PhD Thesis

Quality framework for semantic interoperability in health informatics: definition and implementation

By

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I, Alberto Moreno-Conde confirm that the work presented in this thesis is my own. Where information has been derived from other sources, I confirm that this has been indicated in the thesis

Esta tesis está dedicada a mis padres y hermanos.

Abstract

Aligned with the increased adoption of Electronic Health Record (EHR) systems, it is recognized that semantic interoperability provides benefits for promoting patient safety and continuity of care. This thesis proposes a framework of quality metrics and recommendations for developing semantic interoperability resources specially focused on clinical information models, which are defined as formal specifications of structure and semantics for representing EHR information for a specific domain or use case.

This research started with an exploratory stage that performed a systematic literature review with an international survey about the clinical information modelling best practice and barriers. The results obtained were used to define a set of quality models that were validated through Delphi study methodologies and end user survey, and also compared with related quality standards in those areas that standardization bodies had a related work programme.

According to the obtained research results, the defined framework is based in the following models:

- **Development process quality model:** evaluates the alignment with the best practice in clinical information modelling and defines metrics for evaluating the tools applied as part of this process.
- **Product quality model:** evaluates the semantic interoperability capabilities of clinical information models based on the defined meta-data, data elements and terminology bindings.
- **Quality in use model:** evaluates the suitability of adopting semantic interoperability resources by end users in their local projects and organisations.

Finally, the quality in use model was implemented within the European Interoperability Asset register developed by the EXPAND project with the aim of applying this quality model in a broader scope to contain any relevant material for guiding the definition, development and implementation of interoperable eHealth systems in our continent. Several European projects already expressed interest in using the register, which will now be sustained by the European Institute for Innovation through Health Data.

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List of acronyms

CDA: Clinical Document Architecture

CIM: Clinical Information Model

CIMI: Clinical Information Model Initiative

CEM: Clinical Element Model

CIMP: Clinical Information Modelling Process

CIMT: Clinical information Modelling Tools

DCM: Detailed Clinical Model

D-MIM: Domain Message Information Model

EHR: Electronic Health Record

FHIR: Fast Healthcare Interoperability Resources

HDF: HL7 Development Framework

IA: Interoperability Asset

PDCA cycle: “Plan, Do, Check, Act” cycle

PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-Analyses

QMS: Quality Management System

RIM: Reference Information Model

RM: Reference Model

R-MIM: Refined Message Information Model

SDO: Standard Development Organization

SIQF: Semantic Interoperability Quality Framework

SQUARE: ISO/IEC 25000 standard for Systems and software Quality

Definition of terms

The following definitions were extracted from existing projects and standards focused on health informatics and semantic interoperability:

Asset: anything that has value to a person or organization (ISO/IEC 25010 standard 2011).

Clinical Information Model: Specification of a standardised model to express one or more clinical concepts as a set of data elements to structure an EHR or a data exchange file (SemanticHealthNet project 2014).

Clinical Information Modelling: The activity of defining the set of clinical information and describing its structure that needs to be supported in order to enable data entry, use and display of clinical content in the EHR as well as for data exchange or reuse of that content (SemanticHealthNet project 2014).

Clinical Information Modelling Processes: Sequence of activities resulting in defining a Clinical Information Model (SemanticHealthNet project 2014).

Clinical Information Modelling Tools: Software applications that assists the users to define the specifications of a Clinical Information Model (SemanticHealthNet project 2014).

Interoperability asset: Any resource that can be applied to support the design, implementation and successful adoption of eHealth services that can exchange data meaningfully. Some examples may include functional requirements, specifications, standards, guidance on how standards may be used concurrently, implementation guides, educational resources, and other resources (EXPAND project D4.1 2015)

Quality: Attribute of a product or a service indicating its conformance to an expected level of satisfaction (SemanticHealthNet project 2014).

Quality in use: degree to which a product or system can be used by specific users to meet their needs to achieve specific goals with effectiveness, efficiency, freedom from risk and satisfaction in specific contexts of use (ISO/IEC 25010 standard 2011)

Quality model: defined set of characteristics, and of relationships between them, which provides a framework for specifying quality requirements and evaluating quality (ISO/IEC 25000-SquaRE standard 2014).

Maturity: degree to which a system meets needs for reliability under normal operation (ISO/IEC 25010 standard 2011).

Infostructure: A formal process for the governance of semantic interoperability resources (eHealth Innovation Project)

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The results of this research produced three published papers in journals with a high impact factor, an additional manuscript is under review and one contribution is scheduled for presentation at a scientific conference. The following experts also contributed towards these results: David Moner, Pascal Coorevits, Montse Robles, Jesús Moreno, Francisco Jódar, .Jose Alberto Maldonado, Wellington Cruz, Marcelo Dos Santos, Inge Lamote and Geert Thienpont.

Moreover, the performed research was able to provide requirements for the clinical information modelling field based on the point of view of the following experts who participated either in face to face meetings, online surveys or interviews: Ian McNicoll, Gerard Freriks, Jessica Rosenalv, Torbjorn Nystadnes, Heather Leslie, Archana Tapuria, Alfonso Soto, Stan Huff, Kensaku Kawamoto, William Goosen, Koray Atalag, Stefan Sauermann, Charlie McCay, Eduardo Vigil , Christian Lovis, Marc Overhage, David McCallie, Xabier Pastor, Naveen Maram, Diego Boscá, Catalina Martínez, Barry Smith, Erik sundvall, Grahame Grieve, Diego Kaminker, Derek Corrigan, Cui Tao, Borut Fabjan, Torbjorn Nystadnes, Vesna Lesnik, Josep Vilalta, Amos Ndague, Francisco Pascual, Eric Brownne, Jan Talmon, Jose Calado, Leonardo Lezcano, Kay

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Chapter 1. Introduction

1.1 Hypothesis

This thesis aims to define a new quality framework for semantic interoperability by addressing the development process for clinical information models, the functionality of tools used to develop them and quality metrics for the clinical information models themselves including those relevant for end user acceptance. The hypotheses that this work sets out to validate are:

- It is possible to define recommendations and quality metrics for clinical information modelling processes independently of the implemented EHR specification.
- It is possible to define a set of requirements for scaling up the development process to promote sustainability of clinical information modelling processes.
- It is possible to identify generic requirements for clinical information modelling tools, and propose new requirements to guide the evolution of tools in the coming years according to the level of fulfilment by existing tools.
- It is possible to specify quality metrics for clinical information models associated with user acceptance for healthcare professionals, decision makers and IT developers.
- It is possible to implement the defined semantic interoperability quality framework as part of a European register for semantic interoperability resources. This register would support end users to identify relevant interoperability resources for their projects and organisations, as well as, providing guidance to developers of interoperability resources about the quality of their adopted methodologies clinical information models, specifications and value sets.

1.2 Description of the problem being addressed

Within the health informatics domain, structuring clinical information has proved to be a complex field. After more than 30 years of transition from paper based records to EHRs, the mechanisms for structuring clinical information to support information sharing, processing and analysis are now recognised as being of great importance.

There are some requirements in the healthcare domain that are not currently well met by EHR systems. Patients receive care at multiple institutions and their information needs to be

accessible and available throughout their lifetime at all future healthcare locations. Information collected in each healthcare centre within its local information system should be available to support future care providers to make the right decision at the point of care. The information combined from multiple sources needs to be appropriately collected, represented, stored, transferred and then processed by subsequent EHR systems at future care locations in order to ensure patient safety. The lack of correct (complete, accurately interpreted) information can lead to wrong clinical decisions or recommendations from clinical decision support systems with adverse consequences for patients. There are some barriers that make difficult to achieve the semantic interoperability of clinical information:

- Healthcare professionals need to collect information that is highly dependent on their local practice. This depends on their local workflows and their adopted clinical practices.
- Healthcare professionals work under stressful conditions with a limited amount of time allocated to documenting clinical information.
- Healthcare professionals use agreed recommended practices in the form of clinical guidelines but the level of detail in these does not specify the information that should be collected to comply with each guideline.
- In order to reuse clinical information from multiple clinical departments, public health or research there is mismatch in the level of detail required by each stakeholder.
- The clinical information recorded in EHR systems evolves continuously with the inclusion of new diagnostic tests, drugs and therapies.
- The process of defining the clinical information to be collected in a specific domain requires a substantial effort from clinical experts.
- Collected clinical information usually includes many terms that are not well defined such as “mild pain”. The lack of agreement on those terms, when they are integrated from multiple clinical practices, makes very challenging to compute the information collected by different healthcare providers.
- At a technological level, systems also require different levels of detail. Departmental Health Information Systems and monitoring devices generate information with more detail than the level required to be stored in EHR systems. For instance, a monitoring device could be continuously recording patient information but only a subset might be recorded in the EHR and viewed by clinicians as a patient monitoring report. At a technological level, the information therefore needs to be consistently modelled between all involved systems.

As a consequence, to ensure patient safety, it is necessary to establish good quality processes to define how clinical information will be structured in multiple systems, and to obtain a level of consensus on this at a large scale. It is equally important to be able to confirm that the information exchanged between EHR systems has been structured consistently and reflects the consensus requirements of healthcare providers and the scientific (clinical research) community.

1.2.1 Semantic challenges

To ensure that clinical information is able to be safely transferred and interpreted between multiple systems, it is necessary to propose a technological solution flexible enough to represent the information at a varying level of detail, as well as combining it with the right contextual information. As first step to achieving this, a set of technological standards and specifications have been published that harmonise how information can be structured in order to be transferred between multiple EHR systems. Although there are several technological standards and specifications for EHR communication that can structure clinical information, the problem of addressing semantic interoperability remains elusive for the health informatics domain because there are still several barriers to be overcome:

- The definition of semantic structures for EHR communication requires specifying the structure in the form of a clinical information model, as well as, specifying the concepts that will be recorded using it, preferably from an international terminology, classification or ontology. Without a common methodology for developing such models, clinical information modellers could produce very different models for the same kind of information, each of which is semantically correct but the systems using them won't be able to communicate with each other. Figure 1 shows an example of how the information related with a heart failure diagnosis could be modelled with different levels of granularity.

- Clinical information modellers could define how an EHR is able to organise the information with a vast amount of detail that will be semantically correct but clinicians won't be able to spend the required time to record all of that information. If many of those detailed items were specified as mandatory this could have a high impact on the clinical workload, whereas if they are optional relevant information might be omitted.

- Traditional strategies for integrating a reduced number of systems deployed in hospital settings are not scalable. With the establishment of national/regional health IT projects, it is now required to satisfy the needs for a larger number of systems, which increases the complexity of making them interoperable. Nowadays, many people move between countries temporarily for business or holidays, or permanently for work. It is therefore an

increasing requirement that EHRs provide appropriate management of information across multiple healthcare providers across regions and countries.

- Knowledge integration from clinical practice, clinical research and bio-medicine through harmonised semantic resources remains as a challenge due to the need for representing the information in a format that satisfies the individual viewpoint of each of the involved actors.

- Greater alignment is needed from Standard Development Organisations, national eHealth programs, European projects and other bodies to develop interoperability assets such as EHR documents, templates, vocabularies and educational resources where clinical consensus and accepted evidence have proved the value of computerised clinical data. Unfortunately these are largely accessible in *ad hoc* ways and result in scattered fragments of a solution space that urgently needs to be brought together.

There is a lack of guidance for developers, clinicians and decision makers about how to select relevant interoperability resources able to be reused or adapted in their systems or organisations. Decisions about the suitability of an interoperability resource should be made based on objective measurements in order to avoid the adoption of interoperability resources that are obsolete, incomplete or without adequate technological robustness and support.

Figure 1. Granularity mismatch in clinical information modelling

1.2.2 Expected benefits from improved semantic interoperability

The proper management of clinical information based on semantic interoperability will allow the collection, integration and analysis of data from across large populations and from different countries. As a result, it will be possible to provide almost real time information that can be the basis for facilitating the generation of evidence based medicine, rather than the current expensive and time consuming method of gaining evidence through clinical studies. This large volume of clinical data will support individualised predictions for patients built on the patterns

and outcomes recorded for all similar patients in a population. Data mining will be applied to this scenario, providing better information about disease interactions. Moreover, this will allow complementing clinical trials with the analysis of large volume population data in order to accelerate knowledge discovery and provide the means to reduce the amount of time required for new evidence to be generally adopted in clinical practice (Kalra 2011).

Likewise, the definition of semantically interoperable solutions is a key instrument for ensuring that patient specific information is appropriately interpreted during the execution of decision support systems.

In order to provide technological solutions that are able to be applied to a vast number of clinical scenarios and clinical concepts, different initiatives working in the semantic interoperability field have claimed that additional research is required (i) to establish good modelling governance practices, (ii) to assure the quality of clinical information models, (iii) to scale up the resource development process, and (iv) to support education about implementation and use (Stroetman, Kalra et al. 2009).

1.2.3 EHR vendors

EHR systems are purchased by healthcare providers due to the existing experiences that reported benefits associated with increased efficiency and reduction of medical errors (for example, as recently reported by King, Patel et al. 2014). According to a recent report published by Transparency Market Research, the size of the EHR market is estimated to be $18.9 billion. These systems are expected to increase in their adoption and acceptance and to reach a market size of $30 billion by 2023 (Transparency Market Research 2016).

On the other hand, EHR systems are critical infrastructures, and any problem in their successful use could have a great impact on healthcare delivery. Vendors usually provide redundancy in an infrastructure and 24/7 technical support in order to ensure that any problem is solved immediately. As a consequence, healthcare providers usually prefer to trust big IT vendors with previous experience in the field in order to minimise risks. Nowadays some of the most relevant IT vendors are Epic Systems, Allscripts Healthcare Solutions, Inc., eClinicalWorks, Athenahealth, Inc., GE Healthcare, Cerner Corporation, Greenway Health, LLC, Medical Information Technology, Inc., 4medica, McKesson Corporation, and NextGen Healthcare. These vendors commercialise their own EHR product and compete for the market share. Most of them send representatives to standardisation organisations such as HL7 and ISO but their implemented systems have in general limited levels of interoperability.

There are multiple factors that influence this lack of adoption:

- adopting interoperability standards require a strong effort from highly skilled IT developers;

- implementing new interoperability functionalities usually requires the redesign of some components of a system that is already deployed.
- most of vendors do not identify enough financial incentives to implement interoperable transfer of information to other vendor products, because they usually provide their systems as a full solution that does not require connecting with external systems (except for standard reporting and billing systems);
- large IT vendors with a strong market penetration usually benefit from the lack of interoperability of existing systems because this is a barrier for smaller (innovative) companies, protecting their business position;
- only customers with enough budgets are able to request these vendors to adapt their systems to provide the interoperable capabilities.

The VALUeHEALTH project is working on developing an evidence-based business plan for sustainable interoperability on eHealth. This project aims to be able to provide cost-effective assessment that to be able to identify the value of eHealth interoperability. Based on the research performed it is expected to describe how cost savings and healthcare delivery benefits can justify investments in this area with minimal dependency upon public funding (VALUeHEALTH Project 2016).

1.2.4 European and international policies

The European Commission identified the need for development of an eHealth Network to drive increased cross-border interoperability as an essential instrument to support the free movement of citizens between Member States (eHealth Network 2015). Moreover, additional measures are in progress to support movement to and from non-European countries such as the US.

As part of the eHealth Action Plan, the European Commission has identified that eHealth is an emerging market which should continue expansion. Multiple systems based on mobile technologies and devices can benefit citizens and support more efficient and effective healthcare interventions. In the current situation where the European population is ageing fast, healthcare systems are facing the challenge of providing care to large population of the elderly when the active population is reducing. To foster the establishment of a European eHealth Network and to develop a common European market, it is required that eHealth systems will be able to support the flow of citizens and patients across the multiple EC Member States. (eHealth Action Plan 2012) As a result, the EC defined a European eHealth Interoperability Framework (EIF) combined with a framework for testing, quality labelling and certification to overcome current barriers for eHealth interoperability (EIF 2013). These frameworks are based on the results of past and current EC research projects in this area. Some of the most relevant projects in the semantic interoperability field, SemanticHealthNet, Antilope, EXPAND and HITCH, have

analysed how semantically interoperable artefacts based on standards can be effectively adapted to specific use cases (profiled) and implemented.

The European eHealth Interoperability Framework (EIF) has specified how standards and profiles can be applied in some of the most common health information exchange scenarios (EIF 2013). Each of its interoperability scenarios details a set of profiles to be applied to share clinical relevant information, and includes testing and validation mechanisms.

Moreover, at the international level Europe is promoting policies that support semantic interoperability. There is a Memorandum of Understanding (MoU US EU 2010) between the US and the European Commission to support eHealth/health IT cooperation with the aim of addressing the need for "international interoperability of Electronic Health Records information, to include semantic interoperability, syntactic interoperability, patient and healthcare provider mediated data exchange (including identification, privacy and security issues surrounding exchange of health data)" (MoU Roadmap 2013).

Although these policies aimed to provide guidance in the implementation of EHR semantic interoperability in our continent, the EIF only defined how to apply specifications for eleven use cases. Many relevant healthcare scenarios such as covering the essential information related to chronic diseases such as diabetes mellitus, COPD or heart failure are still not fully addressed. As a result, the EIF provides limited guidance to clinicians, developers and decision makers about the recommended specifications to apply in their local scenario. This research aims to provide additional guidance based on objective quality metrics for semantic interoperability resources.

1.3 Overview of the chapters

This document is organised in the following chapters:

- **Chapter 2 – Background:** Provides an overview of the background of the core topics underpinning this thesis including: clinical information models, tools and processes associated with their definition, and details of the quality specifications and interoperability resources that are relevant for this thesis.
- **Chapter 3 – Proposed Semantic Interoperability Quality Framework:** Details the proposed Semantic Interoperability Quality Framework overall methodology carried out through the multiple research studies included in this thesis, and the relationship with multiple quality standards related with this framework.

- **Chapter 4 – Individual Research Studies:** Details the objective, methodology, results and discussion of the multiple research studies performed. This chapter includes four research studies focused on obtaining better understanding of the organisational, human and technical factors associated with the clinical information modelling process. An additional research study has defined metrics associated with end user expectations in order to be able to evaluate the quality of the interoperability resources. Lastly, a comparison was performed with existing draft standards associated with evaluating the quality of CIMs and the establishment of a quality management system as part of the development process.

- **Chapter 5 - Discussion:** Provides information about the implementation of the defined quality framework as part of an online register focused on containing and classifying multiple interoperability resources and analysing the future evolution of the quality framework based on the relationship between multiple quality models and interactions with EHR vendors, healthcare providers and regulators.

- **Chapter 6 - Conclusion:** Explains the main conclusions from the individual studies performed and how they are interlinked the overall research. Moreover, this chapter provides a description of the recommended areas for further research.

- **Chapter 7 – References:** This chapter includes the list of references associated with the thesis document in alphabetical order.

- **Chapter 8 – Appendix:** This chapter includes supplementary material associated with the multiple research studies developed in this thesis.

1.4 Summary of introduction chapter

This chapter has described the hypotheses that this research aimed to validate. The hypotheses were focused towards the definition of quality metrics associated with semantic interoperability in EHR systems.

This chapter has described the problems associated with the clinical information modelling within EHR systems, relating them to the needs within the healthcare domain and its semantic interoperability challenges. In addition, it has presented the EHR vendor point of view complemented with initiatives carried out by the European Commission to provide guidance in the semantic interoperability field were presented and analysed.

Lastly, it has provided a description of how this document is structured, explaining the content provided in each chapter and the list of acronyms applied in this thesis.

Chapter 2. Background

2.1 Introduction

This chapter includes an overview of the existing specifications defined to support semantic interoperability for EHR communication. The identified EHR standards and specifications are classified into three groups according to their proposed modelling approach. The provided description does not include a detailed comparison of possible overlaps between individual specifications since the presented research is focused on identifying requirements for clinical information modelling based on any EHR specification. This information is complemented by an explanation of those processes adopted for defining clinical information models within the health informatics field detailing some of the most relevant initiatives. In addition, the most relevant differences between the Software Development Process with the process applied for defining clinical information model are provided.

As another relevant factor influencing the clinical information modelling process, this section details the most relevant tools that support processes associated with the definition, validation and testing EHR communication based on existing EHR specifications.

This section explains how the SemanticHealthNet and Expand projects aimed to establish guidance about how to organise multiple interoperability resources relevant for designing, developing or implementing EHR systems in Europe. This research established links with these projects in order to define a Semantic Interoperability Quality Framework that aimed to contribute to achieve their objectives.

Finally, this chapter also provides a description of the existing quality measurements and specifications that are usually applied to ensure that products and systems will fulfil the end user/customer expectations related to the Semantic Interoperability Quality Framework.

2.2 Clinical Information Models

The increased adoption of EHR systems has facilitated sharing patient information across multiple systems to support continuity of care. To this end, Standard Development Organizations (SDOs) and other relevant organisations have each defined a set of specifications that aim to enable interoperable communications between systems by defining how the information contained in patient records should be structured. Current trends followed by most of those specifications rely on differentiating the representation of the information from the definition of the clinical information models used by the information systems.

In this research, we will use the expression clinical information model (CIM) as a generic term that includes any technical specification that defines how clinical information is organized inside an EHR system. A CIM defines both the information structures and the semantic relationships between clinical concepts. CIMs are a fundamental semantic artefact to facilitate registering, storing and displaying clinical data, exchanging that data between different EHR systems. The representation of information based on CIMs can also be applied to performing queries analytics and decision support based on EHR data. This term is used as part of this research in order to be able to describe the multiple existing EHR specifications.

The main CIM modelling approaches are summarized in Figure 2. In the first set of columns HL7 CDA and its Version 3 modelling approaches are based on a common Reference Information Model. In the second set of columns is the dual model or two level approach of the EN ISO 13606 standard and the openEHR specifications. Finally, the right hand columns show the efforts being made by the Clinical Information Modeling Initiative to develop generic and reusable CIM patterns, and other proposals such as the Detailed Clinical Model standard. These three approaches are described in more detail in the following sections.

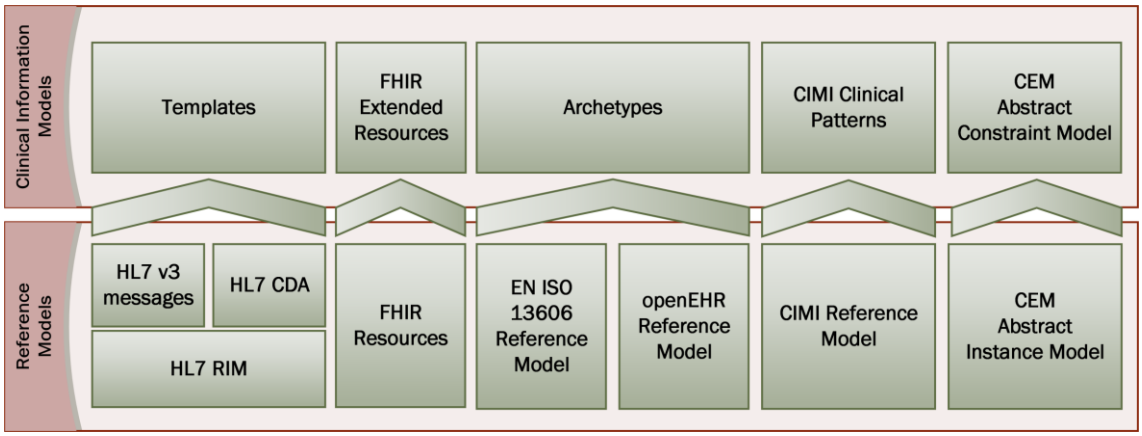


Figure 2. Summary of Reference Models and their Clinical Information Model definition artefacts

2.2.1 HL7 RIM based standards

In 1995, the HL7 Foundation started the development of an HL7 Reference Information Model (RIM) containing around 70 different classes that aimed to represent the business logic of any health environment (e.g. Act, Observation, Role, etc.) (HL7-RIM 2010). The HL7 RIM addressed the definition of the administrative and clinical domain in a generic form. Figure 3 details the UML classes defined as part of the HL7 RIM standard.

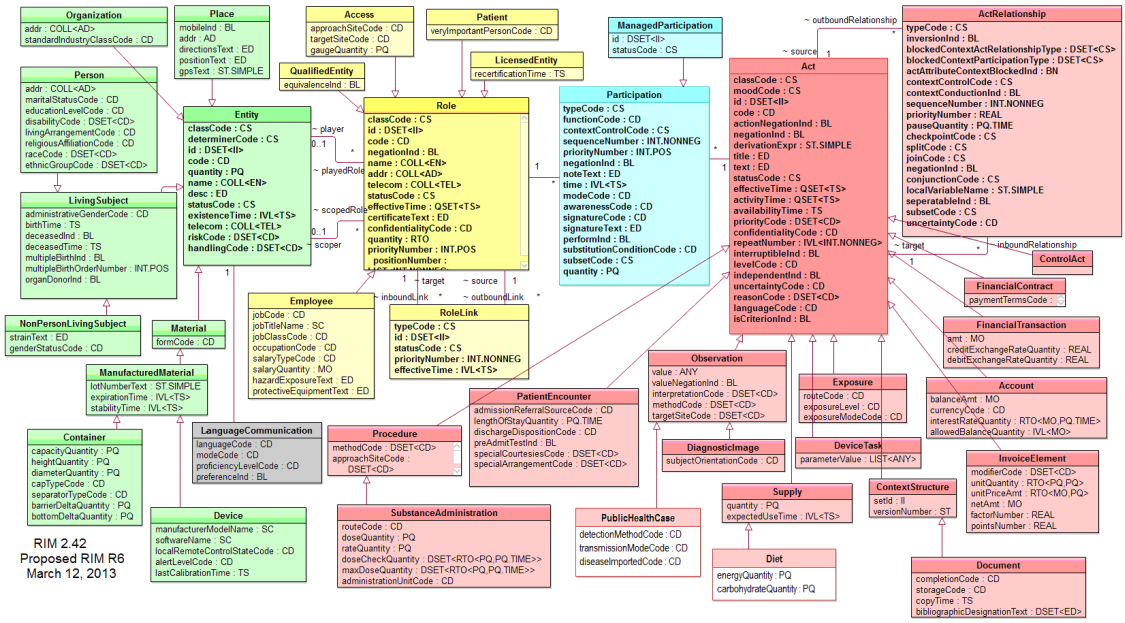


Figure 3. HL7 RIM UML diagram of the classes (source: Release 6 of the ANSI Normative HL7 RIM)

In parallel, a Model Driven Architecture development process called the HL7 Development Process was proposed as a methodology to define messages and documents based on a set of generic classes defined in the HL7 RIM. This methodology aims to provide a consistent semantics within messages and documents based on a rigid definition of the classes contained in the HL7 RIM. The HL7 standards that are based on HL7 RIM are HL7 v3 messages (Beeler 1998), HL7 Clinical Document Architecture (CDA) (ISO/HL7 27932 2009), and HL7 FHIR (FHIR. 2014).

HL7 v3 defines the messaging structure based on a formal methodology (the HL7 Development Framework - HDF) and object-oriented principles. The defined methodology describes how classes defined in the RIM are derived to create a Domain Message Information Model (D-MIM) and later in a Refined Message Information Model (R-MIM), As a result, it is possible to create consistent messages derived from a common reference model.

