectives
Fit Criterion	Data related to the patient's activity level and meal characterization should be included in the model representation framework
Priority	High
Conflicts/Relations	No conflicts currently identified
Author	CERTH
Revision	Initial Version V1.0
Proposed solution	New types of archetypes will be created to cover the parameter related to the lifestyle of patients; either they are assessed automatically by sensing devices or through questionnaires.

5.3.13 Addressing requirements for asthma indicators

ID	IND-RE01
Name	Representation of asthma indicators
Description	The MyAirCoach model Representation scheme should be able to include informative attributes that are strongly correlated with asthma exacerbations or disease worsening situations
Rationale	The evaluation of hidden correlations between different clinical, behavioral, physiological, environmental parameters and asthma exacerbation episodes is a crucial component of the MyAirCoach objectives
Fit Criterion	Indicators of the risk of asthma attacks should be represented in the MyAirCoach patient model.
Priority	High
Conflicts/Relations	No conflicts currently identified
Author	UPAT
Revision	Initial Version V1.0
Proposed solution	New types of archetypes will be created to cover the asthma indicators and to allow automatic assessed by the intelligent information processing module. This type of data will be covered by the entities of "Asthma Indicators" and

	"Exacerbation Risks"

5.3.14 Addressing requirements of computational modelling parameters

ID	MPAR-RE01
Name	Representation of Computational Modeling Parameters
Description	The MyAirCoach model Representation scheme should be able to include different computational modeling parameters, such as the geometric representation of the patient's lung, including parameters related to the level of narrowing in different bronchial tree generations, and air flow distribution in different parts of the lung.
Rationale	The evaluation of the air and flow distribution at the different part of the lung after taking into account the airway alterations as they are attributed to different levels of inflammation, is essential for predicting particle deposition on the airway walls. The results of this process are expected to allow: i) the clinician to study the way the drug or other harmful irritants are dispersed inside the lungs for different stages of a the exacerbation and for different levels of inflammation ii) the user to determine the effectiveness of an inhale medication delivery system.
Fit Criterion	The three dimensional geometry of patient lung airways should be represented in the proposed patient model. In addition the calculated velocity and pressure of air in the patients' airways should be represented in the MyAirCoach model.
Priority	High
Conflicts/Relations	No Conflicts currently identified
Author	UPAT
Revision	Initial Version V1.0
Proposed solution	New types of archetypes will be created to cover the computational modeling parameters and be automatically accessible by the computational modeling module. The entity of "Computational Modelling Parameters" will cover all the required fields of this type of data.

6 Conclusions

The main objective of this deliverable will be to provide a detailed definition of the patient model representation format adopted within the MyAirCoach project. All the described representation approaches in this report, can offer fundamental insights for the adaptation and extension of OpenEHR towards the goals and functional requirements of the myAirCoach system. The OpenEHR has been selected as it is a reference model for building Clinical- and User Models using archetypes, and it is supported by a huge open source community and a variety of tools. However, the HL7 will be also investigated during the project duration.

Most of the part of this document is devoted to the identification of the entities/concepts of interest that have been selected for the patient models construction within the myAirCoach. All these entities have been categorized into data related to the user identification, clinical data essential to the clinician and the data recorded from the wireless body area network and the integrated sensors. In addition a list of parameters that are related to the statistical processing (e.g., time series attributes, questionnaire attributes) and to the computational modelling (e.g., 3d meshes describing the lung geometry, air and pressure distribution inside the lung, e.t.c.) are also provided. However the integration of these parameters will be further investigated in the deliverables D4.2, D4.3 and D4.4.

Finally, indicative examples of OpenEHR archetypes that have been created during the project but also a proposed database structure are also defined and described in section 5.

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