In order to reuse definitions of semantic structures according to HL7 v3 and HL7 CDA, it is possible to define clinical information models in the form of HL7 templates (HL7 templates 2011). Templates are able to specify how the clinical information is structured for specific purposes. Those templates can be then reused to build other templates or to analyse data created based on those specifications.

HL7 FHIR (FHIR. 2014) is a new generation specification that uses modular components called Resources. These resources (definitions of common reusable patterns of clinical information) can be combined or extended in order to provide particular solutions to health information

systems. Therefore, they are also to some extent CIMs that are aligned with the classes defined in HL7 RIM.

2.2.2 Two level modelling

The two levels or dual level methodology (Beale 2000) is based on the definition of a very simplified and generic Reference Model (RM) that is designed to represent the most basic properties and structures of any EHR. For example, a RM can represent the basic data structures such as folders, compositions, sections, entries and elements, together with audit information, functional roles, related parties, attestation information and demographics. This simplified RM is focused on reducing the impact on implemented systems based on the evolution of clinical knowledge and its associated semantics, by providing a stable RM that will not evolve. Complementing the RM, semantics are defined in the form of constraints over that RM, called archetypes. Archetypes define specific information structures for a clinical domain or use case that express how clinical information is structured (i.e. how particular clinical information organised using the RM classes) in order to be stored or transferred between EHR systems. This approach is focused on providing flexible capabilities for CIM definitions, including reuse by aggregation or specialization, and management and publication through public archetype repositories.

This two level modelling is supported by the EN ISO 13606 standard (ISO13606 2008-2010) and the openEHR specifications (OpenEHR 2014). Both models have just slight differences in their RMs and share the archetype approach for expressing constraints on their RM.

At an additional level of abstraction, the Archetype Object Model defines how multiple clinical concepts can be recorded within a patient record expressing the semantic relationships for clinical content and context required for the EHR. This is expressed in the form of constrains defined in the Archetype Description Language over the underlying Reference Model. As a result, it is possible to define a library of semantic structures that can be reused for designing clinical forms and for communication (interoperability) between systems.

2.2.3 Generic clinical information models

The two previous modelling approaches are closely linked to the development of implementation resources that use specific EHR standards. Additional modelling approaches have emerged, focused on defining information structures at a conceptual level, without depending on a specific implementable specification. This is based on the assumption that the same medical concepts can be represented using different standards and specifications, and that they will only differ in the way they are implemented. This approach aims to work in defining generic and sharable CIMs. They are used to model the clinical concept without being implemented in any particular way for interoperability purposes. They are required to be mapped to other interoperability standards at implementation stage to transfer information

between EHR systems. In order to achieve this, the approach aims to make sure that a mapping is always possible from the generic CIM to an implementable specification (for example, from a generic form to an HL7 template or to an EN ISO 13606 or to an openEHR archetype). As a result, the specifications included in this approach aim to provide increased efficiency and safety because their protagonists claim that defining and structuring medical data is the most difficult and costly part of most IT projects in health care.

The specifications based on this approach are:

- **The Clinical Information Model Initiative (CIMI).** CIMI is an international not-for-profit collaboration that is dedicated to providing detailed specifications of health information contents, so that semantically interoperable information may be created and shared in health records, messages and documents (CIMI 2014). The aim of CIMI is to develop a library of CIMs in the form of archetypes, based on a generic and standard-neutral reference model and described through international terminologies such as SNOMED CT.

- **Detailed Clinical Model (DCM).** DCM has been often used as a generic term for "an information model of a discrete set of precise clinical knowledge which can be used in a variety of contexts" (ISO/DTS 13972 2015). Rather than being constrained by specific implementation needs, this standard defines requirements for defining DCMs without specifying a normative reference model. As a result, DCMs could be considered as formalism specifically designed to be independent from specific technical implementation.

- **Clinical Element Model (CEM).** CEM is one specification for representing clinical information in EHR systems. This specification uses a language called Constraint Definition Language to model the structure of data elements for clinical documentation. (Coyle, Heras et al. 2008)

Figure 4 details the aspiration for CIMI models to serve as core representation of clinical model content. The image shows how CIMI initiative has defined a reference model that is expected to be generic enough to be able to define CIMs that would be able to be implemented through translation mechanisms towards multiple specifications at implementation stage (model dissemination). They aim to define a repository of CIMs based on the existing experience of modelling semantic resources from openEHR, ISO13606, CDA templates, FHIR, DCM.

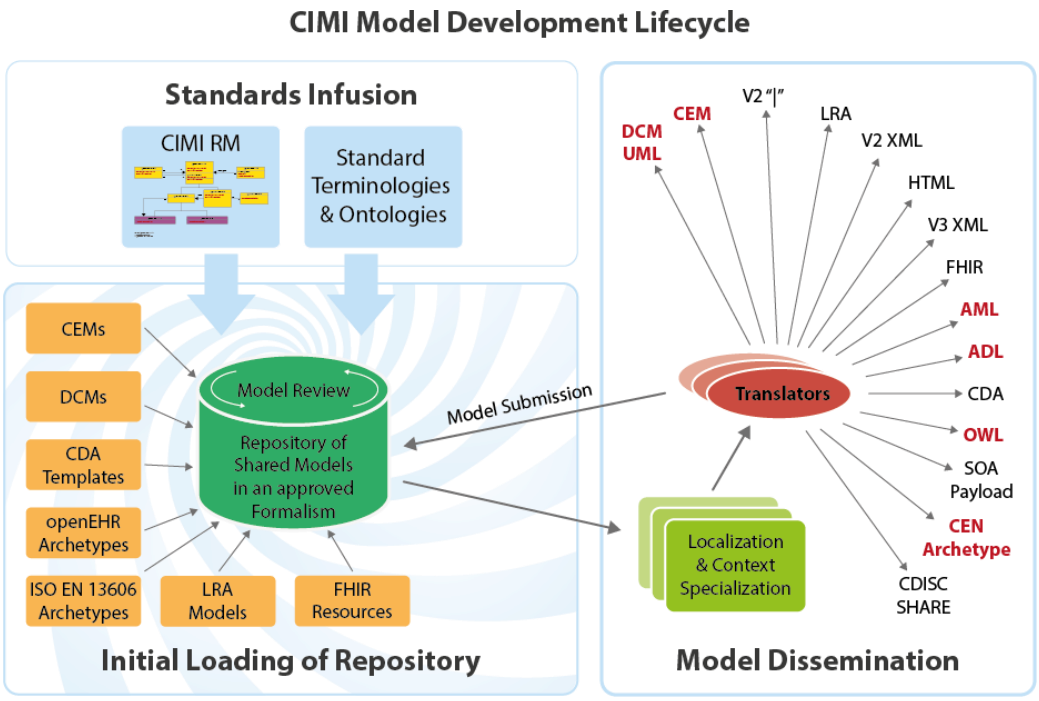


Figure 4. CIMI modelling approach

2.2.4 Comparison between existing EHR modelling specifications

The presentation of the EHR specifications in Figure 4 implies that all of them are able to define how clinical information is to be structured in order to transfer information between EHR systems and the decision about what is the best solution to implement is not fully clear. All the above presented specifications are implemented in EHR systems and have the support of their own community of IT developers. In order to select which specification is the appropriate one to be used in an eHealth interoperability project, it is required to have a strong understanding of the multiple specifications and to evaluate multiple non-technical factors that would influence the decision. This thesis aims to be able to define objective measurements that would help decision makers, IT developers and clinicians in the comparison between multiple CIMs defined with overlapping specifications.

HL7 RIM based standards

HL7 RIM based standards are based on implementing a reference model that is dependent on the clinical context. As it is detailed in Figure 3, the HL7 RIM fully details UML classes aiming to cover any transaction of information for the healthcare domain. As a result, this reference model is the most complex to be implemented. In addition, the consensus on how clinical information is structure is continuously evolving, resulting in new releases of the HL7 RIM that would represent a big impact on the development of new releases of the systems. A new HL7 RIM release will require modifications on persistence, logic and presentation layers of the system. Moreover, there are studies that have identified semantic inconsistencies between the multiple

classes included in HL7 (Hasman 2006). Nevertheless, despite the criticism associated with this approach, HL7 RIM based specifications have the stronger support from large IT vendors and healthcare providers than other initiatives.

Two level modelling specifications

Two level modelling specifications have defined a simpler reference model that is not dependent on the clinical information that is transferred. This approach includes mechanisms that allow defining the semantics associated with the clinical context in the form of archetypes without requiring modifications of the reference model. As a result, systems implemented according to this approach would be more flexible to accept changes in the clinical information that is expected to be transferred, based on the use of a generic (reference model) specification that is independent to clinical content. On the other hand, a governance process is not ensured with the application of this technology: it is required to obtain consensus between the healthcare providers about how to model clinical information. This research has aimed to contribute towards the definition of quality metrics that would help to obtain this agreement.

Generic clinical information models

According to the evolution of technology, the generic clinical information models approach is based on the independence of clinical information models from any implemented EHR specification. This approach was proposed as a mechanism for obtaining better management of the semantics in those scenarios where, for example, it may later be required to implement HL7 RIM based specifications. This approach aims to provide a mechanism to define the semantics of EHR information. The defined generic information models in the form CIMI models or DCM models must include enough resources to subsequently map to the selected specification HL7 CDA, HL7 FHIR or HL7 v3. The generic clinical information model approach recognises the archetype based specifications such as openEHR or ISO 13606 as another set of specifications that could be mapped at implementation stage. Due to the similarities in their reference model these latter mappings would require less effort than HL7 specifications. This generic CIM approach has been promoted as a practical solution for trying to harmonise the development of resources without creating another specification for implementing EHR systems. On the other hand the presented approach is still relatively new and some time will be required to verify the level of support from industry and healthcare providers for it.

In conclusion, the large number of EHR interoperability specifications shows that the market is still not mature enough to identify a clear widely adopted specification for clinical models and for semantic interoperability. The decision about which specification should be implemented for an eHealth interoperability project would depend on multiple factors that make impossible to provide a single and universal recommendation. The recommendation for adopting a technology might differ depending on the type of organisation that is going to implement the EHR system.

For instance, an SME company would be more open towards adopting a new EHR specification because allows easier access to the market in case that this specification gets widely adopted. On the other hand, a healthcare provider would be, in general, in favour towards conservative technologies that have a strong adoption by other healthcare providers in its region.

Moreover, none of the presented specifications include much metadata about the process carried out to develop the CIMs and how the specifications were adopted. As a result, the definition of a quality framework for supporting this decision based on objective measurements is essential to reduce the risk of failure of the implemented systems and to encourage trust in the models from the vendors who will need to invest in implementing them. This research aims to be able to supplement the existing specifications by the defining (additional) relevant quality metrics that would help end users to identify the level of trust of existing CIMs.

2.2.5 Clinical information models and terminologies

Clinical information models have a close relationship with medical terminologies. As described before, each CIM can be semantically described through bindings to medical terminologies, thus obtaining one unequivocal definition for each of the elements of the CIM information structure. Furthermore, terminologies are also used to specify value sets, i.e. the set of possible codes that can be assigned as values of each leaf node within a clinical information model. These terminology bindings are specific to each CIM according to the needs of the clinical scenario in which it will be applied. As a conclusion, dealing with terminology bindings is required as part of CIM development processes.

2.3 Clinical Information Modelling Processes

A clinical information modelling process (CIMP) is the process of defining, validating and maintaining semantic artefacts in the form of clinical information models. This process will usually require the cooperation of experts with technical and clinical backgrounds in order to obtain a final implementable definition of one or more CIMs that satisfy the clinical needs. During that process of CIM development, and once CIMs have been initially defined, governance mechanisms can be applied to ensure good practice in the lifecycle management and future evolution of the defined semantic artefacts. It is also important to note that a clearly defined CIMP has the potential to improve CIM quality and interoperability. A commonly agreed CIMP could promote and emphasize the importance of analysing the information covered in a particular domain, the collaboration between different clinical and technical professionals and the search for consensus in the definition of CIMs. It might also minimize the diversity of ways in

which a CIM can be designed and will make terminology bindings more consistent. This is directly related to the improvement of the quality of CIMs (Kalra and Carpenter 2012).

Goosen et al. summarised some of the most relevant initiatives working in clinical information modelling indicating differences and similarities between approaches (Goossen, Goossen-Baremans et al. 2010). This includes the following:

- Clinical Element Models defined from Intermountain Healthcare (Oniki, Coyle et al. 2014)
- ISO EN 13606 Archetypes defined by ISO/CEN EN13606/Open-EHR in Australia, England, Sweden (Leslie 2008, Rosenalv and Lundell 2012).
- Clinical Templates project in Scotland (Hoy, Hardiker et al. 2009)
- Clinical Contents Models in South Korea (CCM 2014)
- Health Level 7 templates (HL7 templates 2011, HL7 Templates 2014)
- Detailed Clinical Model instances (Boterenbrood, Krediet et al. 2014).

2.3.1 Comparison with software development processes

Although CIMs will be implemented in EHR systems and other healthcare systems, CIMP may differ from the traditional software development process. Table 1 details the steps included as part of the Software Development Process by Mykkänen and Tuomainen 2008 (Mykkänen and Tuomainen 2008) to perform a comparison with the steps included as part of the CIMP:

Step	Name	Description
1	Requirements definition:	This step is focused on determining relationship to legislation, the scope, the fit for systems defined using the defined methods.
2	Domain analysis	This step includes the definition of a common domain model that will be the basis for the implementation of the final system.
3	Design	This step defines information elements, operations, interface technologies, architectural considerations that the final system will satisfy
4	Implementation	This step includes the development of the technical infrastructure to support the interfaces and could benefit from using implementation tools.
5	Deployment and introduction	This step covers the adaptation of the system to different environments, configurations, adapters in order to be compliant with the end user requirements.
6	Maintenance and versioning	This step covers the migration strategies, configuration management and the release of new functionalities as part of the system.

Table 1. Software development process steps defined by Mykkänen and Tuomainen 2008

According to previous publications (Buck, Garde et al. 2009, Kalra and Carpenter 2012, Moner, Moreno et al. 2012), CIMP is also a process of defining how clinical information is structured based on a domain analysis, design and implementation of the semantic artefacts in the form of CIMs, and a governance process to maintain the quality of those CIMs over time. Although these steps show similarities with Software Development Process, the aim of CIMP is to generate artefacts that encompasses the requirements of different clinical stakeholders and scenarios, and may be used in different systems in order to facilitate the semantic interoperability between them. As a result, there will be relevant differences because CIMP is only focused on the requirements associated with the clinical information that needs to be incorporated with EHR systems. Moreover, CIMs will be represented using standard specifications and formats, which enables the reuse of existing CIMs and the publication and sharing of newly created ones to enable future reuse. These two additional steps to the traditional software development methodologies (the reuse of existing CIMs and the publication of the new ones) require a standardization of the CIM definition methodologies, so that CIMs are developed in consistent ways. To achieve that coordination is necessary to first agree on the common and exact steps of the CIMP.

2.4 Clinical Information Modelling Tools

Clinical information modelling tools (CIMT) are software platforms and applications designed to support the processes associated with the definition of CIM, implementation of EHR communications and systems based on CIMs as well as establishing governance for the multiple CIMs applicable within an infrastructure or domain. As has been explained, different users such as modellers, clinicians and technologists participate in CIMP and therefore multiple tools are used for the management of CIM. Model authoring tools have an important relevance to promote the adoption of good CIMP practices and to facilitate the implementation of EHR interoperable infrastructures, further information about the importance of tools in section 4.3.3.3 according to the opinion from interviewed experts in this field. Existing tools adopted as part of the CIMP can be classified under five main headings. Figure 5 depicts the main areas of functional support that CIM tools may provide, and maps the most commonly used tools to the areas they primarily support. However, it should be noted that the tools may provide some of the other functional areas to a limited extent.

2.4.1 CIM Editors

The definition of clinical information models according to a formal specification or standard is not always an easy task since it will require a minimum level of proficiency in the chosen specification. To support the definition of clinical information models there are multiple tools that

provide the means of representing the clinical information according to a particular specification. Some tools, mostly UML based (DCM-ModelCreator 2014), can define clinical information models such as DCM without being restricted to a specific implementation specification. A second group includes tools such as archetype editors (LiU Archetype Editor 2007, LinkEHR-Ed 2015, OpenEHR Modelling Tools 2016) that enable the definition of CIM based on the two levels modelling approach.

Other tools are more focused on the implementation of CIMs, this is the case of CDA editors (CDA Generator 2012) that are able to define structures for how clinical documents are modelled for communication between EHR systems according to the HL7 CDA standard.

2.4.2 Screen definition tools

Although CIM are defined mainly as an agreed definition for communication (interoperability) purposes, they will be aligned with clinical information collected by clinicians as part of the care process. As a result, there are tools that are able to define the screen layout based on the CIMs. The openEHR template designer is able to define how multiple archetypes will be displayed as final form customised for a clinical scenario (Ocean Template Designer 2013). The adoption of tools that link a screen definition to CIMs allows a team to easily visualise a user view of the CIMs they have defined, and to coordinate version management between the information layer and the presentation layer.

2.4.3 Technological Validation & Testing tools

Testing and validation tools verify system or software performance to ensure the appropriate fulfilment in an interoperability scenario. This group includes test management tools, conformance testers, interoperability validators, simulators/stubs, and test data generators. The ANTILOPE project defined a classification for testing tools, including the most relevant tools designed to support EHR interoperability (Antilope Project 2015). These tools are directly dependent on defined clinical information models but most of the available examples of testing tools (CDA Validator 2015, Gazelle 2015) are not integrated with clinical information model definition tools or repositories. The coordination of the full CIMP from requirements definition to software development and testing will improve if tools increase their capabilities to be integrated with the rest of the tools involved in this process.

2.4.4 Knowledge Managers & Repositories

Repositories are tools specially designed to host a set of clinical information models. They support tasks related with sharing and reviewing semantic artefacts with the community of users involved in the hosting organisation based on a centralised system that allows access to the defined CIMs. Large healthcare providers and other health informatics organisations may use these as an agreed and trusted storage location for clinical information models they have

chosen to adopt locally. These tools can be useful for people involved in CIMP and IT systems within a technological infrastructure (CEM Browser 2015). Multiple national and regional projects such as in Spain (Spanish Clinical model repository 2014), Australia (Australian DCM library), Sweden (Swedish archetype repository 2014), the region of Minas Gerais (Brazil) (Minas Gerais archetype repository 2012) publish their defined CIMs within repositories, represented according to the modelling specification chosen for their region.

With increased capabilities to support community-based and community-reviewed definitions of clinical information models, knowledge manager tools act as an online, collaborative, interactive repository to support editorial, coordination and validation tasks within the group of participants in CIMP. Knowledge manager tools may also support the implementation of a modelling governance process supporting the establishment of multiple roles for CIM authors, reviewers and external users (OpenEHR CKM 2014).

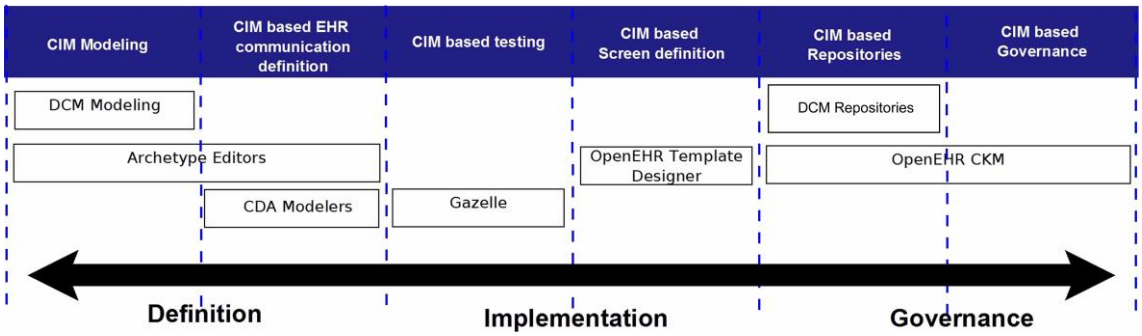


Figure 5. Classification of CIM tools

2.4.5 Other tools related to clinical knowledge management

There are additional tools that are involved in the definition and management of clinical knowledge that will be incorporated within health information systems that do not work with clinical information models but are closely related to the CIMP. Although this research considers knowledge representation by ontology modelling and terminology building as separate steps to CIMP, multiple clinical information modelling tools can benefit from (and complement) ontology or terminology management tools. CIMTs may include functionalities that facilitate the integration of CIMP with terminology and ontology management to ensure that clinical concepts are consistently applied across multiple systems.

Although the process of binding terminologies and ontology concepts to CIMs presents similarities, this chapter includes separated sections for ontology and terminology management tools based on the different functionalities that these tools support.

2.4.5.1 Ontologies

Ontologies can be incorporated into CIM editors in order to guide clinical information model definition based on the semantics of the concepts that are embedded within each node of the structure, or may be applied for validation purposes in order to verify the defined clinical information model is internally consistent (Knublauch, Musen et al. 2004).

Methodologies have also been described for how multiple domains interrelate with system design such as the Generic Component Model, identify how terminology modelling, ontology modelling are to be included as part of the software engineering process, and where clinical information modelling fits within a multi-model approach for EHR system definition (Lopez and Blobel 2009).

Similarly, the SemanticHealthNet project has defined an additional semantic layer between ontology and CIM that makes explicit the semantics of the information represented in clinical information models, in a way that can be interpreted by computers independently of the degree of granularity in which it has been provided (Martínez-Costa, Kalra et al. 2014). The formal and unambiguous representation of additional meaningful elements extends the Reference Model semantic capabilities with benefits for mapping across standards and extended query capabilities (Schulz and Martínez-Costa 2013).

In this field, Protégé is the most widely used tool for ontology editing and management (Noy, Crubézy et al. 2003). This open source tool is able to define ontologies in multiple languages such as OWL and RDF. The benefit of adopting this semantic specification is the ability of invoking reasoners that will be able to provide inferences based on the semantic relationship between concepts previously defined.

2.4.5.2 Terminologies

Terminologies are able to define clinical concepts in an agreed form without necessarily specifying all of the semantic relationships between the concepts. To support processes associated with the development, editing, maintenance and deployment of terminologies in healthcare infrastructures it is common to apply specialised software tools called terminology management systems. These tools are related to the modelling environment because clinical information modelling requires binding CIM nodes to international and local terminology codes

Some terminology management systems provide a terminology development environment that allows the collaboration of multiple terminology experts in the definition of new concepts and relationship between them (Pathak, Solbrig et al. 2009, Apelon DTS 2016, LexEVS 2016). Others have a reduced set of functionalities and act as a terminology browser showing concepts and relationships.

At a technological level, these systems are able to act as terminology servers able to coordinate the terminologies applied by multiple systems deployed in a healthcare infrastructure. The ISO/HL7 27951 Health informatics Common terminology services standard details web services to allow the query, interchange and update of terminological content between systems (ISO/HL7 27951 2009).

2.5 Interoperability Assets

According to the four levels of interoperability identified as part of the European Interoperability Framework: legal, organisational, technical and semantic, in order to achieve interoperable EHR systems that support the continuity of patient care, a level of agreement is required between implemented solutions that goes further than adopting published interoperability standards (EIF 2013). To address this aim many national eHealth programs, Standards Development Organisations, European projects and other bodies have developed formal specifications, templates, vocabularies, guidelines, and educational resources etc. that are useful and help to ensure the quality of integrated care, also across borders. Unfortunately, these are largely accessible in ad hoc ways and result in scattered fragments of a solution space that urgently need to be brought together. At present, it is known that new initiatives and projects will reinvent assets of which they were unaware, while those assets which were potentially of great value are forgotten, not maintained and eventually fall into disuse. In addition, the large number of specifications make difficult the comparison and analysis of multiple interoperability resources. Objective quality measures will be able to provide additional guidance about the suitability of adopting interoperability resources for a specific healthcare scenario.

Aligned with this identified need, the SemanticHealthNet project identified the need for a recognised point of reference at a European level that would contain relevant material for guiding the definition, development and implementation of interoperable eHealth systems and ICT solutions in Europe. As a pioneer initiative to address this need, the EXPAND project, aimed to define, design and assess the development of a European Interoperability Asset Register able to contain, classify and quality assess any relevant material for analysis, design, implementation, adoption or benefits realisation of interoperability within eHealth environments, also known as interoperability assets (IA).

This research established links with the above mentioned projects in order to define a Semantic Interoperability Quality Framework (SIQF) for a broad sample of interoperability resources known as interoperability assets. This collaboration allowed maximising the impact of this research, providing resources for implementing a European register that aims to contain interoperability resources developed by multiple organisations involved in the definition or

adoption of interoperability resources. Additional information about this register is provided in section 5.2.

2.6 Quality Specifications for Semantic Interoperability

Quality metrics are usually defined in order to develop, test and/or procure products and services that are able to satisfy a desired level of performance. These metrics are useful to allow end users and regulators to compare products and services, making it possible to determine if they can to be applied to the intended usage scenarios. This section analyses existing quality instruments that have been defined to support interoperability, providing an overview of their possible dependences and overlaps.

The definition of a quality framework for clinical information models to support semantic interoperability for EHR systems will require an analysis of how CIMs and their associated processes can be evaluated. This section summarises the metrics defined as part of the work carried out in ISO to define quality requirements associated with the CIMP for implementing a Quality Management System (ISO 13972 standard) and quality metrics to evaluate CIMs (ISO 18864 standard).

Moreover, there is a close dependence with those standards focused on data quality models such as ISO/IEC 25000 – the SquaRE standard. This section details the metrics defined in this standard for system and software quality requirements in order to identify metrics that could be incorporated as part of the SIQF.

Lastly, such framework must be integrated within implemented processes for establishing quality management systems, testing, certification and accreditation. This section includes an example about how could be implemented a Quality Management Systems based on ISO9000 for interoperability testing. This example is relevant for defining in future sections a Quality Management System for CIMP.

2.6.1 Quality processes for Clinical information modelling

Quality processes were defined within part 1 of the ISO 13972 standard - Detailed Clinical Models. This standard recommends the participation of a broad set of clinicians/users within the definition and validation stages to ensure that defined Detailed Clinical Models (DCMs) are able to fully meet the intended scope and requirements. This standard recommends establishing a structure of committees to provide a governance process for DCMs that will

define how modelling processes will be managed, to determine which models will be developed, who will participate, how inputs from experts will be collected and the level of consensus required. As was detailed in section 2.2.3, DCM is considered as a logical model that defines representations of clinical concepts independent of its implementation. In contrast, CIM is defined as a wider term that also covers the implementable version of the models. Nevertheless, the requirements and quality metrics defined as part of this standard for DCMs are also applicable to CIMs.

2.6.2 Clinical information models quality metrics

A new work item has been recently started in ISO to develop a technical specification for a set of quality metrics to objectively evaluate CIMs. This ISO/DTS 18864 Health Informatics - Quality Metrics for detailed clinical models aims to be used to support the development process of clinical information models. Also, based on this quantitative assessment, it expected that clinical users and IT developers would benefit from better decision making when selecting existing CIMs. They can use the metrics to select clinical information models for their specific use case and implement them in their clinical systems. This work item is based on the results obtained in a Delphi study carried out with 9 international experts about this topic (Ahn, Huff et al. 2013). In this case, the requirements and quality metrics defined as part of this standard for DCMs are also applicable to CIMs.

This specification defined metrics to evaluate design and development and governance that are closely related with the results obtained in this research. Moreover, there is a set of metrics that evaluate individual CIM and data elements according to multiple characteristics such as defined metadata, the representation standard applied and terminology binding. Based on the metrics, proposed clinical information models can be compared and evaluated in a systematic and objective manner.

2.6.3 ISO/IEC 25000 – SquaRE standard

The ISO/IEC 25000 standard for Systems and software Quality Requirements and Evaluation (SQUARE) specifies requirements and recommendations to implement and manage product quality in software and systems. . SQUARE defines three quality models addressing the final product, how the product is used and data (ISO/IEC 25000-SquaRE standard 2014).

Especially relevant for this research is the SQUARE data quality model that includes the following areas: (i) accuracy, (ii) completeness, (iii) consistency, (iv) credibility, (v) currency, (vi) accessibility, (vii) compliance, (viii) confidentiality, (ix) efficiency, (x) precision, (xi) traceability, (xii) understandability, (xiii) availability, (xiv) portability and (xv) recoverability. Some of these identified major dimensions for data quality will need to be included within the evaluation of CIMs due to their impact on semantic interoperability.

2.6.4 Deployment of interoperable solutions

In order to deploy a system, the Antilope project defined a quality manual that details how to adopt the Quality Management System (QMS) for Interoperability Testing and interoperability testing processes (Antilope Project 2013). This QMS is defined as a continuous improvement cycle. The definition of a "Plan, Do, Check, Act" (PDCA) cycle promotes the continuous adaptation of processes and measurements within each of the steps to obtain improved quality in the final product based ISO 9000 family of standards (ISO 9000 2005). This is represented in Figure 6 as the Deming cycle. The definition of a QMS will include a set of policies, processes and supportive documentation in order to allow the establishment of a consistent PDCA cycle within the organization. As well, in order to include competences for interoperability testing of applications within the eHealth domain recommendations for Interoperability, Testing Processes were defined based on the ISO 17000 series.

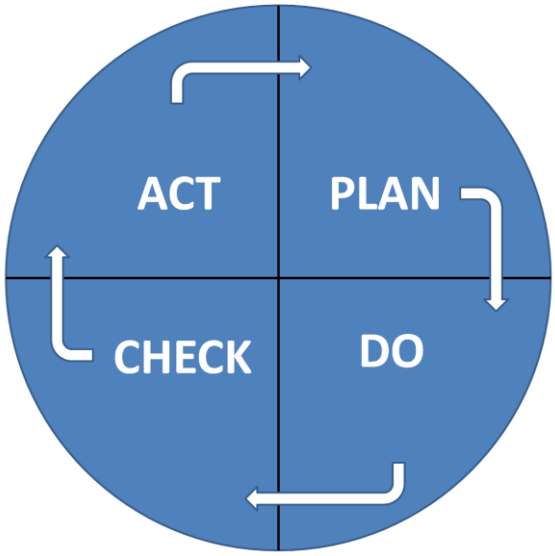


Figure 6. PDCA cycle (source: The Deming wheel. named after W. Edwards Deming. A model for continuous improvement)

2.7 Summary of the background chapter

Clinical information models: This section detailed the multiple specifications applicable for structuring clinical information within EHR system that have been published by SDOs and health informatics organisations. They were classified into three groups to allow the reader to understand the multiple modelling approaches that they propose. Moreover, in order to define requirements for clinical information modelling without being restricted to one specific

technological solution, this thesis defined the term Clinical Information Model as a concept able to be implemented using any of the detailed EHR specifications.

Clinical information modelling process: This section provided a description about relevant factors associated with the CIMP and detailed some of the most relevant modelling initiatives. Moreover, there were analysed the similarities and differences of CIMP with the Software Development Process.

Clinical Information Modelling Tools: Aligned with the needs for CIM edition, revision, validation and publication, the most relevant tools applicable in the clinical information modelling field were detailed. Tools were described and classified according to the main role they play in this process.

Quality Standards: In order to be able to identify objective metrics able to measure relevant characteristics associated with semantic interoperability resources, the existing quality standards and draft specifications that could contribute towards the definition of a SIQF were explained. The requirements identified in the above-described quality standards will be applied to propose a framework composed of a set of quality models able to characterise and evaluate the quality associated with CIMs. The previously identified quality standards are relevant for:

- Defining quality management systems associated with development processes (ISO 9000 2005).
- Defining of quality metrics or requirements for CIMs and associated processes (ISO 13972 2014, ISO/DTS 13972 2014, ISO/DTS 13972 2015)
- Defining of quality in use, quality product and data quality models for software and systems, which are products closely related to CIMs (ISO/IEC 25010 2011).

It is expected that results obtained in the multiple research studies carried out as part of this thesis will be able to identify additional attributes from CIMs and their development processes in order to objectively determine to what level each specific CIM can satisfy user needs. The next chapter explains with further detail how the presented quality standards fit in the SIQF.

Chapter 3. Proposed Semantic Interoperability Quality Framework

3.1 Introduction

This chapter describes the general methodology applied for defining and implementing a semantic interoperability quality framework addressing the quality development process, product quality and quality in use. Further, this chapter details the connections established between this research and relevant European projects and the relationships to relevant quality standards.

3.2 Reference standards

In order to develop a semantic interoperability quality framework based on CIMs, this research defined a methodology that connected multiple research studies to determine a comprehensive set of requirements for the CIM field. These quality requirements could be applied to support the efficient, reliable and trustworthy quality labelling and certification of the interoperability capabilities of healthcare information resources and/or systems.

As has been described in section 2.6, the definition of a quality framework for semantic interoperability has been identified as a need for supporting the quality of care, patient safety, reducing redundant tests, promoting continuity of care and facilitating clinical research. The proposed SIQF is based on the following reference quality standards:

- ISO 9000: Quality Management Systems
- ISO 18864: Quality Metrics for Detailed Clinical Models
- ISO 13972: Health informatics Detailed Clinical Models
- ISO/IEC 25000: Systems and software engineering -- Systems and software Quality Requirements and Evaluation (SQuaRE)

In order to facilitate the management of quality requirements and quality evaluation of the proposed framework the multiple characteristics related with semantic interoperability and their relationships identified were classified under three quality models:

- **Quality development process model:** This dimension includes the human and organisational factors that are required for defining, drafting, reviewing and publishing CIMs. There are also technical functionalities in those tools used during the process of defining and maintaining CIMs that could have an impact on their resultant quality. The

adoption of appropriate processes and tools should promote consistent definitions across diverse authoring teams, for example by ensuring appropriate validation of stakeholders who are independent from the CIM definition team.

- **Product quality model:** The definition of objective requirements for meta-data, data elements and terminology bindings in a CIM, which could allow a potential adopter to determine what level of semantic interoperability it may support.
- **Quality in use:** is defined as the "degree to which a product or system can be used by specific users to meet their needs to achieve specific goals with effectiveness, efficiency, freedom from risk and satisfaction in specific contexts of use" (ISO/IEC 25010 2011). It includes specific measurements for usability and evidence.

Figure 7 details the list of reference standards that were applied for defining each individual quality models.

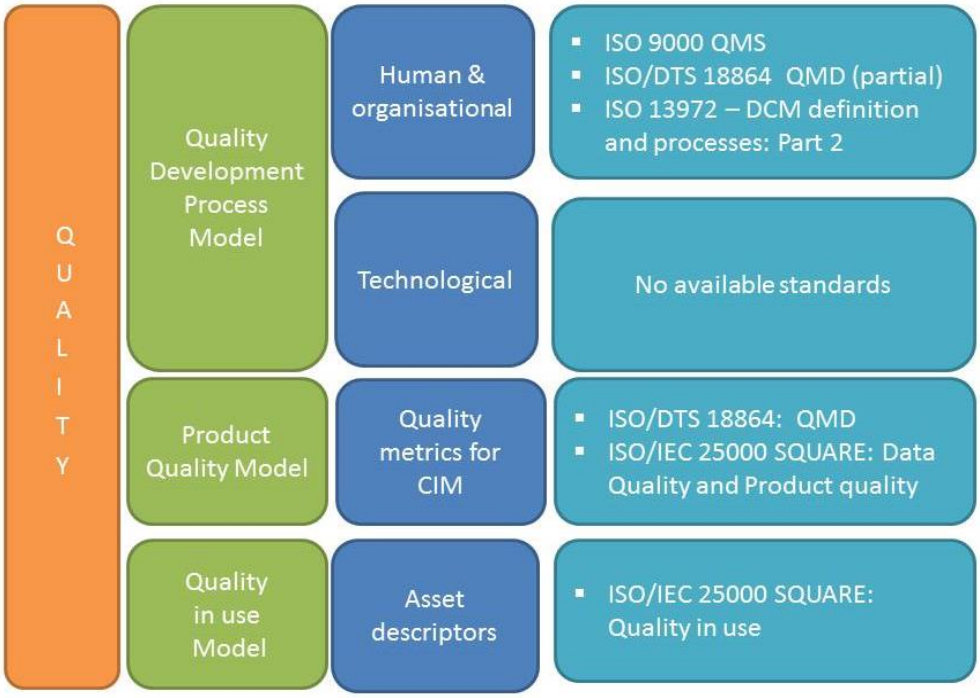


Figure 7. Relationship of SIQF with reference quality standards

3.2.1 SIQF Relationship with reference quality standards

This section details how the multiple reference standards fit with the multiple quality models included as part of the SIQF. This thesis analysed possible requirements that could be incorporated from multiple quality standards. Among the four standards identified, ISO18864 and ISO13972 are especially relevant since they have been specifically designed for the semantic interoperability field.

3.2.1.1 ISO 9000: Quality Management System

The definition of a quality management system is based on the process approach. The definition of a quality development process for semantic interoperability resources is the basis to establish a quality management system for semantic interoperability according to the ISO 9001 standard. This is a common practice in the adoption of the ISO 9000 standards and there are previous examples such as the definition of an adaptation of the standard to a specific domain. As previously detailed, this approach was adopted by the Antilope project to define a Quality Management System for Interoperability Testing. Another example is the guideline created for the application of QMS to computer software (ISO 90003 2014) that is based on the Software Life Cycle Process (ISO/IEC 12207 2008).

The definition of a process that is able to be mapped to those requirements identified in the ISO 9000 standard series will facilitate the adoption of quality management systems for semantic interoperability. Next is presented the ISO13972 standard that aimed to define how can be implemented Quality Management System for the processes associated with clinical information modelling.

3.2.1.2 ISO 13972: Detailed Clinical Models Definition and Processes

This standard describes the quality processes that will lead to the good definition of detailed clinical models. Moreover, the standard details a set of testable quality attributes of these resulting models and how to implement a Quality Management System for CIMP. A detailed analysis about the alignment of the multiple metrics included as part of ISO 13972 standard with the requirements identified as part of the development process quality model is detailed in section 4.8.

3.2.1.3 ISO/DTS 18864 Quality Metrics for DCM

The scope of the QMD standard could be directly mapped within the Product Quality Model and the Quality Development process model described as part of the SIQF. A detailed analysis of the alignment of the multiple metrics included as part of the ISO 18864 draft standard with the requirements identified as part of the development process quality model is detailed in section 4.7.

3.2.1.4 ISO 25000 SQUARE

The SQUARE standard applies three quality models to describe the quality characteristics (Product quality model, Quality in use model, Data quality model). SQUARE standards evaluate many properties related to systems that are not relevant to semantic interoperability such as hardware, source code documentation, recoverability of data in case of failure, system performance and many others. Given that semantic interoperability is a functionality that has to

be implemented in software systems, the SQUARE standard has a broader scope than the proposed SIQF and is used to evaluate many different products.

The SIQF is proposed as a product quality model that inherits a subset of those characteristics identified as part of the SQUARE Data quality model. The proposed subset of characteristics excludes those that are system dependent. This set of characteristics will be complemented by those identified in the multiple studies carried out as part of this thesis.

3.3 Standardisation process for semantic interoperability quality standards

The evaluation of some of the quality models defined as part of the SIQF is already in the ISO and CEN standardisation roadmap. Figure 8 details how the multiple evaluation standards are aligned with the SIQF. A couple of standards are at the thesis submission time still in the development stage. Our obtained results with the identification of requirements and quality metrics for SIQF were compared with the related draft quality standards:

- **The ISO 13972 draft standard** details the processes for development, application and governance of CIMs including a Quality Management System (QMS) based on the ISO 9001 standard. This is expected to be the first step to establishing a certification program for those organisations working on the definition of CIMs.
- **ISO18864 draft standard** is expected to become the international instrument for certifying and quality labelling CIMs. The standard aims to develop a set of quality metrics to evaluate CIM representation of information, metadata, development process and compliance to technological standards.

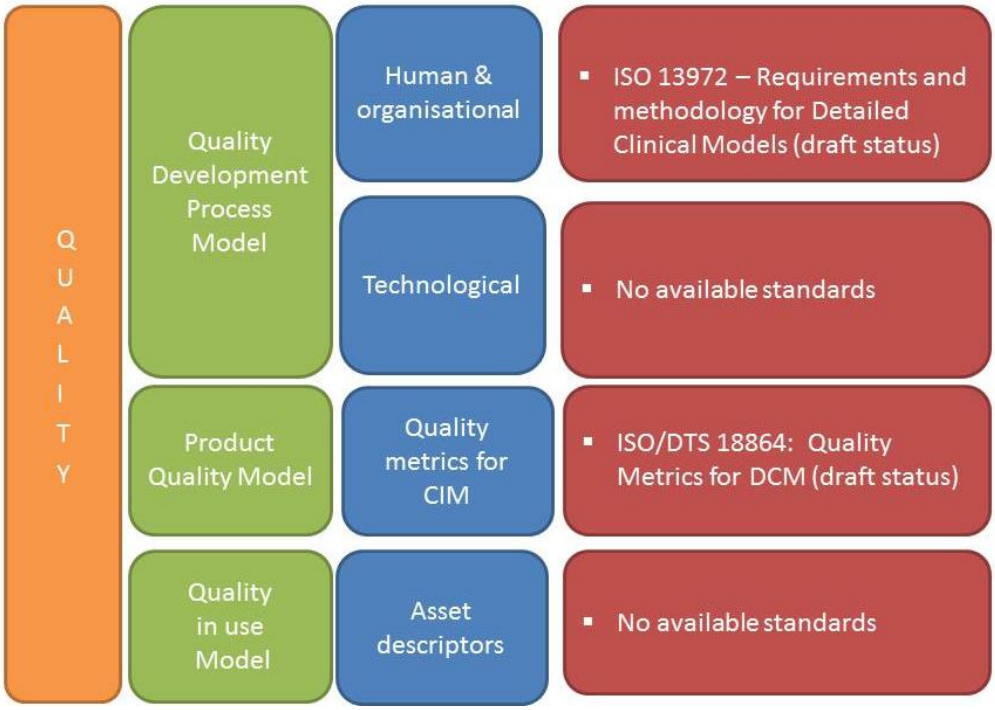


Figure 8. Standards that aim to evaluate the individual quality models

3.4 Overarching methodology

3.4.1 Exploratory stage

This research started with an exploratory stage focused on understanding those factors associated with EHR semantic interoperability. A systematic literature review was performed about development processes associated with semantic interoperability in EHR systems. Based on the obtained results, it was determined that it was required to obtain further detail about the processes associated with clinical information modelling. As a consequence, an international survey was undertaken about the currently-adopted methodologies and barriers associated with the definition of functional requirements and clinical information modelling for EHR systems. This research focused on collecting experiences from experts involved in tasks associated with the definition of CIMs for EHR systems. The analysis of the reported experiences was applied to define requirements, metrics and recommendations addressing the human, organisational and technological issues associated with the development of interoperability resources.

Lastly, additional requirements were collected through multiple workshops organised by the EXPAND project, plus direct interactions with experts from multiple countries about their perception of the relevant information that they require in order to decide the suitability for

adopting existing interoperability resources. This research focused on collecting the opinion of decision makers and end users that aimed to reuse existing interoperability resources.

3.4.2 Definition of the quality models

The information collected was applied to define the following set of requirements and metrics aligned with each of the quality models defined as part of the SIQF:

Development process quality model: Multiple stages associated with the CIMP were defined, including requirements to ensure that the most relevant barriers associated with this process could be overcome. The defined requirements for CIMP were mapped to the ISO13972 standard in order to support its review process carried out by Technical Committee (TC) 251 in ISO. A set of functional requirements were proposed for those tools used as part of the CIMP. These requirements for CIM Tools (CIMT) led to the definition of quality metrics that were prioritised and validated based on a Delphi study and by testing the metrics against existing tools.

- **Quality in use model:** Based on workshops and consultations with a representative sample of experts a set of metrics were defined to evaluate the suitability of adopting interoperability resources by end users as part of their local projects and organisations. These metrics were focused mainly on technical and semantic interoperability assets. The proposed quality model was tested with real examples and a survey was performed for assessing the end user agreement.

- **Product quality model:** The defined requirements for CIMP were mapped to the ISO18864 standard in order to support its definition process carried out by TC251 in ISO.

3.4.3 Implementation

The defined quality framework was implemented in a platform that acts as a register for quality assurance, updating, version-managing, distributing and auditing pan-European interoperability resources. This European register for interoperability assets was implemented as a result of the collaboration with the EXPAND project. The defined quality metrics were designed primarily to satisfy the needs of technical and semantic interoperability assets. Moreover, a subset of these metrics was identified to be suitable to also characterise organisational, legal or methodological assets. This was aligned with the wider scope of the EXPAND project.

Figure 9 details the chronological order of the individual research studies carried out in this thesis. Figure 10 shows how outputs of the individual studies are inter-related within the SIQF.

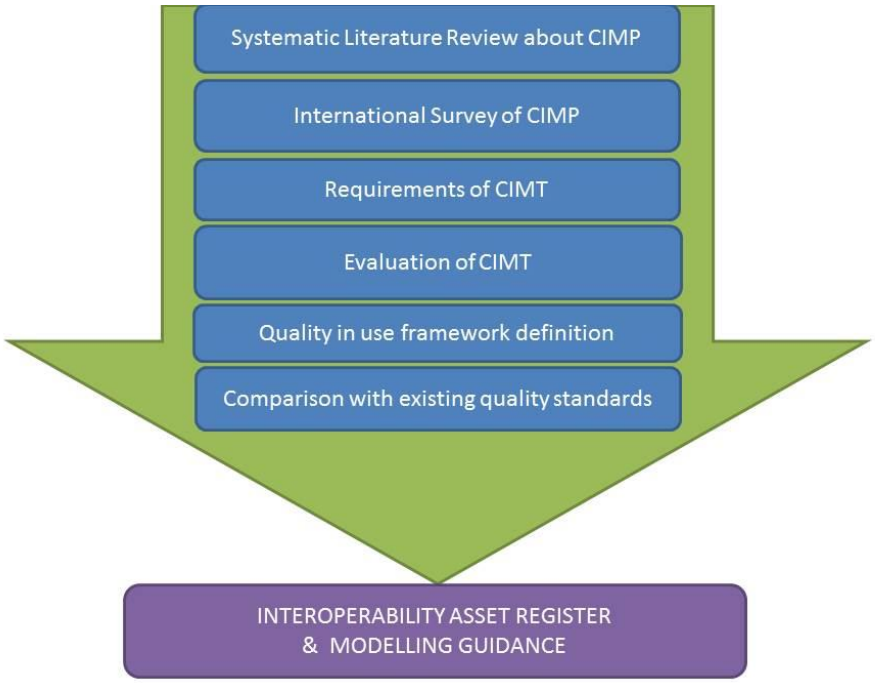


Figure 9. Overview of the research studies carried out in this thesis

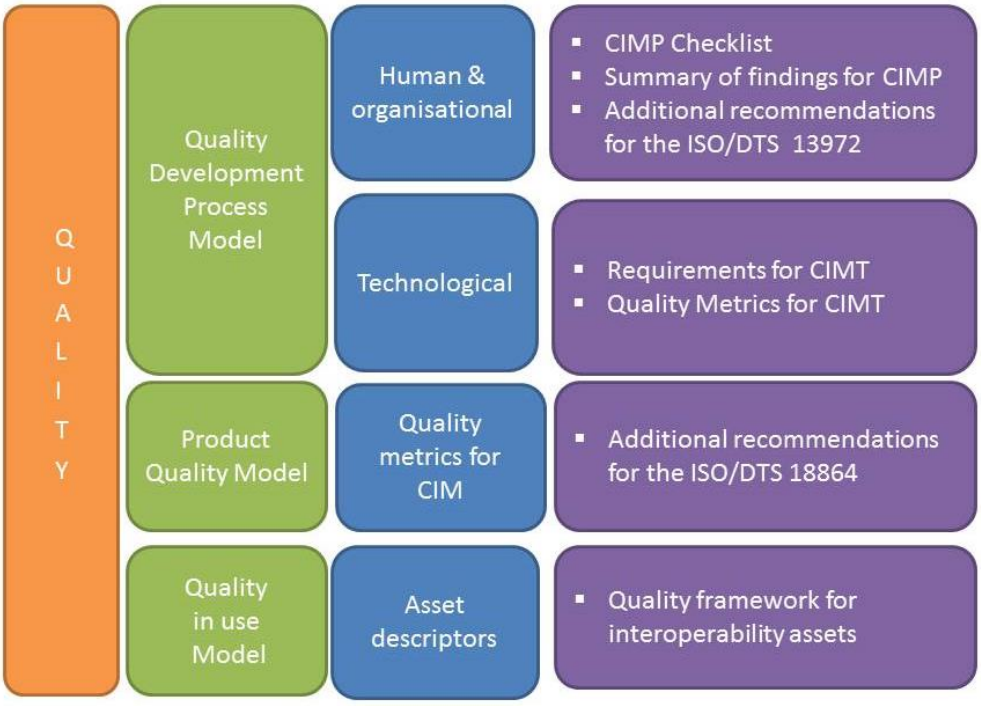


Figure 10. Mapping the outputs of this thesis with the Semantic Interoperability Quality Framework

3.5 Collaboration with European projects

As part of this research the author collaborated as a partner or invited expert within the following projects, contributing towards achieving their objectives:

- **SemanticHealthNet Project** (Grant agreement no.: 288408) was a Network of Excellence that aimed to develop a scalable and sustainable organisational and governance process for the semantic interoperability of clinical and biomedical knowledge at a European level. This project was focused on producing informatics resources to support semantic interoperability for the management of chronic heart failure and cardiovascular prevention. EHR architectures, clinical data structures, terminologies and ontology were defined based on existing European consensus for supporting patient care, public health and clinical research across healthcare systems and institutions. This was obtained with the participation of Clinical and Industrial Advisory Boards composed of members from Health authorities, clinical professionals, ministries, vendors, purchasers, insurers and some of the most influential European projects in the health informatics domain. The presented research contributed to this project through tasks related to the development of the following deliverables:
    - D3.1 Initial methodology for developing semantic interoperability resources,
    - D3.2- Generalised methodology and analysis framework for semantic interoperability,
    - D5.1 Quality criteria & proposals for certification of semantically interoperable resources and systems
    - D5.2. Design and roadmap for a semantic interoperability infostructure
- **EXPAND project** (grant agreement no: 620980) was a Thematic Network that aimed to provide support to Member States in the deployment of eHealth plans and cross-border care. EXPAND promoted the maintenance and expansion of the already available infostructure resources such as those developed in the epSOS and other European projects. In order to promote these assets, it was required to define quality criteria and assessment processes for interoperability assets. The presented research contributed to this project through tasks related to the development of the following deliverables:
    - D4.2 Quality labelling criteria for European eHealth interoperability resources

Chapter 4. Individual research studies

4.1 Introduction

This chapter details the multiple research studies carried out as part of this thesis in order to define and implement a Semantic Interoperability Quality Framework for interoperability assets.

Systematic literature review and international survey on modelling practices

The chapter starts with the analysis of the existing literature that provides a first description of the CIMP. This research was complemented by the international survey of modelling initiatives, based on semi-structured interviews, which was able to further describe the processes, barriers and recommendations associated with this process.

Requirements and evaluation of Clinical Information Modelling Tools

Given that the multiple experts reported during the performed interviews that existing CIMT presented limitations in the support of the modelling process, the identified recommendations about the CIMP were applied to define a set of requirements for CIMTs that were prioritised based on expert opinion collected through a Delphi study. The most relevant requirements were declared as essential and translated into quality metrics in order to evaluate existing CIMTs.

Interoperability Asset Quality Framework

Through an iterative process for collecting multiple stakeholder needs based on workshops, online and face to face meetings, a set of metrics was defined to characterise interoperability assets from end user quality, acceptance and re-usability points of view. The metrics were validated through an online survey with a sample of experts from this field.

Comparison with Quality Standards

The multiple metrics identified in the previous research studies were compared with the quality metrics proposed in ISO 188064 and the ISO 13972 draft standards in order to evaluate the level of alignment and identify areas of improvement in these standards.

4.2 Systematic literature review

4.2.1 Research objective

This study aimed to identify and compare the existing clinical information modelling processes and methodologies that were published in the literature. In particular, a systematic review and

an inductive content analysis were performed in order to learn about methodologies and experiences in building CIMs for semantically interoperable EHR systems. The question being addressed in this study was to discover if an emergent consensus (good practice) strategy in building CIM artefacts exists; and to know if it is therefore possible to propose a common or unified CIMP.

4.2.2 Methodology

In order to perform the systematic review of the existing literature we chose the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) methodology (Moher, Liberati et al. 2009). This methodology proposed a 27 item checklist and a flow diagram in order to guide the authors during the conduct of a systematic review (PRISMA 2015).

The eligibility criteria, i.e. the characteristics to be taken into account to perform the search, were:

- Papers with any of the following terms in their title or abstract: “Electronic Health Record”, “Hospital Information System”, “Clinical Information System”, “Health Information System”, “EHR”, “medical record system”, “automated medical systems”, “Electronic Medical Record”.
- Papers with the terms “semantic interoperability” or “clinical information model” in their title or abstract.
- Published between January 2000 and August 2013 (the date of the review).

When deciding on the search criteria, it was preferred to have a broad scope focused on the semantic interoperability for EHRs rather than searching for each of the specific EHR mechanisms that could be applied for clinical information modelling such as “archetype” or “template”. The variability of terms and technologies related to the definition of CIMs was so broad that we needed to avoid the risk of leaving out important references or experiences that used formalisms such as object-oriented models, entity-relationship models, XML Schemas or ontologies. The inclusion of the semantic interoperability filter helped in excluding EHR traditional development experiences that did not have a focus on the reuse of the information structures that were developed.

4.2.2.1 Searches performed in databases

The sources of information where the search was performed were PubMed (PUBMED 2015), IEEE Xplore (IEEEXplore 2015) and ScienceDirect (ScienceDirect 2015). The performed search queries applied the selected databases are presented in table 2.

Database	Search Query
PubMed	("electronic health records"[MeSH Terms] OR "hospital information systems"[MeSH Terms] OR "health information systems"[MeSH Terms] OR "electronic health records"[Title/Abstract] OR "electronic medical records"[Title/Abstract] OR "clinical information systems"[Title/Abstract] OR EHR[Title/Abstract] OR medical records systems[Title/Abstract] OR automated medical systems[Title/Abstract] OR "Health Information Systems"[Title/Abstract]) AND ("clinical information model"[Title/Abstract] OR "semantic interoperability"[Title/Abstract]) AND ("2000/01/01"[PDAT] : "2013/08/30"[PDAT])
ScienceDirect	(("electronic health records" OR "health information systems" OR "electronic medical records" OR "hospital information systems" OR "EHR" OR "clinical information systems" OR "medical record systems" OR "automated medical record systems") AND ("semantic interoperability" OR "clinical information model"))
IEEE Xplore	(("Abstract": “Electronic Health Record” OR "Document Title": “Electronic Health Record” OR "Abstract": “electronic medical record” OR "Document Title": “electronic medical record” OR "Abstract": “clinical information system” OR "Document Title": “clinical information system” OR "Abstract": “hospital information system” OR "Document Title": “hospital information system” OR "Abstract": “automated medical system” OR "Document Title": “automated medical system” OR "Abstract": “Health Information System” OR "Document Title": “Health Information System” OR "Abstract": “EHR” OR "Document Title": “EHR” OR "Abstract": “medical records system” OR "Document Title": “medical records system”) AND (("Abstract": “clinical information model” OR "Document Title": “clinical information model”) OR (Abstract:"semantic interoperability" OR "Document Title": "semantic interoperability")))

Table 2. Search queries in databases

4.2.2.2 Review process

According to the PRISMA methodology, a two-phase procedure was established for the systematic review. In Phase 1 (study screening) a first review was made based on the title and abstract of the papers returned as result of the queries. Two additional exclusion criteria were adopted: (a) the paper does not include information about CIMs, and (b) the paper does not include information about CIMP. In case of doubt due to the limited information available in the titles and abstracts, the papers were accepted for full review. In Phase 2 (full review) the full text of the selected papers was reviewed. The objective of this full review was twofold: to reject

those papers that did not fit the purpose of the systematic review and, only from those that were finally accepted, to extract a set of data items and indicators to perform further analysis.

In addition to the systematic review, an inductive analysis was performed to discover the CIMP steps described in the selected papers. A methodology called Inductive Content Analysis was applied (Elo and Kyngäs 2008). This methodology was recommended to avoid creating preconceived categories when the existing literature is limited or heterogeneous. According to this methodology, a set of tags that qualify the CIM definition processes described at the selected papers were iteratively refined to represent an abstraction of CIMP steps. The information about the modelling processes was organised into categories, in order to provide a high level and summarized description of those steps.

4.2.2.3 Research team

This research study was carried out in collaboration with a team of six researchers (including the thesis supervisor) who collaborated with the author in tasks related with manuscript screening and peer review. They reviewed the results of the inductive content analysis performed by the author. They contributed and approved the interpretation of the obtained results.

4.2.3 Results

As a result of the literature search described in methodology section, 374 papers were found, of which 18 were duplicates. Additionally, the authors identified four extra references that met the search criteria and were relevant to the review, but not indexed by the search engines. In total, 360 paper titles and abstracts were screened by the authors, and 53 of them were accepted for a full-text review, through which it was discovered that only 36 papers contained relevant data for the objectives of this research. The summary of this review process is presented in Figure 11.

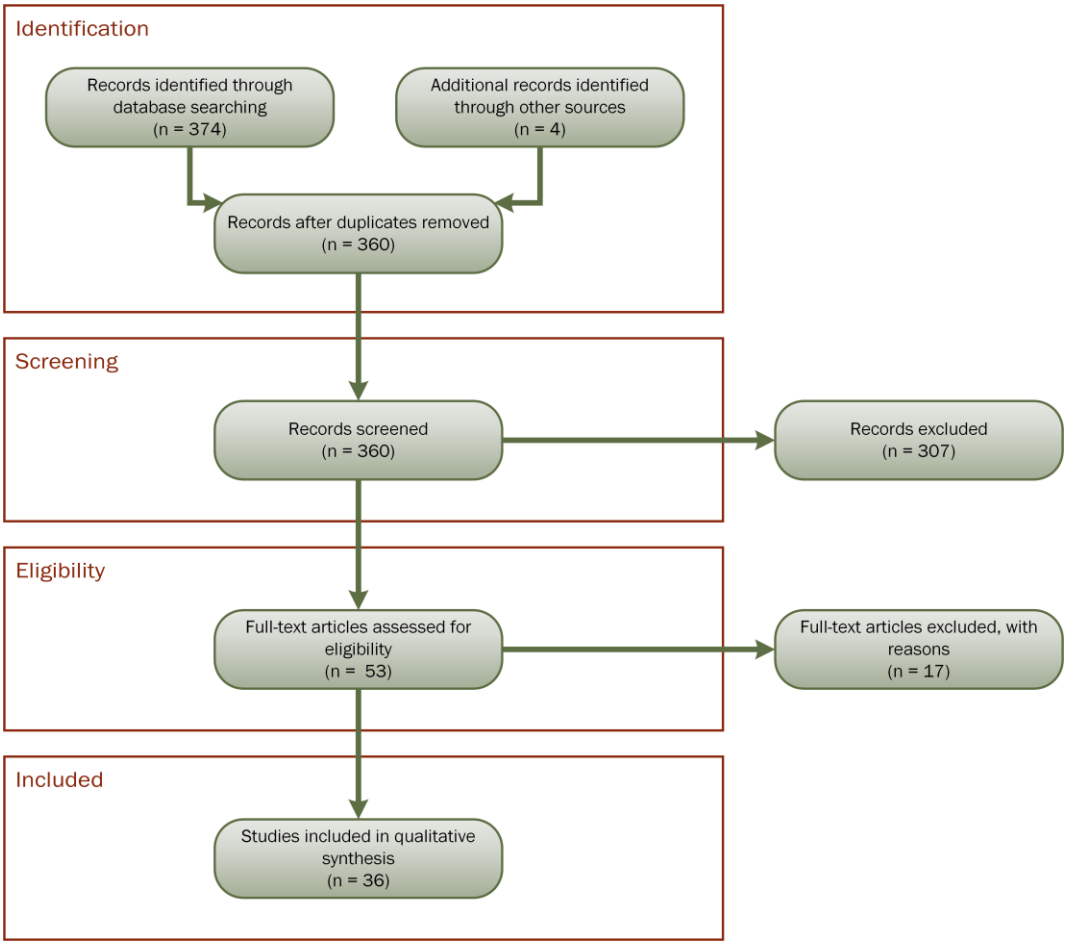


Figure 11. Summary of the systematic review process

The main reasons for exclusion were that the analysed papers did not contain information about modelling or clinical information models. In three cases the full text of the articles was not available. Table 3 shows the annual distribution of the selected papers. Note that the search in 2013 only included the period between January and August.

Year	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013
No. of papers	1	0	0	3	4	6	4	4	8	6

Table 3. Annual distribution of papers

4.2.3.1 Analysis of indicators from published literature

50% of the selected papers were focused on one specialized care department, while the others were focused on multiple departments, national/regional projects or described a theoretical approach. The papers cover a large variety of clinical domains, including nursing, oncology, neonatology, genetics or infectious diseases. Most of the papers (83.3%) described a real deployment. 73.2% of the papers also mentioned the participation of health professionals during the development process. Table 4 details a summary of the information collected in the paper

review associated with the clinical domains where CIMP was applied, the participation of health professionals and their implemented in real environment.

Indicator	Values	References	Total (%)
Application domains	Theoretic application	(Goossen, Goossen-Baremans et al. 2010), (Muñoz Carrero, Romero Gutiérrez et al. 2013)], (Kalra and Carpenter 2012), (Moner, Maldonado et al. 2010), (Lopez and Blobel 2008)	5 (13.9)
	Regional / national projects	(Santos, Bax et al. 2012), (Lopez and Blobel 2009), (Lopez and Blobel 2008), (Jian, Hsu et al. 2007), (Buyl and Nyssen 2009)	5 (13.9)
	One healthcare department	(Rinner, Kohler et al. 2011), (Hsu, Taira et al. 2012), (Anderson, Weintraub et al. 2013), (Spigolon and Moro 2012), (Liu, Wang et al. 2008), (Knaup, Garde et al. 2007), (Goossen, Ozbolt et al. 2004), (Garcia, Moro et al. 2012), (Duftschmid, Rinner et al. 2013), (Buck, Garde et al. 2009), (Kim and Park 2011), (Späth and Grimson 2011), (Nagy, Hanzlicek et al. 2010), (Dias, Cook et al. 2011), (Garde, Hovenga et al. 2007), (Marcos, Maldonado et al. 2013), (Moner, Moreno et al. 2012), (Hoy, Hardiker et al. 2009)	18 (50.0)
	Multiple healthcare departments	(Smith and Kalra 2008), (Jing, Kay et al. 2012), (Yuksel and Dogac 2011), (Kohl, Garde et al. 2009), (Leslie 2008), (Puentes, Roux et al. 2012) (Liu, Wang et al. 2010), (Khan, Hussain et al. 2013)	8 (22.2)
Implementation in real environment	Yes	(Goossen, Goossen-Baremans et al. 2010), (Rinner, Kohler et al. 2011), (Santos, Bax et al. 2012), (Hsu, Taira et al. 2012), (Anderson, Weintraub et al. 2013), (Puentes, Roux et al. 2012), (Leslie 2008), (Liu, Wang et al. 2010), (Lopez and Blobel 2009) , (Liu, Wang et al. 2008), (Knaup, Garde et al. 2007), (Kim and Park 2011), (Khan, Hussain et al. 2013), (Hoy, Hardiker et al. 2009), (Garcia, Moro et al. 2012), (Duftschmid, Rinner et al. 2013), (Buck, Garde et al. 2009), (Smith and Kalra 2008), (Späth and Grimson 2011), (Spigolon and Moro 2012), (Nagy, Hanzlicek et al. 2010), (Dias, Cook et al. 2011), (Garde, Hovenga et al. 2007), (Marcos, Maldonado et al. 2013), (Moner, Maldonado et al. 2010), (Lopez and Blobel 2009), (Lopez and Blobel 2008), (Kohl, Garde et al. 2009), (Jian, Hsu et al. 2007), (Buyl and Nyssen 2009)	30 (83.3)
	No	(Kalra and Carpenter 2012), (Muñoz Carrero, Romero Gutiérrez et al. 2013), (Goossen, Ozbolt et al. 2004), (Jing, Kay et al. 2012)	4 (13.9)
	Not specified	(Moner, Moreno et al. 2012), (Yuksel and Dogac 2011)	2 (5.6)
Participation of health professionals	Yes	(Goossen, Goossen-Baremans et al. 2010), (Rinner, Kohler et al. 2011), (Muñoz Carrero, Romero Gutiérrez et al. 2013), (Santos, Bax et al. 2012), (Hsu, Taira et al. 2012), (Anderson, Weintraub et al. 2013), (Leslie 2008), (Liu, Wang	26 (73.2)

		et al. 2010), (Knaup, Garde et al. 2007), (Kim and Park 2011), (Khan, Hussain et al. 2013), (Hoy, Hardiker et al. 2009), (Goossen, Ozbolt et al. 2004), (Garcia, Moro et al. 2012), (Duftschmid, Rinner et al. 2013), (Buck, Garde et al. 2009), (Smith and Kalra 2008), (Spigolon and Moro 2012), (Nagy, Hanzlicek et al. 2010), (Dias, Cook et al. 2011), (Garde, Hovenga et al. 2007), (Marcos, Maldonado et al. 2013), (Moner, Maldonado et al. 2010), (Jing, Kay et al. 2012), (Jian, Hsu et al. 2007), (Buyl and Nyssen 2009)	
	Not specified	(Kalra and Carpenter 2012), (Puentes, Roux et al. 2012), (Lopez and Blobel 2009), (Liu, Wang et al. 2008), (Späth and Grimson 2011), (Lopez and Blobel 2009), (Lopez and Blobel 2008), (D, Sebastian et al. 2010), (Moner, Moreno et al. 2012), (Yuksel and Dogac 2011)	10 (27.8)

Table 4. Indicators associated with application domain, participation of healthcare professionals and implementation in real environment

The preferred type of technical artefacts used to implement CIMs were archetypes (44.4%) followed by HL7 templates (25.0%). Regarding the reference models used for the definition of CIMs, openEHR (25.0%), HL7 v3 (25.0% including messages and CDA), and EN ISO 13606 (16.7%) were the most mentioned. Other works made use of proprietary reference models, expressed in UML, XML or as ontologies. Table 5 details the type of CIM and Reference Model applied in the analysed papers.

Indicator	Values	References	Total (%)
Type of CIM	HL7 templates	(Yuksel and Dogac 2011), (Nagy, Hanzlicek et al. 2010), (Lopez and Blobel 2009), (Lopez and Blobel 2009), (Lopez and Blobel 2008), (Knaup, Garde et al. 2007), (Goossen, Ozbolt et al. 2004), (Anderson, Weintraub et al. 2013), (Jian, Hsu et al. 2007)	9 (25.0)
	EN ISO 13606 or openEHR archetypes	(Spigolon and Moro 2012), (Späth and Grimson 2011) , (Smith and Kalra 2008), (Santos, Bax et al. 2012), (Moner, Moreno et al. 2012), (Moner, Maldonado et al. 2010), (Marcos, Maldonado et al. 2013), (Leslie 2008), (Kohl, Garde et al. 2009), (Garde, Hovenga et al. 2007), (Garcia, Moro et al. 2012), (Duftschmid, Rinner et al. 2013), (Dias, Cook et al. 2011), (Buck, Garde et al. 2009), (Rinner, Kohler et al. 2011), (Muñoz Carrero, Romero Gutiérrez et al. 2013)	16 (44.4)
	Other	(Puentes, Roux et al. 2012), (Liu, Wang et al. 2010), (Liu, Wang et al. 2008), (Kim and Park 2011), (Khan, Hussain et al. 2013), (Jing, Kay et al. 2012), (Hsu, Taira et al. 2012), (Hoy, Hardiker et al. 2009), (Goossen, Goossen-Baremans et al. 2010), (Kalra and Carpenter 2012), (Buyl and Nyssen 2009)	11 (30.6)
Reference Model	HL7 v3 / HL7 CDA	(Anderson, Weintraub et al. 2013), (Lopez and Blobel 2009), (Knaup, Garde et al. 2007), (Nagy, Hanzlicek et al. 2010), (Lopez and Blobel 2009), (Goossen, Ozbolt et al. 2004), (Moner, Moreno et al. 2012), (Yuksel and Dogac 2011),	9 (25.0)

		(Jian, Hsu et al. 2007)	
	openEHR	(Leslie 2008), (Garcia, Moro et al. 2012), (Buck, Garde et al. 2009), (Späth and Grimson 2011), (Spigolon and Moro 2012), (Dias, Cook et al. 2011), (Garde, Hovenga et al. 2007), (Marcos, Maldonado et al. 2013), (Kohl, Garde et al. 2009)	9 (25.0)
	EN ISO 13606	(Rinner, Kohler et al. 2011),]], (Santos, Bax et al. 2012), (Duftschmid, Rinner et al. 2013), (Smith and Kalra 2008), (Moner, Maldonado et al. 2010)	6 (16.7)
	Other	(Goossen, Goossen-Baremans et al. 2010), (Kalra and Carpenter 2012), (Hsu, Taira et al. 2012), (Puentes, Roux et al. 2012), (Liu, Wang et al. 2010), (Liu, Wang et al. 2008), (Kim and Park 2011), (Khan, Hussain et al. 2013), (Hoy, Hardiker et al. 2009), (Lopez and Blobel 2008), (Jing, Kay et al. 2012), (Buyl and Nyssen 2009)	12 (36.1)

Table 5. Indicators associated with the type of CIM and Reference Model applied in the analysed papers

All the references included in this systematic review apply a CIMP for defining CIMs, but only 52.8% of them described it with some degree of detail, and even then usually quite superficially. Table 6 shows the papers that provide a description of the CIMP.

Indicator	Values	References	Total N(%)
CIMP is described	Yes	(Yuksel and Dogac 2011), (Spigolon and Moro 2012) , (Späth and Grimson 2011), (Smith and Kalra 2008), (Santos, Bax et al. 2012), (Puentes, Roux et al. 2012), (Lopez and Blobel 2009), (Liu, Wang et al. 2010), (Liu, Wang et al. 2008), (Kim and Park 2011), (Goossen, Ozbolt et al. 2004), (Garde, Hovenga et al. 2007), (Duftschmid, Rinner et al. 2013), (Buck, Garde et al. 2009), (Anderson, Weintraub et al. 2013), (Rinner, Kohler et al. 2011), (Muñoz Carrero, Romero Gutiérrez et al. 2013), (Jian, Hsu et al. 2007), (Buyl and Nyssen 2009)	19 (52.8)
	No	(Nagy, Hanzlicek et al. 2010), (Moner, Moreno et al. 2012), (Moner, Maldonado et al. 2010), (Marcos, Maldonado et al. 2013), (Lopez and Blobel 2009), (Lopez and Blobel 2008), (Liu, Wang et al. 2008), (Kohl, Garde et al. 2009), (Knaup, Garde et al. 2007), (Khan, Hussain et al. 2013), (Jing, Kay et al. 2012), (Hsu, Taira et al. 2012), (Hoy, Hardiker et al. 2009), (Garcia, Moro et al. 2012), (Dias, Cook et al. 2011), (Goossen, Goossen-Baremans et al. 2010) ,(Kalra and Carpenter 2012), (Kohl, Garde et al. 2009)	17 (47.2)

Table 6. Indicators associated with the description of the Clinical Information Modelling Process

In most of the studied papers, modelling of CIMs was centred on the structural definition (e.g. a hierarchy of fields and grouping headings) without detailing how these structures were bound to

terminologies (i.e. without mapping the field names to terms, nor specifying terminology value lists for fields with textual values). 36.1% of analysed papers did not include any mention to the use of terminologies. Regarding the others, SNOMED CT was the most widely adopted terminology (22.2%). Only four of the papers (Garde, Hovenga et al. 2007, Nagy, Hanzlícek et al. 2009, Santos, Bax et al. 2012, Muñoz Carrero, Romero Gutiérrez et al. 2013) provided a detailed description about how they conducted the terminology binding process. The same lack of information can be found about the metadata associated to the CIMs created (provenance, authorship, endorsements, related bibliography, etc.), which was rarely mentioned. Table 7 provides information about the terminologies presented in the analysed papers.

Indicator	Values	References	Total N(%)
Terminologies used	SNOMED CT	(Hsu, Taira et al. 2012), (Lopez and Blobel 2009), (Khan, Hussain et al. 2013), (Hoy, Hardiker et al. 2009), (Späth and Grimson 2011), (Nagy, Hanzlicek et al. 2010), (Garde, Hovenga et al. 2007), (Marcos, Maldonado et al. 2013)	8 (22.2)
	Other	(Santos, Bax et al. 2012), (Anderson, Weintraub et al. 2013), (Puentes, Roux et al. 2012), (Liu, Wang et al. 2010), (Liu, Wang et al. 2008), (Knaup, Garde et al. 2007), (Kim and Park 2011), (Goossen, Ozbolt et al. 2004), (Duftschmid, Rinner et al. 2013), (Smith and Kalra 2008), (Spigolon and Moro 2012), (Jing, Kay et al. 2012), (Yuksel and Dogac 2011), (Jian, Hsu et al. 2007)	14 (38.9)
	Not specified	(Goossen, Goossen-Baremans et al. 2010), (Rinner, Kohler et al. 2011), (Muñoz Carrero, Romero Gutiérrez et al. 2013), (Kalra and Carpenter 2012), (Leslie 2008), (Garcia, Moro et al. 2012), (Buck, Garde et al. 2009), (Dias, Cook et al. 2011), (Moner, Maldonado et al. 2010), (Lopez and Blobel 2009), (Lopez and Blobel 2008), (Kohl, Garde et al. 2009), (Moner, Moreno et al. 2012), (Buyl and Nyssen 2009)	14 (36.1)

Table 7. Indicators associated with the terminologies applied in the analysed papers

Sharing publicly the defined CIMs at the end of the CIMP is a mechanism to provide credibility and acceptance to developed artefacts, and to facilitate their reuse. Only 41.6% of papers mentioned sharing the resulting CIMs. Interestingly, 72.2% of papers mentioned reusing existing CIMs as part of their development process. Table 8 details the collected descriptors associated with sharing and reusing CIMs in the analysed papers.

Indicator	Values	References	Total N(%)
Are existing CIMs reused?	Yes	(Goossen, Goossen-Baremans et al. 2010), (Rinner, Kohler et al. 2011), (Muñoz Carrero, Romero Gutiérrez et al. 2013), (Kalra and Carpenter 2012), (Santos, Bax et al. 2012), (Hsu, Taira et al. 2012), (Anderson, Weintraub et al. 2013), (Leslie 2008), (Lopez and Blobel 2009), (Hoy, Hardiker et al. 2009), (Garcia, Moro et al. 2012), (Duftschmid, Rinner et al. 2013), (Buck, Garde et al. 2009), (Smith and Kalra 2008), (Späth and Grimson 2011), (Garde, Hovenga et al. 2007), (Marcos, Maldonado et al. 2013), (Moner, Maldonado et al. 2010), (Lopez and Blobel 2009), (Lopez and Blobel 2008), (Kohl, Garde et al. 2009), (Jing, Kay et al. 2012), (Moner, Moreno et al. 2012), (Yuksel and Dogac 2011), (Jian, Hsu et al. 2007), (Buyl and Nyssen 2009)	26 (72.2)
	No	(Puentes, Roux et al. 2012), (Liu, Wang et al. 2010), (Knaup, Garde et al. 2007), (Kim and Park 2011), (Goossen, Ozbolt et al. 2004), (Spigolon and Moro 2012), (Nagy, Hanzlicek et al. 2010), (Dias, Cook et al. 2011)	8 (22.2)
	Not specified	(Liu, Wang et al. 2008), (Khan, Hussain et al. 2013)	2 (5.6)
Are resulting CIMs shared?	Yes/Planned	(Santos, Bax et al. 2012), (Moner, Moreno et al. 2012), (Moner, Maldonado et al. 2010), (Marcos, Maldonado et al. 2013), (Leslie 2008), (Kohl, Garde et al. 2009), (Hoy, Hardiker et al. 2009), (Garde, Hovenga et al. 2007), (Garcia, Moro et al. 2012), (Buck, Garde et al. 2009), (Anderson, Weintraub et al. 2013), (Rinner, Kohler et al. 2011), (Muñoz Carrero, Romero Gutiérrez et al. 2013), (Goossen, Goossen-Baremans et al. 2010), (Kalra and Carpenter 2012)	15 (41.6)
	Not specified	(Yuksel and Dogac 2011), (Spigolon and Moro 2012), (Späth and Grimson 2011), (Smith and Kalra 2008), (Puentes, Roux et al. 2012), (Nagy, Hanzlicek et al. 2010), (Lopez and Blobel 2009), (Lopez and Blobel 2008), (Lopez and Blobel 2009), (Liu, Wang et al. 2010), (Liu, Wang et al. 2008), (Knaup, Garde et al. 2007), (Kim and Park 2011), (Khan, Hussain et al. 2013), (Jing, Kay et al. 2012), (Hsu, Taira et al. 2012), (Goossen, Ozbolt et al. 2004), , (Dias, Cook et al. 2011), (Jian, Hsu et al. 2007), (Buyl and Nyssen 2009)	21 (58.3)

Table 8. Indicators associated with the type of CIM and Reference Model applied in the analysed papers

A recurring demand nowadays in healthcare is to use and produce specific tools and processes to solve problems related to electronic recording of clinical data process (Santos, Bax et al. 2012). The use of appropriate design tools helps users to manage the complexity of a detailed specification and helps to ensure the syntactical correctness of the resulting model. Tool use should therefore contribute to the quality of the CIMs. In this context, it was found that 67.7% of

publications mentioned the use of specific tools for the creation of CIMs. Archetype editors had the leading adoption (41.6%), followed by UML or similar visual design tools (13.9%). The other papers mentioned the use of tools such as spreadsheets, mind maps, XML editors or Protégé. Table 9 details the information about tools reported in the analysed papers.The complete list of publications can be found in Appendix A.

Indicator	Values	References	Total N(%)
Tools used	Archetype editor	(Spigolon and Moro 2012), (Späth and Grimson 2011), (Santos, Bax et al. 2012), (Moner, Moreno et al. 2012), (Moner, Maldonado et al. 2010), (Marcos, Maldonado et al. 2013), (Leslie 2008), (Kohl, Garde et al. 2009), (Hoy, Hardiker et al. 2009), (Garde, Hovenga et al. 2007), (Garcia, Moro et al. 2012), (Duftschmid, Rinner et al. 2013), (Dias, Cook et al. 2011), (Buck, Garde et al. 2009), (Rinner, Kohler et al. 2011)	15 (41.6)
	UML / Visual modeller editor	(Puentes, Roux et al. 2012), (Lopez and Blobel 2008), (Lopez and Blobel 2009), (Goossen, Ozbolt et al. 2004), (Anderson, Weintraub et al. 2013)	5 (13.9)
	Protégé	(Liu, Wang et al. 2010), (Jing, Kay et al. 2012)	2 (5.6)
	Other	(Lopez and Blobel 2009), (Knaup, Garde et al. 2007)	2 (5.6)
	Not specified	(Yuksel and Dogac 2011), (Smith and Kalra 2008), (Nagy, Hanzlicek et al. 2010), (Liu, Wang et al. 2008), (Kim and Park 2011), (Khan, Hussain et al. 2013), (Hsu, Taira et al. 2012), (Muñoz Carrero, Romero Gutiérrez et al. 2013), (Goossen, Goossen-Baremans et al. 2010), (Kalra and Carpenter 2012), (Jian, Hsu et al. 2007), (Buyl and Nyssen 2009)	12 (33.3)

Table 9. Indicators associated with the tools applied in the analysed papers

4.2.3.2 Inductive content analysis of published literature

The inductive content analysis was performed to discover the CIMP steps described in the selected papers. This methodology is recommended to avoid creating preconceived categories when the existing literature is limited or heterogeneous.

According to this methodology, the information from each of the selected papers about CIMP was extracted and content was analysed with the NVIVO v10 Software. Each task or step about the CIMP detailed in the extracted content is assigned an individual tag. These tags are later analysed and harmonized to identify common categories that contain the steps described the multiple papers that provided information in this regard. The process of harmonizing and classifying tags into categories has been performed iteratively making possible to provide a high

level and summarized description of the CIMP steps. Each category could contain one or more tags that were identified in previously analysed text extracts. For example, upon reading Buck et al. (2009) and Garde et al. (2007) reviewers identified within their described process the following tags “Merge items into concepts” and “identify overlappings” respectively. In the further analysis, these tags were included into the common category “Conceptual Modelling of data elements” within the step of “Design of clinical information models”

Figure 12 details how steps are identified in the content extracted from Leslie (2008). In this example, content is assigned to existing categories such as *1.Scope definition, 4. Definition of implementable clinical information models*, *6. Publishing & maintenance*. As well, a new tag was created within the category *5.Validation* because it was not previously described validation by “review in a clinical board”.

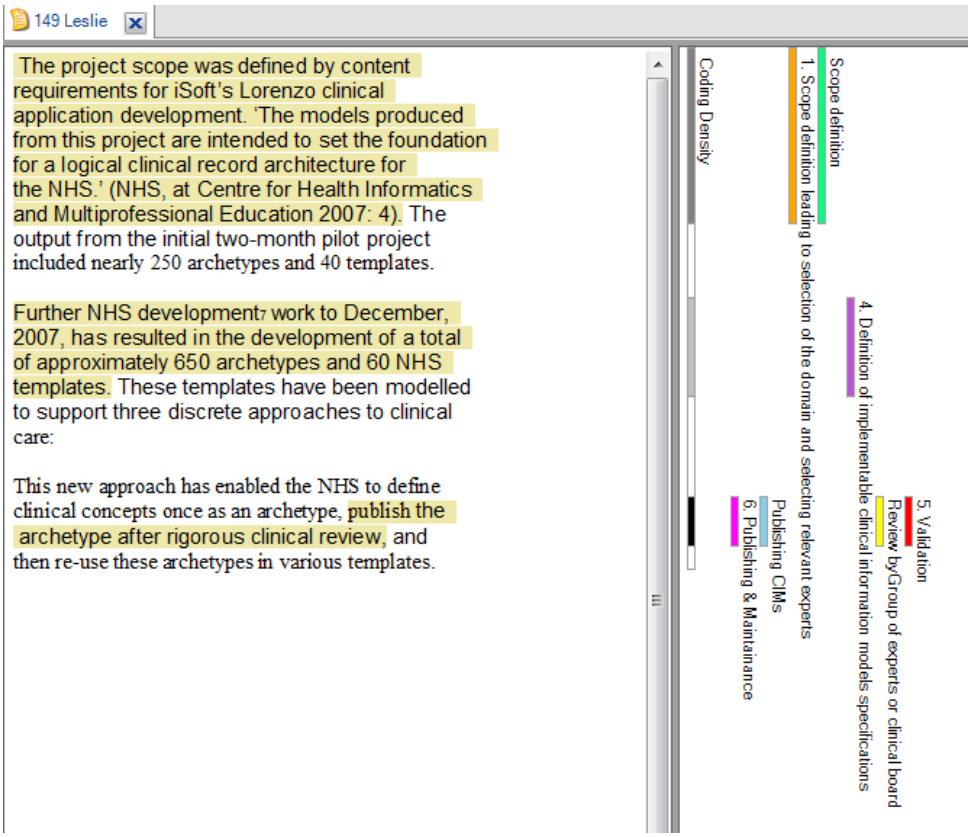


Figure 12. Example of tagging process with the Nvivo 10 Software

Figure 13 details the final distribution of tags obtained as part of the inductive content analysis from the information extracted from the analysed papers

Name	Sources	Reference
1. Scope definition leading to selection of the domain and selecting relevant experts	5	6
Creation of a workgroup	1	1
Scope definition	1	1
Some actors can include citizen, caregivers, healthcare professionals & technology	2	2
2. Analysis of the information covered in the specific domain	26	36
1. Determine entities, attributes and value sets	24	34
Processes	5	6
Agreement & workshops	3	4
Interviews	2	2
Sources of information	16	21
Analysis of the existing documentation infrastructure.	4	5
analyzing the questions the user wants to answer with the help of the documentation system	1	2
Analyzing, sorting, formalizing, structuring and standardizing data elements for clinical use.	1	1
checking national regulations specifications and technical guidelines, other health information projects and	1	2
EHR structures	2	2
evidence-based literature, guidelines & validated scales	5	5
identify tasks, responsible persons, artifacts, products, guidance, phases, and workflows	3	3
Metadata about the healthcare process	1	1
3. Design of clinical information models	16	26
1.Conceptual modeling of data elements, structures and relationships for clinical use, independently of their technic	13	16
data harmonization. Conflicts between names of data items, concepts that data	1	1
Determine the structure of attributes associated with this concept	2	2
Identify overlappings	2	2
Identify the extent of commonality in the structure	1	1
identifying the structure of clinical concepts	2	2
Merge items into concepts	2	3
One concept per CIM	2	2
Understanding and SOAP (Subjective, objective, assessment, plan)	1	1
2. Determine value sets & Terminology analisys	4	7
1. Define data items	0	0
2.Define terminology bindings	3	4
4. Definition of implementable clinical information models specifications	26	47
1. Reviewing and searching existing CIM	8	11
2. Reuse existing CIM	4	4
3. Adapt or develop new CIM	12	15
Design templates for local purpose	2	2
5. Validation	12	18
Evaluate the implications of these models to produce implementation guidance.	1	2
Prototype and evaluate an option for publication of templates,	2	3
Review byGroup of experts or clinical board	5	5
testing examples	3	3
To ensure quality control of DCMfor clinical purpose, based on clinical needs and involvement, governance and ap	1	1
Validation in real practice	2	2
6. Publishing & Maintainance	5	9
Maintainance of CIM	1	1
Publishing CIMs	4	4
7. Governance	1	7
Define process for quality review, certification and publication	1	1
Ensure suitable team composition	1	1
Identify changes in regulations, guidelines and standards	1	1
Monitor development	1	1
Monitor usage and adoption	1	1
Prioritize	1	1
Relationships with other projects and organizations	1	1

Figure 13. Final distribution of tags obtained in the inductive content analysis

After the tagging and categorization of the information extracted about the CIMP steps described in the selected papers, the following seven non-mutually exclusive categories of related information were found. Table 10 summarizes the papers including information related

to each category and Figure 14 details how the multiple steps of the identified process are interrelated.

- **Scope definition leading to selection of the domain and selecting relevant experts.** Whether the scope of a CIM is local or it is designed for wider use, it will be necessary to identify the domain to be covered and the expected uses of the CIMs to be developed (Leslie 2008). Based on the identification of the care setting, healthcare activities, and clinical requirements, it is possible to create a work group of relevant experts in that clinical domain, responsible for the design of the CIMs (Anderson, Weintraub et al. 2013).

- **Analysis of the information covered in the specific domain.** This step requires obtaining an understanding of clinical scenarios, workflows and users, to determine the data items that will be supported by CIMs (Lopez and Blobel 2008, Lopez and Blobel 2009, López and Blobel 2009, Dias, Cook et al. 2011, Puentes, Roux et al. 2012). It is necessary to identify how the existing systems have been implemented and documented (Liu, Wang et al. 2008, Jing, Kay et al. 2012). Reviewing guidelines, literature and validated clinical scales allows the design team to ensure that information covered by the CIMs will meet the requirements of clinical practice (Hoy, Hardiker et al. 2009, Spigolon and Moro 2012, Anderson, Weintraub et al. 2013). To collect this information, interviews and workshops with clinical experts may be performed (Moner, Moreno et al. 2012, Santos, Bax et al. 2012).

- **Design of clinical information models.** After identifying the necessary data items, these are merged and harmonized into CIMs avoiding possible overlapping (Buck, Garde et al. 2009, Liu, Wang et al. 2010, Rinner, Kohler et al. 2011). Each CIM will detail the possible set of attributes associated with it in a structured way (Garde, Hovenga et al. 2007, Goossen, Goossen-Baremans et al. 2010, Muñoz Carrero, Romero Gutiérrez et al. 2013). Each data item associated with a clinical concept can be detailed in form of a value set or CIM node (Nagy, Hanzlicek et al. 2010, Hsu, Taira et al. 2012, Khan, Hussain et al. 2013, Marcos, Maldonado et al. 2013). It is also important to identify domain terminologies that are applicable to the studied domain, in order to map them to the CIMs (Knaup, Garde et al. 2007, Santos, Bax et al. 2012). The definition of CIMs can be focused either on just determining the essential data sets as a common minimum communication requirements (Spigolon and Moro 2012) or in satisfying the application of CIMs for multiple purposes, ensuring a basic compatibility across domains.

- **Definition of implementable clinical information model specifications.** In order to make the defined CIMs compatible with existing EHR information standards an implementable technical specification is needed. The process of implementing the

modelled CIMs into technical artefacts starts with the search and review of existing CIMs (Moner, Maldonado et al. 2010, Yuksel and Dogac 2011, Diego, Cabral et al. 2013). Those CIMs that suit the scope of the project will be reused or adapted (Späth and Grimson 2011). This will increase the interoperability between systems with different local needs but using similar CIMs. For those clinical concepts that are not still covered by existing CIMs, new ones will be created.

- **Validation**. Multiple techniques have been adopted to validate the defined models, including peer review and the creation of prototype screens (Goossen, Ozbolt et al. 2004, Smith and Kalra 2008, Kim and Park 2011). Further evaluation using routinely collected clinical data from multiple patients will provide stronger validation for the defined CIMs (Duftschmid, Rinner et al. 2013).

- **Publishing and maintenance**. Those CIMs that are created should be transferred into a public repository in order to be accessible by any other user (D, Sebastian et al. 2010). CIMs published in the repository should include a method for receiving feedback from those projects and organizations that adopt them (Kalra and Carpenter 2012).

- **Governance**. This final step is not properly part of the CIMP, but closely related to it (D, Sebastian et al. 2010). The organization responsible of the development and maintenance of CIMs will be in charge of establishing an effective governance of them. This governance will determine the process for quality review and publication of CIMs, and the relationship with other projects and organizations working in the same domain covered by those CIMs. This could include certification of CIMs by the developer organization or other external bodies (Kalra and Carpenter 2012).

Category	Published papers
1. Scope definition and creation of a work team	(Hsu, Taira et al. 2012), (Anderson, Weintraub et al. 2013), (Puentes, Roux et al. 2012), (Leslie 2008)
2. Analysis of the information covered in the specific domain	(Goossen, Goossen-Baremans et al. 2010), (Rinner, Kohler et al. 2011), (Muñoz Carrero, Romero Gutiérrez et al. 2013), (Hsu, Taira et al. 2012), (Anderson, Weintraub et al. 2013), (Puentes, Roux et al. 2012), (Leslie 2008), (Moner, Moreno et al. 2012), (Lopez and Blobel 2009), (Liu, Wang et al. 2010), (Liu, Wang et al. 2008), (Knaup, Garde et al. 2007), (Kim and Park 2011), (Khan, Hussain et al. 2013), (Hoy, Hardiker et al. 2009), (Goossen, Ozbolt et al. 2004), (Garcia, Moro et al. 2012), (Duftschmid, Rinner et al. 2013), (Buck, Garde et al. 2009), (Smith and Kalra 2008), (Späth and Grimson 2011), (Spigolon and Moro 2012), (Santos, Bax et al. 2012), (Nagy, Hanzlicek et al. 2010), (Jing, Kay et al. 2012), (Dias, Cook et al. 2011), (Jian, Hsu et al. 2007), (Buyl and Nyssen 2009)
3. Design of clinical information models	(Goossen, Goossen-Baremans et al. 2010), (Rinner, Kohler et al. 2011), (Muñoz Carrero, Romero Gutiérrez et al. 2013),

	(Hsu, Taira et al. 2012), (Leslie 2008), (Liu, Wang et al. 2010), (Knaup, Garde et al. 2007), (Kim and Park 2011), (Khan, Hussain et al. 2013), (Hoy, Hardiker et al. 2009), (Duftschmid, Rinner et al. 2013), (Buck, Garde et al. 2009), (Santos, Bax et al. 2012), (Nagy, Hanzlicek et al. 2010), (Garde, Hovenga et al. 2007), (Marcos, Maldonado et al. 2013), (Jian, Hsu et al. 2007), (Buyl and Nyssen 2009)
4. Definition of implementable clinical information models specifications	(Goossen, Goossen-Baremans et al. 2010), (Rinner, Kohler et al. 2011), (Muñoz Carrero, Romero Gutiérrez et al. 2013), (Anderson, Weintraub et al. 2013), (Moner, Moreno et al. 2012), (Lopez and Blobel 2009), (Liu, Wang et al. 2010), (Liu, Wang et al. 2008), (Kim and Park 2011), (Khan, Hussain et al. 2013), (Goossen, Ozbolt et al. 2004), (Garcia, Moro et al. 2012), (Duftschmid, Rinner et al. 2013), (Buck, Garde et al. 2009), 11134], (Späth and Grimson 2011), (Spigolon and Moro 2012), (Santos, Bax et al. 2012), (Nagy, Hanzlicek et al. 2010), (Jing, Kay et al. 2012), (Garde, Hovenga et al. 2007), (Marcos, Maldonado et al. 2013), (Moner, Maldonado et al. 2010), (Yuksel and Dogac 2011), (Lopez and Blobel 2009), (Lopez and Blobel 2008), (Buyl and Nyssen 2009)
5. Validation	(Goossen, Goossen-Baremans et al. 2010), (Rinner, Kohler et al. 2011), (Anderson, Weintraub et al. 2013), (Leslie 2008), (Kim and Park 2011), (Hoy, Hardiker et al. 2009), (Goossen, Ozbolt et al. 2004), (Duftschmid, Rinner et al. 2013), (Smith and Kalra 2008), (Jing, Kay et al. 2012), (Garde, Hovenga et al. 2007), (Buyl and Nyssen 2009)
6. Publishing and maintenance	(Leslie 2008), (Hoy, Hardiker et al. 2009), (Duftschmid, Rinner et al. 2013), (Jian, Hsu et al. 2007)
7. Governance	(Kalra and Carpenter 2012)

Table 10. Categories found after the inductive analysis of CIMP steps

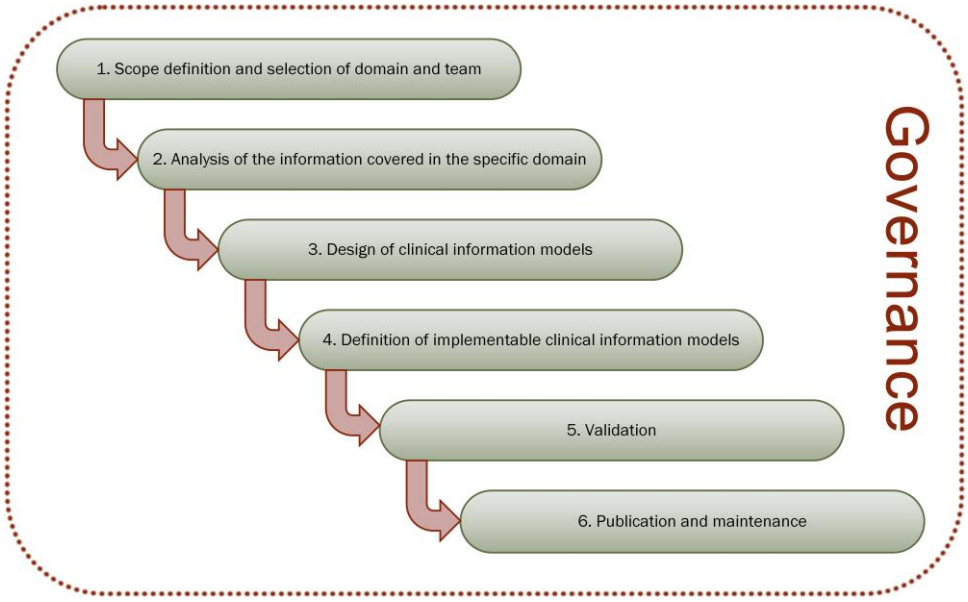


Figure 14. Summary of the clinical information modelling process steps identified in the published literature

4.2.4 Discussion

The systematic review analysed the reported clinical information modelling processes that have been adopted to support the semantic interoperability of EHR systems. Our reflection on the results of the publication searches confirmed that the decision not to include more specific search criteria was appropriate. Using a generic search without including specific terms for the types of CIM proved to be successful, since it allowed including an extensive range of experiences of CIMs development, using different technologies and standards.

4.2.4.1 Discussion on the extracted indicators

The extracted indicators from the selected papers raise several interesting discussion points.

- ***Limited information about the CIMP used to create clinical information models.*** All the selected papers rely on the use of CIMs as a kernel piece of their information systems. However, the methodology followed to create them was not usually described in detail and sometimes not even mentioned. This lack of information might reduce the level of third party trust in the quality of the developed CIMs. Given that currently a standard CIMP does not exist in the literature, we had expected that more authors would have included a detailed description of their own modelling and validation steps.

- ***Resultant CIMs are not shared.*** It was observed that most of the analysed experiences didn't provide any mechanism to access the resultant CIMs. Although it is not mandatory to share them with external groups, it would be a good practice to share these models openly unless there are copyright restrictions. This can improve the quality of the defined models through feedback (Ahn, Huff et al. 2013, D D'Amore, Mandel et al. 2014) and supports to the harmonization of multiple groups developing CIMs in parallel in the same domain, and thus, the semantic interoperability of EHR information.

- ***Limited information about terminology bindings***. It was also observed that many of the published experiences lack detail about how terminologies were bound to CIMs. 36% of the reviewed papers did not even mention the terminological aspect, and most of the others only referred to it as a future work. A CIM cannot be semantically interoperable if it lacks terminological references that describe its contents. The definition of a particular information structure can be affected by the expressivity of the selected terminologies that accompany it and, vice-versa, the design of a particular information structure affects how the value sets to be used in it should be created (Oniki, Coyle et al. 2014). Moreover, a loose definition and use of terminological value sets also affects the final quality and interoperability of the clinical data that is produced (Kalra, Tapuria et al. 2012).

- ***Modelling tools***. CIM definition is a multidisciplinary task where health professionals and technicians collaborate. To this end, it is important to have the appropriate tools that ease the definition and review processes. This study suggests that most of the modelling effort use generic tools to carry out this work, such as UML technologies, mind maps, spreadsheets or XML tools. Only those which rely in the archetype approach make use of specific tooling. In any case, several of the reviewed papers warn about the immaturity of modelling support tools (Garde, Hovenga et al. 2007, Buck, Garde et al. 2009, Späth and Grimson 2011). One can conclude from these results that there is a need for better modelling tools. Although the mentioned papers are from 2007, 2009 and 2011, the evaluation CIMTs performed in section 4.5.3 show that there are relevant areas for improvement.

- ***Mapping to implementable specifications*.** Transforming generic CIM definitions into implementable specifications (i.e. archetypes or templates) is not a direct process since it requires accommodating the information attributes of the CIM in a specific RM structure (Smith and Kalra 2008). This implies that a shared CIM could be implemented in different technical artefacts or standards that were not completely equivalent.

4.2.4.2 Discussion on the inductive analysis results

The methodological approach to create CIMs has been discovered to be similar in all the studied papers where information was available. As was presented in the result section, this process starts with the selection of the scope and the work team, followed by a domain analysis (including the research of references or existing CIMs that could be reused), the design and definition of the structure and semantics of new CIMs (or the modification of existing ones), the validation by health professionals and, finally, the publication of the resulting CIMs.

Although the identified CIMP steps were defined based on the partial information available in the published literature, the level of similarities found between multiple modelling approaches suggests that it would be possible to define a unified process to guide CIM definition, including the description of best practices to increase the quality of the CIMs.

4.2.4.3 *Limitations and risk of bias of this systematic* review

It is recognized that the inclusion of the “semantic interoperability” criterion could have limited the papers found in the search, since the use of this term was limited in the early 2000s. However, this criterion allowed collecting early experiences of CIM-based approaches from promoters of the semantic interoperability concept at that time. Nearly 20 papers published until 2005 were found including that term.

In order to limit the risk of bias of this systematic review, all papers were screened by at least two of the experts involved in the presented literature review, who had to agree in their

suitability for the full-text review phase. In the full review phase, the papers were interchanged between the team of reviewers. Thus, every paper was either screened or fully reviewed independently by different experts involved in this review. In the inductive analysis the review team also achieved a consensus on the steps and classifications of the selected papers, based on the information contained in them.

A limitation of the review is that most papers did not describe in detail the CIMP that was followed in order to define the CIMs. In many cases the modelling process was just mentioned or scattered across the text. This necessitated a careful and detailed reading of each of the papers in order to find out the steps followed by the original authors.

4.3 International study of experts on best modelling practices

4.3.1 Research objective

This study sought to identify best practice in developing and obtaining consensus on the representation of clinical information in order to support EHR semantic interoperability. Based on the lack of detail identified in the published literature about the CIMP, the specific intention was to understand the user engagement, design methods and quality processes presently being used by leading international experts in clinical information modelling, in order to identify if there was an emerging consensus in good practice. This research study aimed to complement the analysed published literature with additional detail by reaching out to EHR experts from healthcare providers and EHR vendors, many of whom are not usually involved in the academic field. According to the selected methodology, it was expected to be able to obtain further detail of the modelling practices that were not reported in the scientific literature.

4.3.2 Methodology

The study was undertaken through semi-structured interviews with 20 recognized experts in the field of clinical information modelling. The interview length was 1 hour and these were conducted either by face-to-face or teleconference meeting. These interviews were transcribed and analysed according to inductive Content Analysis methodology (Elo and Kyngäs 2008). This methodology was recommended in cases where previous published material is either fragmented or lacking. In the case of CIMP, the large number of specifications advocated that this bottom-up methodology should be adopted for content coding.

4.3.2.1 Questionnaire development

Based on a preliminary literature review, the three seminal papers related to quality criteria and quality approaches for clinical information modelling were examined in depth to extract the key topics that should be covered by the questionnaire (Kalra, Tapuria et al. 2008, Kalra and Carpenter 2012, Ahn, Huff et al. 2013). These topics were verified through a second literature review to identify any additional points.

Special effort was made to express the interview questions using a language easily understood by experts, who were expected to come from varied professional backgrounds (i.e. avoiding standards jargon). The questions were open, to invite diverse interviewee responses that could lead to further enquiries to determine how was addressed each topic by the respondent organisation. The questions were reviewed by two independent experts, resulting in some rephrasing and re-ordering. These two experts were then formally interviewed in order to test the openness of the questions and to evaluate if the questionnaire flow required modifications.

The questionnaire was distributed to those interview participants in advance in order to let them evaluate their suitability and to verify their willingness to become part of the study. The questionnaire was divided in three parts: study presentation, personal details and questions.

- **Study presentation:** This section provided the study objective and methodology, explaining clearly that interview responses will be kept as confidential to ensure anonymity of participants.
- **Personal details:** This section was focused on determining the participant experience defining functional requirements for EHR systems and the domain areas covered.
- **Questions:** These were designed to collect exhaustive information about how each site undertook the clinical information modelling process. Additional questions were included to determine how complementary areas were addressed by interviewees such as clinical decision support, clinical workflows, etc. This approach was useful for obtaining better understanding of the CIMP of those projects and initiatives, and analysed by combining generic questions about the process with other more specific about how common tasks impact on the structure of CIMs. Moreover, during the interview, the later questions sometimes helped interviewees to remember additional information about CIMP that was not previously provided. Table 11 lists the subject headings of the interview questionnaire. The final version of the questionnaire is included in Appendix B.

Areas covered	
A. Organization of people involved in requirements definition	I. Knowledge evolution at a larger scale
B. Fulfilling of the requirements by the definitive systems	J. Terminologies
C. Barriers to reach consensus on the definition of the EHR functional requirements	K. Sharing information with other locations and domains
D. Current clinical information modelling process	L. Graphical User Interface functionalities able to be shared between systems
E. Improving the clinical information modelling process	M. Updating EHR systems
F. Mechanisms to ensure quality of clinical information models	N. Areas for prioritization in clinical information modelling
G. Preventing medical errors	O. Non-clinical actors that should participate
H. Using free text and structured data	P. Summarizing information over time
	Q. Alignment with latest clinical evidence
	R. Modelling Clinical Decision support
	S. Modelling Clinical workflows

Table 11. Subject headings of the interview questionnaire

4.3.2.2 Sampling

Experts were selected as those known to have participated in defining clinical functional requirements and specifying the information contained in large scale EHR systems (systems that support care coordination between multiple health department/centres covering a population of more than 500,000 people) with the objective of being able to compare and contrast international approaches to clinical information modelling. They were selected either because they have published multiple papers on the topic or by direct recommendation by a previously identified expert (snowballing), also ensuring broad international coverage. This methodology is specially designed to obtain perceptions from difficult to reach populations when "observations are selected to pursue analytically relevant distinctions rather than establish the frequency or distribution of phenomena" (Emerson 1981). In order to be able to include a broader picture about the definition of EHR CIMs, inclusion was not limited to those with expertise in the set of EHR standards having published literature. This survey applied the snowballing process to include experts from EHR vendors with a strong experience in this field based on proprietary solutions. Thirty one experts were contacted to be interviewed between May 2012 and March 2013. Two experts refused due to a busy agenda, 8 didn't answer and one felt that his background was not suited for the interview. Details about the interviewed experts are given in Table 12.

Interviewed experts details	
Countries of residence	UK, Netherlands, Sweden, Norway, Australia, Brazil, Spain, USA, New Zealand, Austria and Switzerland
National/regional eHealth strategy committees and regional projects	12 experts participate in the eHealth strategy of Norway, New Zealand, Sweden, Australia, Austria, UK, region of Andalusia, region of Geneva in Switzerland and region of Minas Gerais in Brazil
Experience on functional requirements and modelling clinical information for EHR systems	Average 14.8 years of experience (SD=6.3)
Number of papers authored by the experts indexed in PUBMED	Average 17.6 papers (SD=16.2)
SDO and other key initiatives in the semantic interoperability field	11 experts participating in ISO, CEN, HL7, openEHR, CIMI and EN13606 Association
Member of other National Health Informatics Associations	13 experts
Large healthcare providers	5 experts (covering a population of more than 500,000 people)
EHR vendors	2 experts from top EHR vendors (more than $300 million income) 7 experts from Small and Medium Enterprises acting as EHR vendors
Academia	13 experts
Graduated with medical degree	14 experts
Graduated with technical degree	8 experts

Table 12. Personal profiles of the interviewed experts

4.3.2.3 Content analysis

Content analysis was conducted using inductive category development in the coding stage. This was the recommended strategy for studies where the existing literature is limited or heterogeneous, to avoid creating preconceived categories (Elo and Kyngäs 2008). According to this methodology, the information from each interview transcription was analysed with the NVIVO Software (Wong 2008). Each idea included in the interview answers was assigned to an individual tag. These tags were later analysed and harmonized to identify common categories. The process of harmonizing and classifying tags into categories was performed iteratively making possible to provide a high level and summarized description of the CIMP steps. Each category could contain one or more tags that were identified in previously analysed text extracts.

As recommended by Hsieh & Shannon (Hsieh and Shannon 2005), after carrying out the tagging and classification process of the interview transcriptions by a first researcher, to increase the reliability and validity of the results, the content analysis process was reviewed by additional researchers. After randomly selecting 40% of the interviews, two researchers verified that the final tags and categories extracted corresponded with the interview transcriptions and

were correctly developed. The researchers that verified the tagging process agreed with the proposed tags and didn't suggest modifications to the proposed classification.

4.3.2.4 Development process checklist

The identified recommendation, requirements and metrics in the systematic literature review (section 4.2.3) and the international study of modelling practices (sections 4.3.3.1- 4.3.3.21) were applied to develop a checklist that aimed to provide guidance to CIM developers. This checklist is composed by a set of metrics to verify the identified best practices as part of the CIMP.

4.3.2.5 Research team

This research study was carried in collaboration with a team of three researchers (including the thesis supervisor). They collaborated with the author in reviewing the results of the inductive content analysis performed. They contributed and approved the interpretation of the obtained results.

4.3.3 Results

According to the methodology, this section summarises the collected results for each of the questions included within the interviews. The Inductive Content Analysis methodology (Elo and Kyngas 2008) was applied to summarise the interview transcriptions of the 20 international experts participating in this study. This research aimed to complement the information obtained in the literature review with a more detailed description of the CIMP based on the experience of sample of healthcare providers, industry, academic and regulators.

4.3.3.1 Organization of people involved in requirements definition

The interviewees reported that after the project scope and objectives had been defined, those people who participate could usually be classified in three organizational levels. The first level includes the experts who lead the model definition activity. The second level includes a core team of multidisciplinary experts who work in depth on the detailed clinical and technical needs that the system and CIMs will need to satisfy. The third level comprises a larger group of domain experts responsible for validating the proposed system requirements and CIMs. Table 13 details the characteristics of each organizational level and Table 14 includes a set of representative quotes from the performed interviews.

Organizational levels for Clinical Information Modelling Process	
Leading the clinical information modelling team	**Who?** ▪ 1 - 3 people with deep understanding of both clinical practice and health informatics ▪ Business analysts, clinical information modellers and terminologists

	Tasks - Collecting functional requirements from the core team and other sources of documentation such as guidelines and paper forms - Coordinating the core team and its feedback - Applying a methodology to organize and define the requirements - Facilitating alignment with the latest clinical evidence **Recommendation** - Clinical information modellers should have working experience in clinical settings - Technical experts should have working experience in the development and deployment of EHR systems
Core team of domain experts	**Who?** - Between 1 and 5 clinicians, depending on the complexity of the field and the size of the organization. Up to 10 people on very large projects - Recommended to include representatives from each clinical department and clinical specialty that will use that aspect of the EHR system - People highly committed to the success of the project **Tasks** - Providing a detailed definition of the EHR documentation required for the clinical domain where they are experts **Recommendation** - Ensuring that members of this group understand correctly the scope of the EHR system and the clinical information models to be developed, the modelling methodology being adopted and how this project relates to the systems already in use.
Validation Group of domain experts	**Who?** - Larger representative group of domain experts for validation purposes - The selection of the experts depends on the project scope **Tasks** - Verifying that the proposed design for the EHR and system will satisfy their current and projected practice needs **Recommendation** - Non-clinical actors that will make secondary uses of the data or have expertise in the field should be included. (e.g. managers, health authorities, patient associations, public health experts, researchers, professional medical bodies and system vendors)

Table 13. Organizational levels for Clinical Information Modelling Process

Interviewee role	Representative Quote
Member of large healthcare provider	"There were medical informatics who are experts in the representation of the data and there were computer scientists who were knowledgeable in data-base architecture – and they are the people who primarily create the storage-architecture for the system."
Member of Health Informatics organization	"What the modeller does is facilitate that conversation, but the decisions and the trade-offs around what you do, specifically locally, what you share, what the mapping maintains locally. How you synchronize those different perspectives are all issues that the modeller can't determine but the modeller can facilitate those discussions and it's really important that that is done in the context of value of benefits and costs rather than in an ideological way."
Member of large EHR provider:	"In general there are a small number of people who understand the whole picture (of our product) and then they work to make

	sure the teams stay coordinated. It's a big enough product so there is no single person that knows everything."
Member of Health Informatics organisation	"With Open EHR we are working with thousands of people – it's the number of people registered, around 900 since I last looked"

Table 14. Representative quotations about the organisation of the people involved in requirements definition

Figure 15 details the classification of tags obtained in the inductive content analysis about how participants involved in functional requirement definition were organised. The figure includes an index number associated with each tag. This index will be applied in section 4.3.3.21 and 4.3.3.22 as a traceability mechanism to identify the basis for defining the checklist and the key findings associated with the CIMP obtained in this research. In addition, this figure includes the number of interviews and number of references associated with each tag.

	Name	Num Interviews	Extracts
	02.Organisation of the people involved in requirements definition	20	71
1	Core team	14	25
1.1	a board of certified and practiced in medicine, and experience in informatics	1	1
1.2	A group of 3 to 10 people that propose the model for validation to the correspondant clinical com	1	1
1.3	A panel of 3 experts for each medical specialty was consulted by email in order to decide if we in	1	1
1.4	Clinical experts that provide the clinical content	1	2
1.5	Health team had the main role in requirement definition	1	1
1.6	Just one person as core team plus continous updating and feedback after deployment could wor	1	2
1.7	Large IT company has around 7 to 10 clinicians	1	2
1.8	Leading	1	1
1.9	Multistakeholder driven definition. not necessary expert driven	0	0
1.10	National committee plus information modeller	1	1
1.11	Nurses received advice from specialist	1	2
1.12	Perinatology project for national infrastructure I worksed with midwifes, ginecologist and pediatric	1	1
1.13	Small core team	1	1
1.14	Sucesive teams composed by no more than 9 people	1	1
1.15	They usually had more than one clinical background	1	1
2	Healthcare providers organization	5	12
2.1	Andalusian Health Service	1	4
2.2	Delphi study to create a international scale for nursing	1	1
2.3	In 1996 was created a medical informatics department with 3 experts with medical background a	1	1
2.4	In intermountain we create a committee representing involving people from all of the different loc	1	1
2.5	Swiss authorities	1	5
3	Leading clinical modeling team	4	10
3.1	Business analyst discussed with clinicians to set requirements and modeler translated to models	1	1
3.2	Clinical analysts collaborates with modellers and terminologists	1	1
3.3	computer scientist who are knowledgeable in DB architecture	1	1
3.4	Information modeler	2	5
3.5	Medical informaticians who are experts in the represntation of data	1	1
3.6	Small team leading development and large group for validation	1	1
4	Others	0	0
5	Priorizing committee	0	0
5.1	For priorizing had a committee composed by 9 people from medical and nurse background with	1	1
6	Team examples	5	9
6.1	Australian team	1	1
6.2	epSOS team	1	1
6.3	Invitation to relevant organisations for participating	1	1
6.4	OpenEHR team	1	1
7	Technical Team	4	10

Figure 15. Classification of tags and extracts about how participants involved in functional requirement definition

4.3.3.2 Fulfilment of the requirements by the definitive systems

Most interviewees claimed that their systems in general fulfilled the project requirements. They recognized the benefits from adopting iterative development methodologies and prototypes for early involvement of, and feedback from, end users. Conveying the importance of the consistency of clinical information, and the impact of the models on system usability and functionality, as well as, management of expectations, were all considered key success factors. Their experience also indicated that the systems become more mature over time, and would increasingly fulfil the modelling requirements as a continuous improvement cycle. Questionnaires and prototype screen were cited as useful feedback mechanisms.

It was identified that unsuccessful modelling initiatives had either changed in scope during the development process or were influenced by the following set of factors: poor understanding of requirements, organizational changes or greater pressure to meet a deadline than to fulfil the requirements.

Table 15 includes a set of representative quotes from the performed interviews. Figure 16 details the classification of tags obtained in the inductive content analysis about the level of fulfilment of requirements by the developed EHR systems.

Interviewee role	Representative Quote
Member of national healthcare provider	"My systems were highly successful, and the reason was partly due to working with the top experts with most of the requirements already defined, a result of tonnes of prior work of many years."
Member of Health Informatics organization	"What you're doing is making things better you're not getting to a point where the job is finished and you can move one. There is a need for continuous improvement and continuous refinement"
Member of national EHR provider:	"The system fulfilled the requirements in some level. I don't think that it was sufficient until 100% but in some level it was sufficient."

Table 15. Representative quotations about the level of fulfilment of requirements by the developed EHR systems

	Name	Num Interviews	Extracts
	03.Fullfil requirements	20	41
1	Continuous improvement & iterations	6	7
1.1	Continuous Improvement	1	2
1.2	Experts who participated on requirement definition loved quick prototyping becaus	1	1
1.3	Issues arise in new products	1	1
1.4	User was satisfied after iterations	1	1
1.5	You know you are never finished	1	1
2	Failure factors	6	9
2.1	epSOS works but it doesn't satisfy ISO13606	1	1
2.2	given that the requirements were leaded by a person with low understanding of th	1	1
2.3	In 1983 we spend a lot of effort implementing a physician order entry but we had t	1	1
2.4	Organisational changes killed the project	2	2
2.5	The lack of general view of clinicians in the definition of requirements for IT subco	1	1
2.6	When project leader is more focused on meeting deadline than satisfy clinicians n	1	1
3	Key Success factors	8	10
3.1	Fast development but only proof of concept	1	1
3.2	For EHR minas gerais and brazilian health informatics association use ISO1308	1	1
3.3	Fulfill Information needs	1	1
3.4	I had good understanding of medical field because my medical background	1	1
3.5	If you don't explain the benefits of semantic interoperability some achievements ar	1	1
3.6	It is highly important to manage expectations	1	1
3.7	It is required to that clinical and technical requirements were defined by the health	1	1
3.8	These systems were pretty succesful	1	1
3.9	Usability	1	1
3.10	Working with the top experts	1	1
4	Methods for evaluation success development	1	3
4.1	We did a surveys with excellent results	1	1
4.2	We had a great involvement of hospital managers and regional authorities	1	1
4.3	We measured the time that clinicians and nurses using the system and it was well	1	1
5	Our system is robust and is more focused on become a register rather than helping in	1	1
5.1	We are working now in incorporating intelligence to the system	1	1
6	[illegible]	[illegible]	[illegible]

Figure 16. Classification of tags and extracts about the perception of EHR system fulfilment of needs

4.3.3.3 Barriers to reach consensus on the definition of EHR functional requirements

The most common barrier reported was the difficulty in obtaining a common understanding of the consequences of specifying a clinical information modelling requirement (60% of interviews). Respondents often indicated that clinicians did not usually understand why it is essential to define CIMs, and how these would influence the functionalities that their EHR system would subsequently provide. Moreover, they claimed that in those cases that clinical groups within the same organization have different ways of working, each group usually preferred to modify a proposed CIM to fit their practice rather than to examine the evidence to determine a consensus best practice. Multiple interviewees affirmed that, unless there is an experienced health informatics expert leading the CIMP, it was common to find communication

barriers between clinicians and computer scientists. Some of the most critical barriers described to arrive at a clinical consensus arose during the following clinical information modelling tasks:

- ***Determining the level of detail*** that needs to be documented in the EHR, highlighting differences in clinical practice. This is also called the semantic granularity mismatch.
- ***The level of best practice*** that should be prescribed was debated through the definition of which data items to make mandatory.
- ***Determining the useful summary information*** that would help clinicians to manage patient information over time. This is especially relevant for chronic diseases.

Furthermore, interviewees noted organizational barriers related to missing (overlooking, omitting) the participation of some professional specialities that would use the system, and to having enthusiastic experts who forget to include additional stakeholders in the project team.

It was also reported that personal dependence might arise (if projects have only one expert representing a medical speciality) as a consequence of having a domain expert with an emotional attachment to the final models and systems because he invested a lot of personal time as an addition to his daily job, to define the system.

Business reasons was another detected barrier to obtaining consensus on the granularity of information, since the CIMs could result in system modifications or generate indicators that measure clinical performance, with a high impact for suppliers or clinical departments (e.g. on reimbursements, resource allocation).

Finally, some interviewees warned that they found problems in those cases that required major changes to the CIMs after the system was implemented. They recommended that changes in the modelling requirement should be analysed considering the impact on the EHR system as a whole.

Table 16 shows some of the most representative quotes from the performed interviews. Figure 17 details the classification of tags obtained in the inductive content analysis about barriers to reach consensus on the definition of the EHR functional requirements.

Interviewee role	Representative Quote
Member of International clinical modelling initiative	"if we can't come to an agreement we tend to leave it and park it for a little while and the intent is to revisit those when we have more info about requirements. We then try to design it so that the things we have 'parked' can be brought in later as a revision."
Member of Health Informatics organization	"The first step to overcoming those problems is to diagnose them, so to recognize when what you're dealing with is a financial investment issue and when what you're dealing with is an emotional investment issue."
Member of large EHR	"over time we have now moved much more towards a iterative

provider:	model, where we put a prototype of the functionality and very early in the process we engage the client, usually in web based conference calls where we work through the prototype and get feedback"

Table 16. Representative quotations about barriers to reach consensus on the definition of the EHR functional requirements

	Name	Num Interviews	Extracts
	01.Barriers to agree on requirement definition	20	58
1	Changes in requirement definition	1	6
1.1	Defining the shared record for transplant people took	1	6
1.1.1	After 2 years running they want to change everyt	1	5
2	Clinical modeling	5	8
2.1	Defining mandatory items	1	3
2.1.1	how much clinical practice do you force	1	1
2.2	Language & Cultural issues	1	2
2.3	Major changes in clinical model definition with backw	1	1
2.3.1	Evaluate implementors point of view	1	1
2.3.2	Impacts on implementation already deployed	1	1
2.3.3	Makes difficult the modeler decision	1	1
2.4	Semantic granularity mismatch	2	2
2.4.1	eg. somking history could require just a couple of	1	1
2.4.2	Explored solutions for further research	2	6
2.4.3	Hard to get an agreement amongst all users on th	1	1
2.4.4	How much detail including in a model	1	3
2.4.5	The level of detail that is satisfactory for one grou	1	1
2.4.6	The real Challenge for modelling efforts is how to	1	1
3	Commercial, economic and burocracy issues	5	7
3.1	Burocracy problems to approve the Request for Prop	1	2
3.2	Business reasons	1	1
3.3	Commercial or technical reasons	1	1
3.4	Lack of economical resources	2	2
3.5	Permission and licenses associated to vendors could	1	1
4	Difficult challenge	1	1
5	Difficult to agree on a particular screen	1	1
6	Lack of previous clinical consensus before system requir	2	2
6.1	Systems are suppose to provide solutions to the nee	2	2
7	Organisational issues	6	10
7.1	Management & Leadership	2	4
7.1.1	Be legitimated to lead the development	1	2
7.1.2	There was always one person who had final say t	1	1
7.1.3	this leadership helped to achieve coherence amo	1	1
7.2	Personal dependences	2	2
7.2.1	Emotional reasons	1	1
7.2.2	Enthusiastic developers could forget asking for c	1	1

7.3	Users selection for requirement definition	3	4
7.3.1	Missing a professional specialty could not satisfy	1	1
7.3.2	Multiprofessional teams are easier than only doct	2	2
7.3.3	Traditional commercial EHR systems were desig	1	1
8	Scope definition	2	2
8.1	Difficulties in defining scope of the EHR project	2	2
9	Summary for chronic diseases for usability	1	2
10	Technical issues	3	7
10.1	Lack of proper tooling	2	5
10.1.1	Editors and CKM are not well understood by clini	1	1
10.1.2	Use workarounds to apply OpenEHR tools with I	1	4
11.1	Standard limitations	1	2
12	Understanding	9	13
12.1	Clinicians that participate on requirement definition u	1	1
12.2	Definitions are for local use rather than long term inte	2	2
12.2.1	Given that being evidence based is an effort peo	1	1
12.3	Different point of view	2	2
12.3.1	Differences on clinicians way of work	1	1
12.3.2	Research & Enterprise Relationship	1	1
12.4	Different understanding about requirements	1	1
12.5	Difficulties for common understanding among differen	1	1
12.6	experts not ready for change vs others that want the	1	1
12.7	Information is consistent among team members but n	1	1
12.8	Most clinicians dont understand why we need to defin	1	1
12.8.1	Also they don't understand that system don't hav	1	1
12.9	NHS archetype development experience wasn't well	1	2
12.9.1	Given that some modellers had technical backgro	1	2
12.10	Obtaining a common understanding of what the syste	1	1

Figure 17. Classification of tags and extracts about the barriers associated with clinical

4.3.3.4 How to overcome these barriers:

In order to overcome the barriers described above, interviewed experts identified that is critical to recognize and value the contribution that others had made to the existing or legacy systems, and to focus particularly on those aspects that will have a business impact on clinical work. It was recommended that experts with experience in defining requirements and clinical information modelling facilitate this process. According to the interviewees, they should apply methodological approaches, communicate the benefits of interoperability modelling and the importance of using high quality CIMs. When conflicts were identified, it was found beneficial that an expert could facilitate agreement through helping to prioritise the interoperability business drivers. This required an open and inclusive discussion, usually collecting additional information about the underlying functional requirements. Such discussions were often reported to result in a common clinical base model that allows for local specializations (variations, profiling) whilst consistency was preserved for the essential information. At other times, it was

found necessary to wait and review the definition once additional information about the interoperability requirements had been collected.

Figure 18 details the classification of tags obtained in the inductive content analysis about how to overcome barriers associated with clinical information modelling.

	Name	Num Interviews	Extracts
	How to overcome barriers	20	49
1	Apply methodology for clinical modelling guided by expert	5	5
2	Define a consistent agreed archetype and allow local variations for the conflicting	1	1
3	Defining requirements based on a previous system facilitates the work	1	1
4	Diagnose barriers	1	1
5	Discussion	8	14
5.1	Business driver	1	1
5.2	Organizational strategies	3	4
5.3	The important part is resolve conflicts with communication and good understa	2	3
5.4	They can agree on sharing part of the information	1	1
5.5	Web based	1	1
6	Engagement	2	2
7	Exaustive requirements documentation helps	1	1
8	Experienced leading team	1	1
9	Explaining to cliniciansthe general picture surounding the model or system to be d	1	1
10	Focus on getting more information about requirements	1	1
11	Identify benefits	2	2
11.1	Convince clinicians about the benefits of two level modeling to get their involv	1	1
11.2	Interoperability benefits must overcome the pain of changing their daily routin	1	1
12	It is required to provide detailed information about scope before modeling process	1	1
13	Learning process	4	10
13.1	As we obtained additional experiences we moved to an iterative model with e	1	7
13.2	Experience with a previous system was beneficial for our clinical modeller	1	1
13.3	health professional could be trained on methodology if required and results ca	1	1
13.4	There is a learning process on how to model initially you have pressure to defi	1	1
14	Maximal data set approach	1	4
14.1	Also can include discussion about different definitions of the same thing	1	2
14.2	Makes easier defining the elements to include	1	1
15	Park this issue for a while	1	1
16	Stimulate an agreement throgh compromise	1	1
17	Understanding the contribution that people did to legacy system	1	1
18	You can't engineer the solution	1	1

Figure 18. Classification of tags and extracts about how to overcome barriers associated with clinical information modelling

4.3.3.5 Current Clinical Information Modelling Process

According to interviewees, CIMP has the objective of defining semantic structures that can be applied for EHR communication, display, processing or storage by the implemented system. This process was described as a continuous improvement cycle. Substantial benefits were found by adopting an agile development approach because it facilitated rapid and iterative feedback (Martin 2003).

The modelling process usually started with the scope definition and a prioritisation on the basis of management, economic, logistic, regulatory, medical and nursing needs. Next, evidence sources were recommended to be identified including current paper and electronic forms, reporting requirements, technical specifications and existing clinical systems to guide the EHR system definition.

The leading experts usually established the core team composition and organized meetings to collect the clinical and technical requirements. These meetings were online, face-to-face or workshops depending on the number of experts and their geographic distribution. With the support of the clinical information modeller, the CIMs were defined according to the clinical care processes and the documentation that clinicians create. Some methodologies applied included asking clinicians to critique existing CIMs or EHR systems since this facilitated a common understanding and helped to identify new requirements. Other interviewees recommended asking clinicians about the most important information to collect, to establish prioritisation mechanisms and apply a Socratic questionnaire (Riccobene and Schmid 2000) method and knowledge elicitation techniques (Vásquez-Bravo, Sánchez-Segura et al. 2013) to obtain a detailed definition of the clinical domain.

Based on these requirements, CIMs were defined and prototype screens designed by the leading clinical information modelling team with the support of the core team acting in consultative role. The prototype screen was the preferred instrument because it is a mechanism easily understood by clinicians for detailing value sets and entries to be captured in the screen forms. Other supportive instruments such as spreadsheets, mindmaps and word processing documents were also commonly applied and can support the prototype definition process.

Once there was an agreement between the clinicians involved in the core team on the prototype definition, the defined screen were translated to CIMs according to the selected specification. This process was recommended to be carried out by clinical information modellers and terminologists. The definition of the implementable CIM was reported to require reviewing technical specifications, collecting examples of CIMs and establishing terminology bindings. As is detailed in section 4.3.3.11, the terminology binding process was applied to map CIM nodes and value sets to international terminologies.

The final prototype and CIMs were recommended to be reviewed by a separate validation group not involved in the definition process in order to verify that defined system will satisfy the project needs from an independent point of view. Usability could be verified using usability testing techniques and interviews. This was best conducted as an iterative process for validation and to detect overlooked requirements. The system was then implemented, ensuring a feedback mechanism. Finally, a governance and maintenance stage ensured that the system could be updated in a consistent way.

Table 17 details a set of representative quotes from the performed interviews. Figure 19 illustrates the identified ideal steps for a CIMP and Figure 20 details the classification of tags obtained in the inductive content analysis about the adopted clinical information modelling process.

Figure 19. Clinical Information Modelling Process diagram

Interviewee role	Representative Quote
Member of national healthcare provider	"You start with what you find in the field, you bring a structure into that, identify the common elements, and then you design those elements. Then you test how they work on the screen and you get the expertise from others."
Member of Health Informatics organisation	"we applied a rapid prototype environment. That help to improve the perception of the people involved. The people involved in the clinical modelling, we could quite quick show them example screens that reflected their modelling ideas."
Member of large EHR provider:	"If we're building a new domain for a new system that has already been used in the old system we would look at how it worked and ask the user if they wanted it any different or information...never used"

Table 17. Representative quotations about the adopted clinical information modelling process

	Name	Num Interviews	Extra
	04.1. Describe Modeling Process	20	112
1	0 Agile deployment plus continous improvement cycles	6	11
1.1	Clinical Models need to evolve as we get experience reusing them	1	1
1.2	Continous modeling cycle as this work never ends	1	1
1.3	Iterations	2	2
1.4	Over time we'll get better and we'll get a pretty good model but it might take 5 years of iterati	1	1
1.5	Since there are not agreed common models we iterate with our own experts and customer f	1	1
1.6	We used a very agile approach, so we collect requireemnt and our goal was within a week b	1	4
2	0 Feedback & Iterations	1	2
2.1	We collected requireements from both the explanation of clinical workflows and obtaining fe	1	2
3	0 Prioritarization & Scope definition	1	1
3.1	First we identified priorities for our hospital	1	1
4	1 Collecting sources	2	4
4.1	1 our Strategist identify sources and verify that there is nort missed requirements from client	1	1
4.2	Gather requirements from all the different sources	1	2
4.3	Sources	2	5
5	2 Collecting requirements from health and IT professionals	13	57
5.1	Archetype definition in paralel + discussion and harmonisation	1	1
5.2	Bring knowledge people together including nurses, clinicians or whatever depending on the	1	1
5.3	Clinical analist ask clinicians about the care process and how is documented	1	1
5.4	Examples of methodologies	6	23
5.5	Experts define requirements in a document or supported by clinical modelling experts	1	2
5.6	For highly specialised domain only few experts can contribute	1	1
5.7	How to organise the meetings	5	12
5.8	If it's an entirely new domain we ask clinicians what they wanted via the clinical analystists.	1	1
5.9	If you are building a new domain for a system in use we review how the system was used	1	2
5.10	Tools	4	13
6	3 Defining clinical models and Prototype Screens	7	17
6.1	Clinical models	4	9
6.2	Prototype Screens	5	8
7	4 Validation	3	5
7.1	Usability	1	1
7.2	Validation as quality mechanism	2	2
8	5 Implementation	1	1
9	6 Governance and maintainance	3	3
9.1	Clinical models in stable enough are published to be reused in the OpenEHR CKM	1	1
9.2	For quality is required governance process and good team of health professionals	1	1

Figure 20. Classification of tags and extracts associated with the current adoption of the clinical information modelling process in the analysed projects and initiatives

4.3.3.6 Improving the Clinical Information Modelling Process

Interviewees highlighted the need for additional research to improve tools for creating the CIMs and ideally having a drag and drop tool that would create a user-interface based on them. They also recommended defining a formal development process for capturing requirements and modelling clinical information. Many highlighted the need for professional bodies to participate in the definition of policies, good practice for documentation and healthcare professional education. They also expressed a need to improve the interrelationship between structural and semantic health informatics standards.

Further work was felt to be needed on how to handle situations (including legacy data migration) when it is not possible to retain backwards compatibility when developing a new CIM.

A set of representative quotes from the performed interviews are presented in Table 18. Figure 21 details the classification of tags obtained in the inductive content analysis about how to improve the clinical information modelling process.

Interviewee role	Representative Quote
Expert clinical modeller	"There should probably be a more formal way of capturing and documenting their requirements"
Member of large EHR provider	"better tools for creating the models and having a drag and drop tool that would create a user-interface based on the model content. Basically what you would be doing is using the models for the screen content and then as you put things on the screen you are able to change the visual attributes and change the data entry field and be able to create the field traversal order for items on a screen – it would be nice to have a tool that supported that visual creation of a screen."
Member of large EHR provider	"I think that if we can collaborate to gather requirements online rather than working in isolation with the experts we could make the process quicker."

Table 18. Representative quotations about how to improve the clinical information modelling process

	Name	Num Interviews	Extrac
	04.2 Improve Modeling Process	20	41
1	Additional research to improve tools and define formal development process	10	24
1,1	Define a formal process for capturing requirements	2	2
1,2	Formal Evaluations	2	2
1,3	There is not evidence in this field	1	2
1.3,1	that tells you what are the clinical information required	1	1
1.3.2	There are local dependences	1	1
1,4	To fasten the process	2	3
1.4,1	Additional resources for editorial models	1	1
1.4.2	Collaborate online to gather requirements (E.g. Google Docs)	1	1
1.4.3	Publish models in an early stage	1	1
1,5	We wish to have better tools for the modeling process	3	14
1.5,1	Most of the stuff is just down to Word documents and SpreadSheets an	1	1
1.5.2	Tools	2	11
1.5.3	we would like to have is much better tools for creating the models and h	1	1
1,6	Additional resources to cope with feedback and iterative cycles	5	5
1.6,1	having more resources for respond and analyse the significant amount of in	1	1
1,7	Improve the semantic application and definitions of some standards	1	4
1.7,1	Don't ignore the semantics of sections and composition artefacts	1	1
1.7.2	If we want to bridge the worldo of coding systems and ontologies we need a	1	1
1.7.3	Improve the definitions for observation, evaluation action entry because Op	1	1
1.7.4	Long term interoperability requires a precise definition of the models	1	1
1,8	Minimal data sets has been always the easiest way to obtain consensus	1	3
1.8,1	From the experience of obtaining agreement among different Spanish regio	1	1
1.8.2	Systems could collect additional information	0	0
1.8.3	There are 15 or 20 documents that are able to be shared among different ho	1	1
1.8.4	We defined a minimum of 20 data items for discharge summary	1	1
1,9	Professional bodies definition can set policies, good practice document and prof	2	2
1.9,1	It would help the IT industry if clinical modelling was done better and there w	1	1
1,10	That is simple, at hear to the ISO13972 process, respect to the process and the	1	1
1,11	Use the same clinical standards	1	1

Figure 21. Classification of tags and extracts associated with the experts recommendations for improving the clinical information modelling process

4.3.3.7 Mechanisms to ensure quality of models

Factors helping to determine if models are of good quality include the previous adoption of the models by other systems or other communities, a CIM certification process, confirming the level of consensus that was achieved, specifying which stakeholders had participated in the design and validation process, and making sure that CIMs were not simply reused after any change to their scope without an evaluation of the consequences and a further iteration of the validation process.

A second kind of suggested assessment was to incorporate technological validation for syntactic and semantic correctness (against predefined modelling rules) and for consistency. There are tools such as the openEHR Clinical Knowledge Manager (OpenEHR CKM 2014) and the Clinical Element Model Browser (CEM Browser 2015) that verify if CIMs satisfy technical specifications and perform other automatic checking. As modelling efforts scale up globally, it was suggested to have tools that are able to verify if there are semantic overlaps and inconsistencies across multiple CIMs. A tool for clinical information modelling with semantic validation capabilities was mentioned as a mechanism that could increase the quality and consistency of multiple CIMs. These capabilities were already identified to be found in existing tools like Protegé (Noy, Crubézy et al. 2003) and could be considered to be incorporated into CIM editors and Knowledge Manager repositories.

A third kind of proposed quality assessment was monitoring the quality of the data collected according to the models and applying the collected data for making decisions, analysis and reporting. Applying the collected data for e.g. clinical audit and outcomes assessment was reported to be a mechanism to facilitate revision, adoption and feedback about the defined models.

Table 19 includes some of the most representative quotes from the performed interviews. Figure 22 details the classification of tags obtained in the inductive content analysis mechanisms to ensure the quality of the clinical information models.

Interviewee role	Representative Quote
Member of large healthcare provider	“In an ideal world it would be nice to have all that information within a modelling tool – one could think of like Protégé – so that you have some automatic checking of semantic inter-operability and consistency between the different models.”
Member of Health Informatics organization	“check that not only the data is being collected as expected but to actually use it, to come to some, to interesting conclusions because if the data’s being used than the data quality will be sustained”
Member of large IT provider:	“we worked very hard to expose data in a whole variety of ways because it was the end users that were looking at reports about their patients or who were making clinical decisions. They were a far more sensitive detector of data problems than anything else we could imagine”

Table 19. Representative quotations about mechanisms to ensure the quality of the clinical information models

	Name	Num Interviews	Extracts
	04.3 Mechanism to ensure quality of models	20	46
1	In free text fields it is the person who introduces data who has the quality criteria	1	1
2	Increase the clinician perception of usefulness of information	1	1
2.1	Quality of the information improve if	1	1
3	Management of project document versions	1	1
4	Not relevant	2	2
5	Principles to include in the methodology	15	31
5.1	Acceptance	2	2
5.2	Certification	1	2
5.3	Check functional requirements and their exhaustive definition	4	5
5.4	Consensus	1	1
5.5	Experts selection	1	1
5.6	Models were previously implemented	2	2
5.7	Monitor and analysis data and exploitation	3	5
5.8	Quality must be check in each step of the process	1	1
5.9	Scope	1	2
5.10	Understanding	4	4
5.11	Usability	1	1
5.12	Validation	2	5
6	Prognosis of model evolution and validate research is the challenge	1	1
6.1	It is required ot organise how to propose evolution and validate this evolutio	1	1
6.2	The difficulty is in validating the model and how it will remain after 3, 5 or 10	1	1
6.3	The real problem is to establish a process with knowledable and competent	1	1
7	Tools with automatic semantical and syntactical checking	6	9
7.1	Semantical Checking	3	6
7.1.1	There is not developed any automatic semantical check to avoid creatin	1	4
7.1.2	Update archetypes can require extended metadata and SIAMS describe	1	1
7.1.3	We have an strategy with some ideas for validating the models but we d	1	1
7.2	Sintactical and tecnical validation	3	3
7.2.1	Controling that quantitative data is within ranges	1	1
7.2.2	Data restrictions e.g. Blood pressure range	1	1
7.2.3	Technical and statistical requirements are autmatically checked by CK	1	1

Figure 22. Classification of tags and extracts associated with mechanisms to ensure the quality of the clinical information models

4.3.3.8 Preventing medical errors

It was recognized to be difficult to design CIMs that might reduce medical errors without a detailed understanding of how errors arise. A detailed requirements analysis might indicate if particular data items should be mandatory to collect. Interviewees indicated that the way a model is implemented, in particular the user interface, might have a greater impact on the prevention of errors than the design of the CIM itself. It was recognized that checklists could help prevent errors (Gawande and Lloyd 2010), and some CIMs were designed to represent checklist items. Supportive functions for data entry, as well as algorithms and decision support, were reported to be implemented to avoid collecting invalid values and thereby reducing errors.

Table 20 includes a set of representative quotes from the performed interviews. Figure 23 details the classification of tags about how clinical information modelling could be related with preventing medical errors.

Interviewee role	Representative Quote
Member of Health Informatics organization	"there are a number of places within clinical practice where by using a mechanism like the pre-flight check-list the airlines employ is a good way of making sure that people don't make mistakes"
Member of Health Informatics organization	"there are a number of places within clinical practice where by using a mechanism like the pre-flight check-list the airlines employ is a good way of making sure that people don't make mistakes"
Member of large IT provider:	"probably the most important is actually very good visual design … a number of medical errors in medical software are related to poor usability"

Table 20. Representative quotations about how to prevent medical errors

	Name	Num Interviews	Extracts
	05.Prevent Medical Errors	20	40
1	Analysis	5	5
1.1	Analysing how data is collected	3	3
1.2	Focus on type of error, learn from data and measures for prevent	1	1
1.3	Last change in ISO work included ISO9001 (Plan Do Check Act cycle) in the DC	1	1
2	Defined common information structures are helpful for young clinicians data collecti	1	1
3	Education for clinicians and technologist	1	1
4	Focus on deliver better health outcomes rather than data errors	1	1
5	Functionalities	9	12
5.1	Adding in future thresholds in archetypes for triggering actions	1	1
5.2	Automatic check of numbers that don't make sense	1	1
5.3	Bringing algorithms and intelligence to applications can increase patient safety	1	1
5.4	Check list Manifesto	1	1
5.5	Clinical Decision Support and Application functionalities check that values corre	2	2
5.6	Data Restrictions e.g. Blood pressure range	2	2
5.7	Include ranges to prevent typing errors	1	1
5.8	Incomplete data entry	1	2
5.9	Supportive functionalities for data entry	1	1
6	how technology is applied rather than technology prevent errrors	1	1
7	Limitations in preventing errors	5	7
8	Strong work for requirement definition is required	6	9
8.1	Ask to the community or clinicians to check if there is something missing	1	1
8.2	Define mandatory data	1	1
8.3	Good team defining requirements is the best thing for quality	1	2
8.4	Identify right experts, feed back from implementers and public comment on clini	1	2
8.5	More detailed information	2	2
8.6	OpenEHR CKM allows directly involvement of domain experts	1	1
9	Usability & GUI	1	3
9.1	The most important is very good visual design because poor usability is behind	1	3
9.2	eg truncating a number	1	1

Figure 23. Classification of tags and extracts associated with how clinical information modelling could be related with preventing medical errors

4.3.3.9 Using free text and structured data

Interviewees believed that collecting structured information required more data entry time than free text. Described free text limitations were its limited computability, and therefore, limited exploitation capabilities. On the other hand, free text permitted the collection of unanticipated information, and so a balance between structured data and free text was always felt to be required. A few interviewees felt strongly that the focus of clinical information modelling should be to structure only the information that is expected to be exploited to make decisions or to be included in decision support algorithms, keeping the rest of clinical documentation as free text.

Since many clinicians find it easier to document in free text, a few experts proposed using Natural Language Processing to extract relevant information (e.g. patient problems) for confirmation by clinicians and storage in a structured form. Such tools were reported to have recently become more commonly integrated within commercial EHR systems.

A set of representative quotes from the performed interviews are presented in Table 21. Figure 24 details the classification of tags about how to model free text and structured data in EHR systems.

Interviewee role	Representative Quote
Member of large healthcare provider	“don’t collect any data that you don’t know how to use’... leave it as free-text unless you know that this going to be used in algorithms”
Member of large IT provider	“In the early days everything was free text, then we moved pretty aggressively towards making everything structured, and know we are coming back to free text but we are using natural language parsing tools to pull the right important structures out of the free text and have the physician confirm it.”

Table 21. Representative quotations about the use of free text and structured data

	Name	Num Interviews	Extracts
	06.Using FreeText	20	87
1	But I think that the entry should be model and coded	1	1
2	Free text	12	18
2.1	Key benefits	3	3
2.1.1	In structured data include an option for writing free text and put the story	1	1
2.1.2	It is required to preserve the narrative, the story	1	1
2.1.3	We are not able ot have structure information for things like environmental thr	1	1
2.2	Other characteristics	10	15
3	I think free-text shouldn't be clutered together - it needs to be placed in specific forms	1	1
4	If it is a generic field to be used by many different users we give both options FT and S	1	1
5	Information preferred as free text	6	14
6	Information should be structured only when is going to be exploited or included in algo	3	9
6.1	'don't collect any data that you don't know how to use'	1	1
6.2	leave it as free-text unless you know that this going to be used in algorithms	1	1
6.3	We must only structure what has to be structure	1	5
6.4	We understand that it is not possible to force structuration of information	1	1
6.5	you only want to code data when you know that you have a use for that data	1	1
7	OpenEHR approach for not universal value set	1	3
8	Recommendation for free text	9	19
9	Recommendations for structured data	3	5
10	Structured information	6	7
10.1	Choose among a large list of options can also cause errors	1	1
10.2	Difficult on collect data over high structured forms	1	1
10.3	For audit purposes	1	1
10.4	For clinical purposes	1	1
10.5	For DSS	1	1
10.6	very comprehensive structure difficult and long to read	1	1
10.7	We structure information that is important to follow up	1	1
11	Supportive functionalities	2	7
11.1	Semantic Search	1	3
11.2	we apply Natural Language parsing tools to pull the rignt important structures out t	1	1
11.3	We are developing tools to evaluate quality of free text	1	3

Figure 24. Classification of tags and extracts associated with the recommendations about how to model free text and structured data in EHR systems

4.3.3.10 Knowledge evolution at a larger scale

In order to support knowledge evolution at regional, national or international levels, the need was identified for tools that promote team collaboration on the design of CIMs. Moreover, it was recommended for the use of these to be complemented by organizational governance that promotes their acceptance as part of the modelling process. Interviewees provided examples of tools (Lopez and Blobel 2008, Yuksel and Dogac 2011) able to provide a centralized repository with open access to gather design inputs and to facilitate consensus on CIM definitions. An organizational structure was also recommended to maintain and update CIMs. One interviewee suggested that CIMs should be periodically reviewed to check for new evidence, and to monitor if the CIMs are being correctly applied.

An important problem detected was that acceptance of the clinical information modelling approach was still at an early stage since most existing large scale EHR systems could not yet directly implement CIMs represented using the published standards. Interviewees claimed that large scale clinical information modelling may reduce costs, but they found an initial need for substantial funding for the design and governance of CIM development, through activities such as education of clinicians, working with health authorities in charge of an IT infrastructure and promoting awareness within eHealth projects.

Table 22 includes some of the most representative quotes from the performed interviews. Figure 25 details the classification of tags about how to support knowledge evolution at large scale.

Interviewee role	Representative Quote
Member of health informatics association	"We have to get organisations like professional bodies or specialist groups at European level like the European Society of Cardiology. They 've got to have a working party who would help develop models and work with maybe not the vendors directly but with prototyping groups that can develop screens that look like the models"
Member of large healthcare provider	"I have no doubt that all technical mechanisms are in place, but I don't think that the problem is there...we need to find a methodology, a language, a process, that we can explain, teach, "sell" to clinicians at a LARGE scale."
Member of large healthcare provider	"the key thing is to connect to each and every project which is going to benefit from this and also to be in control of the future projects requirements and at least be aware of what is going to happen in the next run"

Table 22. Representative quotations about supporting knowledge evolution at large scale

	Name	Num Interviews	Extracts
	08.2 Support Knowledge evolution at large scale	20	73
1	CIMI group is looking a better way of providing shared models	1	3
2	Clinician engagement	2	5
2.1	Needs to come from the specialty doctors	1	4
3	Collaborative Tools with semantical checking	6	12
4	DCM standard describes a good approach for this	1	2
4.1	defining requirements, applying models and stablish governance structure, ma	1	1
5	Education clinicians about exchange knowledge	1	2
6	Example of national implementation (New Zealand experience)	1	5
7	Minas Gerais Repository	1	3
8	NEHTA	1	2
9	Not relevant	1	1
10	Ontologies, terminologies and archetypes need a LOT of resources	2	4
11	OpenEHR relationship with national projects	1	3
11.1	as much aligned as possible	1	1
11.1	Create core clinical models which are universally useful and allow regional gro	1	1
12	Organisational structures	3	10
12.1	Anual review of models checking evidence and current use	1	2
12.3	National projects should cooperate in the production of archetypes	1	3
12.4	require to involve the organisation for updating and maintenance	1	1
12.5	Small team can build things and scalling up with the involvement of national a	1	1
12.6	The SemanticHealthNet project has to advise EC how to do it	1	1
13	Preferred agreeing at national than regional level to reduce the diferences	3	3
14	Requirements	4	4
14.1	For commercial solutions you require to become formal in software release at	1	1
14.2	It is required a reference environment where templates are agreed at pan nati	1	1
14.3	It is required to improve how is organised evidence available on the literature t	1	1
14.4	It will be required to go from the current structures to others more conceptuals	1	1
15	Standardise Knowledge representation	2	3
15.1	Not all can be a common format	2	2
16	The main issues are not technical problems is the acceptance	5	11

Figure 25. Classification of tags and extracts associated with supporting knowledge evolution at large scale

4.3.3.11 Terminologies

Since multiple terminologies can cover the same domain, mapping between multiple terminologies was identified as a major difficulty. It was found helpful to have clarification on the application of terminologies, for example as provided by the Meaningful Use program specifying which terminologies and vocabularies are applied for each purpose. This would offer some guidance on what terminology should be chosen when more than one have overlapping scopes.

Interviewees also reported difficulties in using the update mechanisms provided by international terminologies, and that terminology development organizations need to provide more support and explanation about the introduction of new terms and changes to hierarchies. It was noted that there are still few rules for post-coordination, which is something that clinicians found very

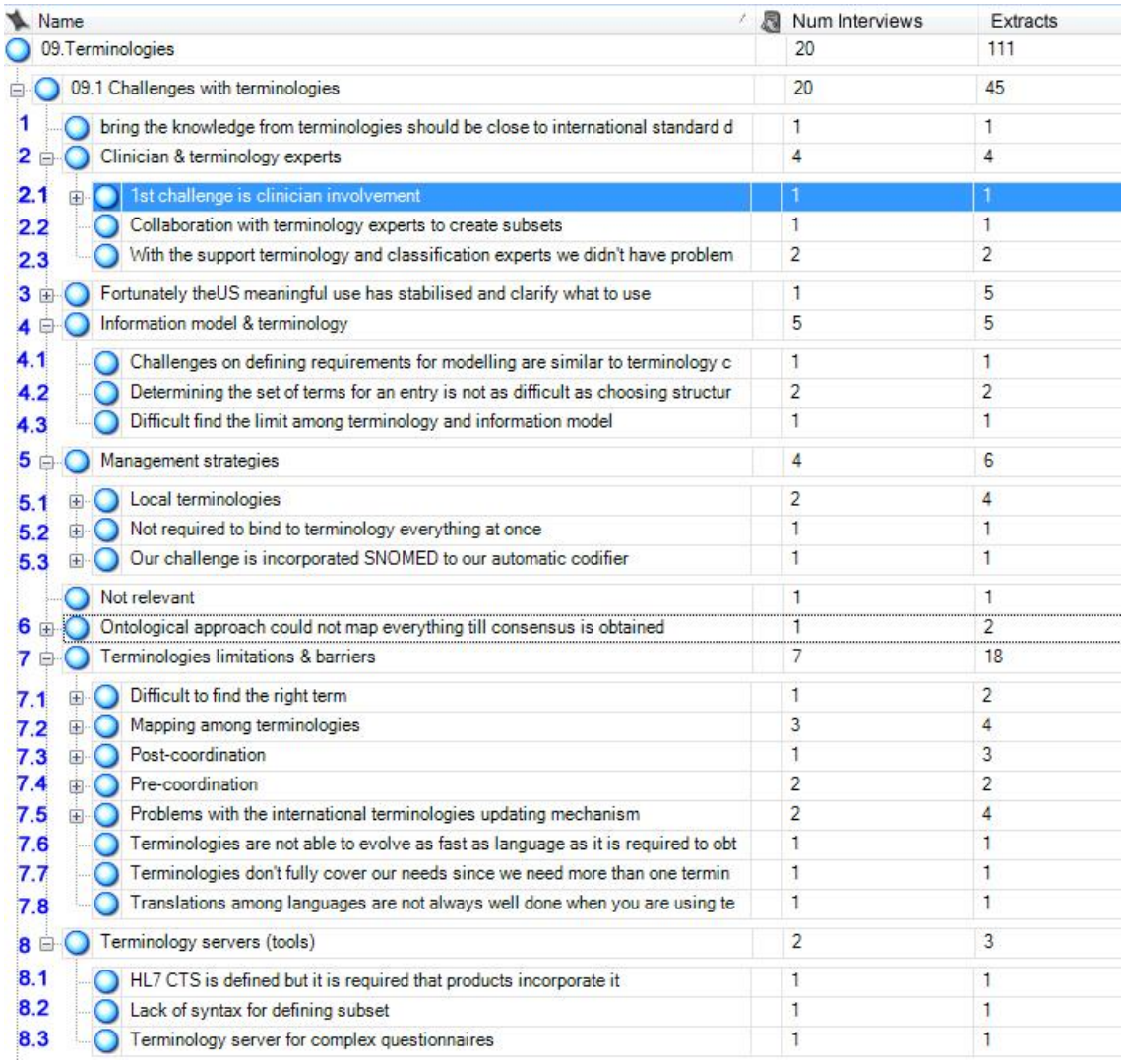
difficult. Given these difficulties, it was felt beneficial to involve terminology experts in clinical information modelling activities.

Many interviewed experts claimed that clinicians prefer to use locally defined value sets that are well-adapted to their needs rather than applying standard terminologies. In addition, it was common to find EHR systems that incorporated their own terminology, with a need to map these terms onto standard terminologies for subsequent uses and for communication. Likewise, some experts identified that value sets were recommended to be bound to CIMs but depending on how universally accepted, how large and how stable a value set is expected to be, their capability to be usefully shared between multiple implementations might vary.

Figure 26 details the classification of tags associated with the current challenges for terminology management and Figure 27 the classification of tags associated with the current adoption of the terminology management process. Table 23 includes some of the most representative quotes from the performed interviews in this area.

Interviewee role	Representative Quote
Member of national healthcare provider	"You don't have to put a terminology binding to each and every data element and if you get the data items right in terms of semantics then you can add these things as required along the way as well."
Member of large IT provider	"Fortunately, in the US, the terminologies are now, are beginning to get stabilized because of meaningful use... So that settles a lot of the old debates that forces us to have many different vocabularies and now it's a little bit less complicated, but it is still hard."
Expert clinical modeller	"The big problem is just lack of pre-coordinated terms. In SNOMED to bind to our data sets. So there are still quite a few rules in post-coordination there are still things we can't bind to using post-coordination. But post-coordination is very difficult for clinicians to understand."

Table 23. Representative quotations about the use of terminologies



	Name	Num Interviews	Extracts
	09.Terminologies	20	111
	09.1 Challenges with terminologies	20	45
1	bring the knowledge from terminologies should be close to international standard d	1	1
2	Clinician & terminology experts	4	4
2.1	1st challenge is clinician involvement	1	1
2.2	Collaboration with terminology experts to create subsets	1	1
2.3	With the support terminology and classification experts we didn't have problem	2	2
3	Fortunately theUS meaningful use has stabilised and clarify what to use	1	5
4	Information model & terminology	5	5
4.1	Challenges on defining requirements for modelling are similar to terminology c	1	1
4.2	Determining the set of terms for an entry is not as difficult as choosing structur	2	2
4.3	Difficult find the limit among terminology and information model	1	1
5	Management strategies	4	6
5.1	Local terminologies	2	4
5.2	Not required to bind to terminology everything at once	1	1
5.3	Our challenge is incorporated SNOMED to our automatic codifier	1	1
	Not relevant	1	1
6	Ontological approach could not map everything till consensus is obtained	1	2
7	Terminologies limitations & barriers	7	18
7.1	Difficult to find the right term	1	2
7.2	Mapping among terminologies	3	4
7.3	Post-coordination	1	3
7.4	Pre-coordination	2	2
7.5	Problems with the international terminologies updating mechanism	2	4
7.6	Terminologies are not able to evolve as fast as language as it is required to obt	1	1
7.7	Terminologies don't fully cover our needs since we need more than one termin	1	1
7.8	Translations among languages are not always well done when you are using te	1	1
8	Terminology servers (tools)	2	3
8.1	HL7 CTS is defined but it is required that products incorporate it	1	1
8.2	Lack of syntax for defining subset	1	1
8.3	Terminology server for complex questionnaires	1	1

Figure 26. Classification of tags and extracts associated with the current challenges associated with terminology management for EHR systems and clinical information modelling

	Name	Num Interviews	Extrac
	09.2 Mechanism Implemented	20	44
1	Adding termsets to clinical models	5	13
1.1	Adding termsets to archetypes	2	10
1.1.1	Internal and external termset differences	1	4
1.1.2	The strategy depends on how universaly, how big and how dinamic the ter	1	5
1.2	We define archetypes and templates that are binded to temset from national d	1	1
1.3	We use Enterprise Architect for modelling and we assign to each note a code fr	1	1
2	Tools	6	16
2.1	Central Terminology management system	1	5
2.1.1	Collect all the terminologies they need	1	2
2.1.2	Spread changes and updates across infrastructure	1	1
2.2	Excel not suited for management of infrastructure and update systems	1	1
2.3	Previolusly we tried Apelon and HLI but they weren't integrated tightly with our	1	3
2.4	SNOMED CT in a few cases supported by Ocean Archetype editor	1	2
2.5	We have a specific module for terminologies	2	3
3	Value list	6	7
3.1	Not required to bind to terminology everything at once	1	1
3.2	Sensible length and adapted to their local needs	1	1
3.3	Table of value sets	1	1
3.4	Users prefer value list adapted to their need rather than apply a terminology	2	2
4	We defined our terminologies at the beguinning and they were later mapped to sta	2	4
4.1	There wasn't any international terminology when we defined our terms	1	1
4.2	We ask clinicians and they provide the terms or create local codes if required	1	2
4.3	We have our internal nomenclature system	0	0
5	We don't have mechanism implemented	1	1
5.1	We expect to define it in the future	1	1
6	We have a common mechanism for templates and terminologies since they are inc	1	1

Figure 27. Classification of tags and extracts associated with the current adoption of the terminology management process in the analysed projects and initiatives

4.3.3.12 Sharing information with other locations and domains

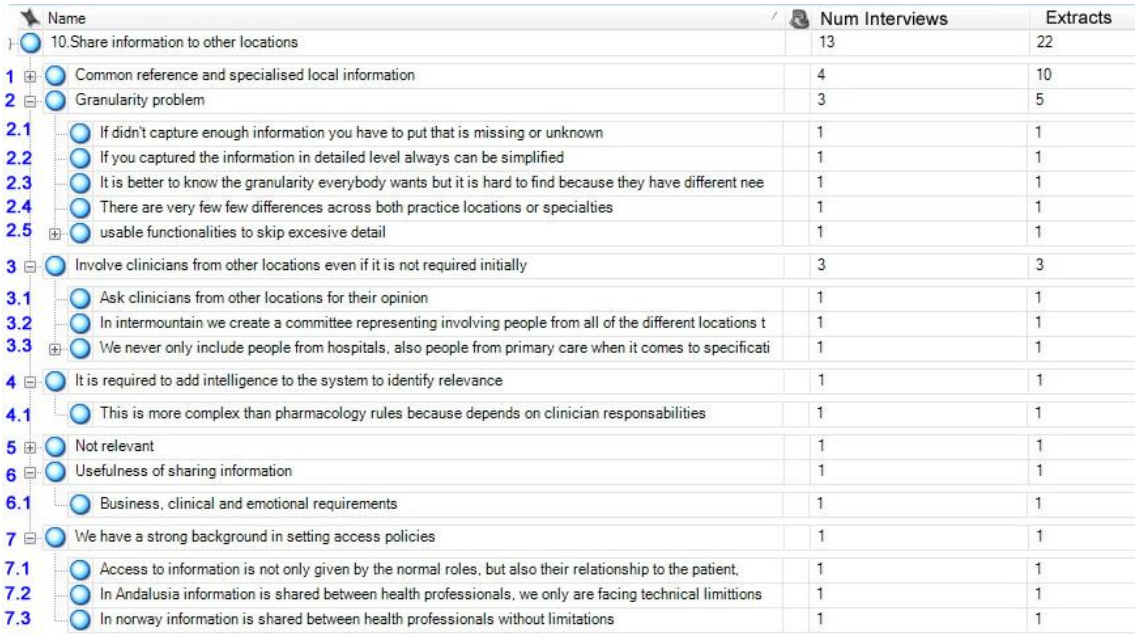
There were consistent answers across the questions relating to the sharing of information, and re-use CIMs, between care settings and clinical domains. Interviewees advocated a modular approach to define common core information structures that can be re-used in different domains. Working simultaneously across domains on these core information structures would allow feedback to be gathered from different environments, and result in a good basis for re-use. This core structure should be able to be specialized (extended) to meet the specific needs of each care setting and specialty. Some of them recommended that the common core structure should be specified in as much detail as possible, as it could be simplified at each local level using templates or masking inapplicable data elements at the application level.

For shared CIM development, it was affirmed that widening the set of experts involved in the model design will mean that it takes longer to obtain a consensus. It was recommended to define criteria at the outset for determining the basis for signing off a CIM: when it is likely to achieve sufficient usability and deliver its intended benefits. Interviewees felt that differences in clinical information requirement across locations and specialties were not very great, and that should be possible to arrive at a harmonized design. The most important objectives were to convince the clinicians of the value of adopting generic wording that would be applicable across domains rather than using their own specialist wording for the data elements. They also needed to be encouraged to reuse previously defined CIMs wherever possible, rather than re-inventing from scratch.

Next, is provided the classification of tags obtained in the inductive content analysis about sharing information with other locations (Figure 28) and clinical domains (Figure 29). Table 24 includes some of the most representative quotes from the performed interviews associated with sharing information with domains and locations.

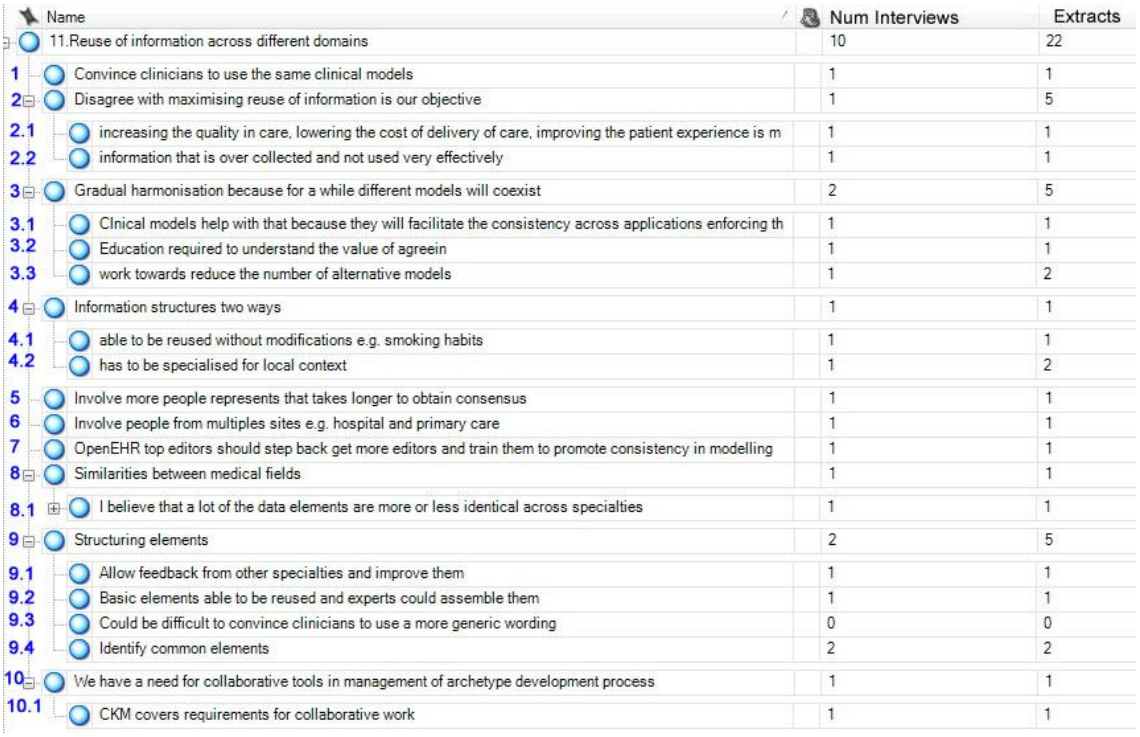
Interviewee role	Representative Quote
Expert clinical modeller	"can we please make the wording generic? In that there is a battle sometimes. They have a particular way of doing, and that is how they want the system to be rather than thinking they are building a system that other might use."
Member of large IT provider	"We have found very little that is different enough across either practice locations or specialities to warrant those differences. So we really have very few, reflect very few differences, so the clinical content is somewhat different."
Member of health informatics organisation	"I think that is better to have two models of diagnosis, which different groups use and each use them completely rather than having a supermodel of diagnosis which everyone uses in different ways."

Table 24. Representative quotations about sharing information with other locations and clinical domains



	Name	Num Interviews	Extracts
	10.Share information to other locations	13	22
1	Common reference and specialised local information	4	10
2	Granularity problem	3	5
2.1	If didn't capture enough information you have to put that is missing or unknown	1	1
2.2	If you captured the information in detailed level always can be simplified	1	1
2.3	It is better to know the granularity everybody wants but it is hard to find because they have different nee	1	1
2.4	There are very few few differences across both practice locations or specialties	1	1
2.5	usable functionalities to skip excesive detail	1	1
3	Involve clinicians from other locations even if it is not required initially	3	3
3.1	Ask clinicians from other locations for their opinion	1	1
3.2	In intermountain we create a committee representing involving people from all of the different locations t	1	1
3.3	We never only include people from hospitals, also people from primary care when it comes to specificati	1	1
4	It is required to add intelligence to the system to identify relevance	1	1
4.1	This is more complex than pharmacology rules because depends on clinician responsabilities	1	1
5	Not relevant	1	1
6	Usefulness of sharing information	1	1
6.1	Business, clinical and emotional requirements	1	1
7	We have a strong background in setting access policies	1	1
7.1	Access to information is not only given by the normal roles, but also their relationship to the patient.	1	1
7.2	In Andalusia information is shared between health professionals, we only are facing technical limittions	1	1
7.3	In norway information is shared between health professionals without limitations	1	1

Figure 28. Classification of tags and extracts associated with modelling clinical information in order to be shared between multiple locations



	Name	Num Interviews	Extracts
	11.Reuse of information across different domains	10	22
1	Convince clinicians to use the same clinical models	1	1
2	Disagree with maximising reuse of information is our objective	1	5
2.1	increasing the quality in care, lowering the cost of delivery of care, improving the patient experience is m	1	1
2.2	information that is over collected and not used very effectively	1	1
3	Gradual harmonisation because for a while different models will coexist	2	5
3.1	CInical models help with that because they will facilitate the consistency across applications enforcing th	1	1
3.2	Education required to understand the value of agreein	1	1
3.3	work towards reduce the number of alternative models	1	2
4	Information structures two ways	1	1
4.1	able to be reused without modifications e.g. smoking habits	1	1
4.2	has to be specialised for local context	1	2
5	Involve more people represents that takes longer to obtain consensus	1	1
6	Involve people from multiples sites e.g. hospital and primary care	1	1
7	OpenEHR top editors should step back get more editors and train them to promote consistency in modelling	1	1
8	Similarities between medical fields	1	1
8.1	I believe that a lot of the data elements are more or less identical across specialties	1	1
9	Structuring elements	2	5
9.1	Allow feedback from other specialties and improve them	1	1
9.2	Basic elements able to be reused and experts could assemble them	1	1
9.3	Could be difficult to convince clinicians to use a more generic wording	0	0
9.4	Identify common elements	2	2
10	We have a need for collaborative tools in management of archetype development process	1	1
10.1	CKM covers requirements for collaborative work	1	1

Figure 29. Classification of tags and extracts associated with modelling clinical information in order to be shared between multiple clinical domains

4.3.3.13 Graphical User Interface functionalities able to be shared between systems

Most of the interviewees claimed that it was necessary to find a balance between standardizing common data elements and allowing for innovation, in order to preserve the capability for different interfaces to be created by vendors. Experts agreed that there are certain safety measures that should be consistent across systems. Some examples are displaying data values that are out of the normal range, presenting together items that are related (e.g. systolic and diastolic blood pressure), They recommended improving guidance on displaying medications, patient headers, warning signs for allergies and emergencies, how to display a navigation bar and improving scrolling. It was suggested that there should be work on the standardization of symbols across EHR systems.

In addition, interviewed experts claimed that GUI functionality is a field where additional research is required. They reported that most of the systems they had encountered do not involve usability experts when designing screens and interactions. There is still little scientific evidence on the impact of interaction with users. Some experts indicated that experience with eye tracking and cognitive load techniques show that it is important to be very careful when introducing intuitive user interactions since the inclusion of highlighting colours, bold font and other display features do not always achieve the expected results. Sometimes these could create confusion rather than simplifying the use of the system. Examples of emerging standards for the presentation of clinical information referenced by interviewees were the NHS Common User Interface specification (Vittorini, Michetti et al. 2008) and Human Computer Interaction book (Dix 2004).

Table 25 includes some of the most representative quotes from the performed interviews associated with graphical user interface functionalities that would be able to be shared across systems. Figure 30 details the classification of tags obtained in the inductive content analysis.

Interviewee role	Representative Quote
Member of health informatics organisation	“there are some common elements that probably should be standardised. On the other hand innovation is a good thing and if we start with the same GUI guidelines we’ll be stuck with the same proxy interfaces from 20 years ago.”
Member of large healthcare provider	“result of our measurements – we use ITracker Cognitive Load etc., proves that we have to be very careful at giving intuitive rules for user interface.”

Table 25. Representative quotations about the graphical user interface functionalities that would be able to be shared across systems

	Name	Sources	References
	07.GUI Functionalities	17	52
1	Balance between consistency and innovation	5	7
1.1	Balance between standardising common elements and innovation	1	1
1.2	Consitency is key for good interface design	1	1
1.3	Disagree that Consistent representation will always reduce errors	1	1
1.4	It is important to convey ranges along the result but we should leave to the system to identify the best way for presentin	1	3
1.5	Models should capture information but leave display choices to user interface design	1	1
2	Functionalities	8	18
2.1	A requirement for placing a set of data element together for scores	1	1
2.2	Change fonts	1	1
2.3	Flag out parameter out of range	1	1
2.4	Improved scrolls	1	1
2.5	Incomplete data in different colour	1	1
2.6	It is important that some items such as diastolic and diastolic blood pressure need to be displayed togheder	1	1
2.7	Medication	1	1
2.8	Medication that is not used in grey	1	1
2.9	Navigation bar on the lef-hand side	1	1
2.10	Patient header, including sex, age and alerts	1	1
2.11	Presenting dates and weight should have clear rules	1	4
2.12	Using colors to draw attention	1	1
2.13	Warning sign for allergies	1	1
2.14	Warning sign for emergency information of discharge summary	1	1
2.15	When clinician needs to sign a document all the information must be shown together	1	1
3	I agree that should be shared	1	1
4	Not relevant	2	2
4.1	Problem orientation system	1	1
4.2	We have developed a UI layer over the comercial solution that we have implemented	1	1
5	References	5	7
5.1	CUI from Microsoft	4	4
5.2	HL7 CCOW standard	1	2
5.3	I used a human-computer interaction book to determine features like size on the scren to avoid lose attention	1	1
6	Research is required	9	17
6.1	balance how to present complex things and make sure that the important parts are seen	1	2
6.2	Different point of view, that means working at template level	1	2
6.3	Educational content	2	4
6.4	Highlight some values can make clinician skip additional important values	1	1
6.5	It is missed a standardized simbology	1	1
6.6	Little evidence or guidelines on system usability	1	1
6.7	Make sure that clinicians color blinded and those with less visual acuicity can detect abnormal results and alerts	1	1
6.8	Relevant topic	1	2
6.9	Required agreement on how to represent different data types	1	1
6.10	Required research on a layer that guides how archetype information should be presented	1	1
6.11	Usability has to be designed to satisfy of 3 concurrent actors doctor, nurse and patient	1	1

Figure 30. Classification of tags and extracts associated with sharing Graphical User Interface functionalities between EHR systems

4.3.3.14 Updating EHR systems

In order to support the update of their systems experts agreed on the benefits of separating software code from clinical knowledge specifications (but not necessarily relying upon any particular model for that specification). This approach would allow changes in terminology without software re-development. However, it was identified that changes in archetypes and templates will require usually a testing stage to ensure that GUI functionalities are correctly implemented. Major changes that include data migration and intensive testing can require around one year to be incorporated within the final system. The experts reported a variety of strategies from a fixed updating schedule to a continuous updating process, since the time expended on the updating process depends on the complexity and urgency of the change.

Some systems can have multiple releases every week for their components and others have a scheduled half-year updates.

Table 26 includes some of the most representative quotes from the performed interviews associated with how are updated EHR systems. Figure 31 details the classification of tags obtained in the performed inductive content analysis.

Interviewee role	Representative Quote
Member of health informatics organisation	" you need to have a compatibility management procedure in place, the other part is to consider the impact of the change; is it clinically ok to make this change. "
Member of large IT provider	"the knowledge base was completely independent of the software and as medical knowledge evolved we would update the knowledge base not the software so that was a strong feature of the system so we never had to change the software, only the physical knowledge changed."

Table 26. Representative quotations about how are updated the EHR system

	Name	Sources	References
	14.Summarising information	16	37
1	Data obsolecense for decision making	2	3
1.1	Clinical data has durability for both chronic and acute patient	1	2
1.1.1	I believe that record should differentiate among active and passive history	1	2
1.1.1.1	Passive record eg. Glucemic CT or ECG has not value after 6 months	1	2
1.2	Grey Color for old data as previously prescribed medicine	1	1
2	For adding intelligence to the data other centralised systems can bring the knowledge for decision support	1	1
3	Increased consistency problems for chronic patients	3	9
3.1	Data will change over time	1	1
3.2	Data will come from different system and needs to be an overall information architecture	1	2
3.3	Follow patient among healthcare system becomes complex	2	4
3.4	For patient with the same treatment over time it is required an agreed and stable document	1	2
3.5	Time functionalities	0	0
4	It will be required to introduce ontologies because other representations such as Arden Syntax have limitations if you go to	1	1
4.1	It will be required to wait long till we see it mature enough	0	0
5	Summarising	7	14
5.1	Decision support for summarising trends	2	2
5.1.1	How was the pain over the last 12 months	1	1
5.1.2	Summarising trends	1	1
6.1	Difficulties to do even agree on manual summaries	1	2
6.2	For chronic patients summarised information could be also long	1	1
6.3	It has to be a clinical activity	1	3
6.3.1	it could be assiged a clinician who takes the role of summarising	1	1
6.3.2	There are human organisation and workflows that can not be covered by models	1	1
6.4	Professional societies have good notion about the core summary information they would liket to know about it if they w	1	3
6.4.1	defining an example of how to summarise the record with a few data elements	1	1
6.4.2	Summary per disease basis it is easier than the whole record because it has a lot of vairability depending on who t	1	1
6.5	Shouldn't be automatic better adding intelligence as supportive functionality	2	3
6.5.1	Creating automatic summary wouldn't be safe	1	1
6.5.2	In Netherlands our national project has a functionality that presents to clinicians a synthesis pf patient information	1	1
6.5.3	It could be possible to help human to synthesing a summary but it is too complex to automate this process	1	1
6.6	That is a problem we don't have answer to and it is important for quality programs in US	1	1
6.7	There is a paper that says only 20 percent of predicted value of all systems is useful	1	2
6.7.1	We have to review how we define alerts and other functionalities because many of them add noise rather than relevan	1	1
6.8	Two set of categories	1	4
6.8.1	Decision support capabilities time-driven that are able to notify clinicians important things happening to the patient	1	1
6.8.2	Standard reporting	1	2
6.9	We use special databases for research, data analysis and statistics purposes	1	1
6.10	Why limit the information. Is there economic or technical reasons that support losing data. All data forever	1	1

Figure 31. Classification of tags associated with how are updated the EHR system

4.3.3.15 Non-clinical actors

The interviewed experts agreed that representatives of the clinicians who would be using a model for direct patient care should be included in the *core team of domain experts*. However, they differed in their recommendations for other (non-clinical) experts that should be included in the modelling team. They also suggested that it depends on the project scope and in most cases their participation will be included as part of the validation group rather than core team. In addition to the suggested groups detailed in the questionnaire (epidemiologists, public health experts, patient associations, professional bodies, system vendors, health authorities) interviewees also requested the participation of additional non-clinical actors. It is important to note that in contrast to the rest of mentioned actors that were mentioned just once, the medical informatics role was requested four times without being included in the questionnaire. The rest of additional non-clinical actors were experts in semantics and ontology, terminologists, non-clinical radiology staff, medical informaticians, researchers, caregivers, linguists, quality improvement specialists and regulators (included in the figure in the "other" tag). It was proposed that with web-based participation there should be no set limit to participation, in order to be able to collect inputs from anyone who has relevant information to provide. Figure 32 shows the number of times that each non-clinical actor was requested to be included by interviewees.

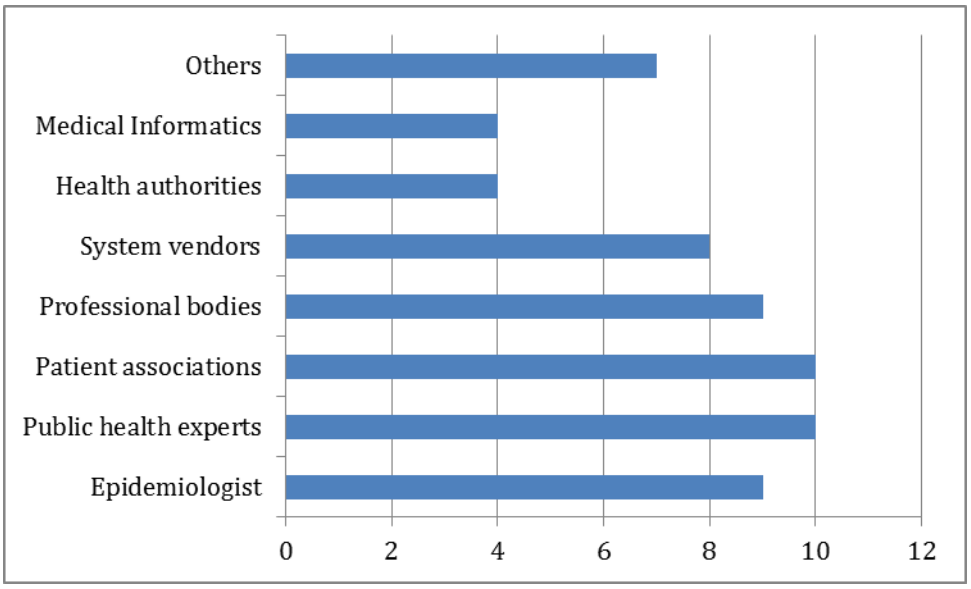


Figure 32. Number of interviewees that proposed to include each of the non-clinical actors

4.3.3.16 Areas for prioritization

Most of experts claimed that the definition of patient summary information should be prioritized, such that it could be applied for referrals and discharge summaries. Since the information to be included within the patient summary may not be similar in all cases, it was especially recommended to focus first on the definition models for medication, problems/diseases and

allergies. As a second step laboratory reports were also claimed to be of priority and later to include images, demographics, and other pathology reports. Figure 33 below shows the ten most frequently advocated priority areas for clinical modelling amongst the interviewed experts.

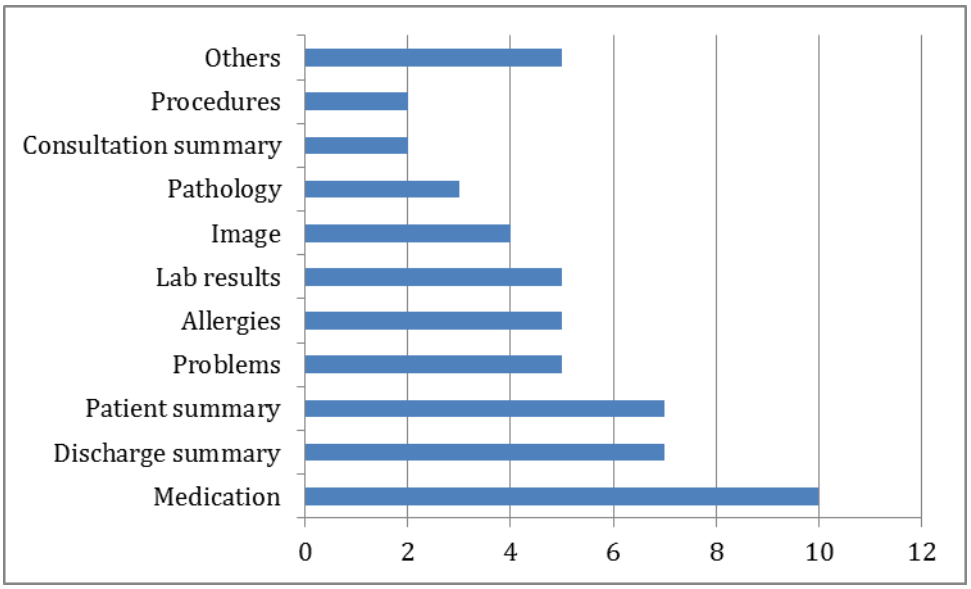


Figure 33. Number times that each clinical information concept was requested to be prioritized by interviewees

4.3.3.17 Summarizing information over time

In the case of patients with chronic diseases the problems related to consistency of information increase since these patients may have health information that has been collected from multiple sites over many years. Given that the way of collecting data will change over time, experts said it was necessary to have a data management environment that enables standard reporting and is able to handle different versions of the same clinical document.

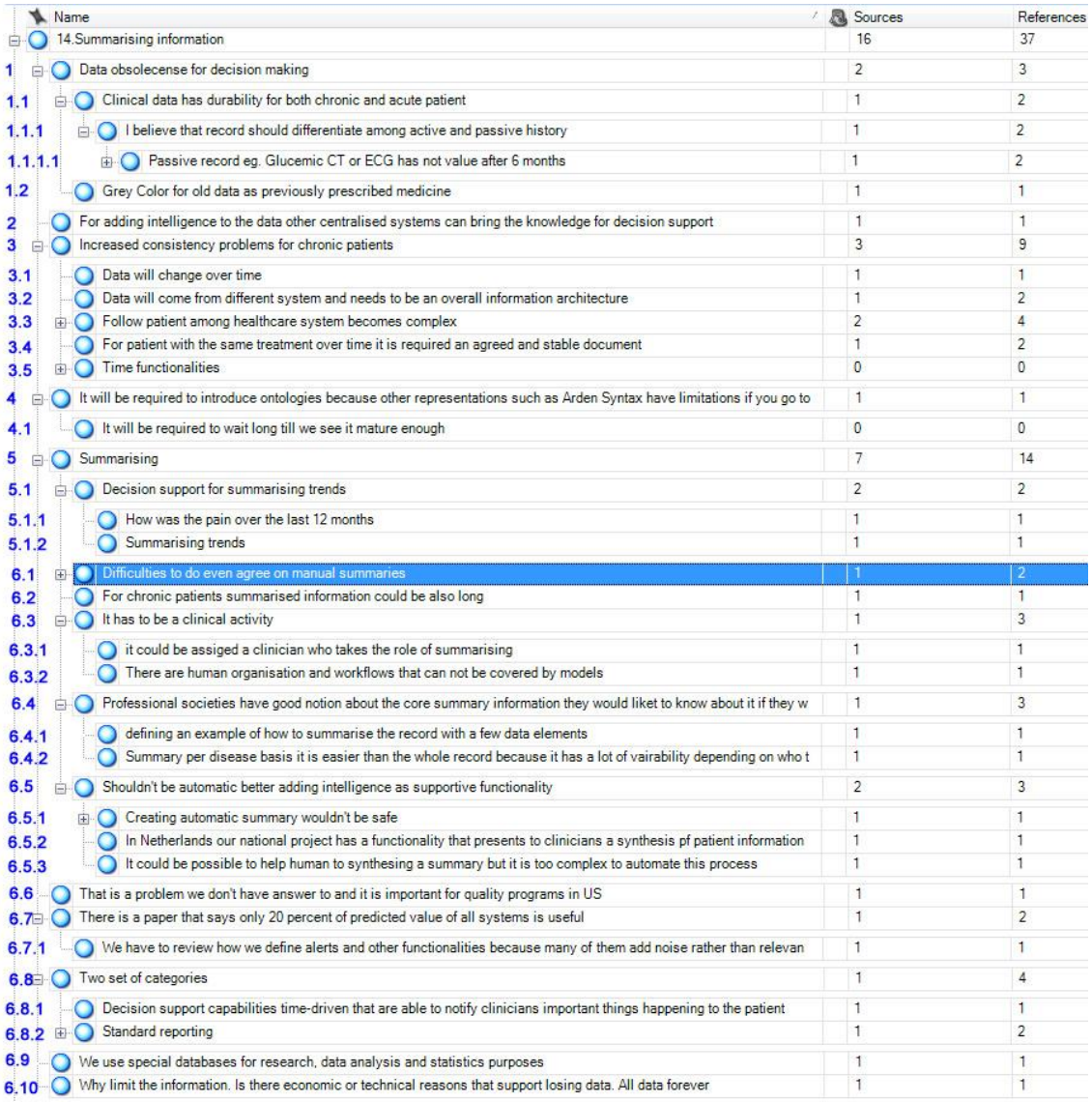
Also it is recognized that summarizing information is highly complex and interviewee experts were concerned about automatic summarizing. This task is highly dependent on the point of view of the person who is performing it and there can be difficulties on reaching agreement on even manual summaries in cases where the scope is not clear. Professional societies can participate defining the core information that will be required for the diseases in which they are specialist. It was recommended to perform this task through a clinician who can be helped by supportive functionalities.

Table 27 includes some of the most representative quotes from the performed interviews associated with the summarisation of information over time. Figure 34 details the classification of tags obtained in the performed inductive content analysis.

Interviewee role	Representative Quote
Expert clinical modeller	“That primarily has to be a clinical activity. To create a proper

	health summary, to create an up-to-date and correct problem list or a medication list, needs to have curation by clinicians ”
Member of large IT provider	“Professional societies have real good notion what the sort of core summary information that they would like to know about it if they were handed a patient with a disease they were specialist in.”

Table 27. Representative quotations about the summarisation of information over time



	Name	Sources	References
	14.Summarising information	16	37
1	Data obsolecense for decision making	2	3
1.1	Clinical data has durability for both chronic and acute patient	1	2
1.1.1	I believe that record should differentiate among active and passive history	1	2
1.1.1.1	Passive record eg. Glucemic CT or ECG has not value after 6 months	1	2
1.2	Grey Color for old data as previously prescribed medicine	1	1
2	For adding intelligence to the data other centralised systems can bring the knowledge for decision support	1	1
3	Increased consistency problems for chronic patients	3	9
3.1	Data will change over time	1	1
3.2	Data will come from different system and needs to be an overall information architecture	1	2
3.3	Follow patient among healthcare system becomes complex	2	4
3.4	For patient with the same treatment over time it is required an agreed and stable document	1	2
3.5	Time functionalities	0	0
4	It will be required to introduce ontologies because other representations such as Arden Syntax have limitations if you go to	1	1
4.1	It will be required to wait long till we see it mature enough	0	0
5	Summarising	7	14
5.1	Decision support for summarising trends	2	2
5.1.1	How was the pain over the last 12 months	1	1
5.1.2	Summarising trends	1	1
6.1	Difficulties to do even agree on manual summaries	1	2
6.2	For chronic patients summarised information could be also long	1	1
6.3	It has to be a clinical activity	1	3
6.3.1	it could be assiged a clinician who takes the role of summarising	1	1
6.3.2	There are human organisation and workflows that can not be covered by models	1	1
6.4	Professional societies have good notion about the core summary information they would liket to know about it if they w	1	3
6.4.1	defining an example of how to summarise the record with a few data elements	1	1
6.4.2	Summary per disease basis it is easier than the whole record because it has a lot of vairability depending on who t	1	1
6.5	Shouldn't be automatic better adding intelligence as supportive functionality	2	3
6.5.1	Creating automatic summary wouldn't be safe	1	1
6.5.2	In Netherlands our national project has a functionality that presents to clinicians a synthesis pf patient information	1	1
6.5.3	It could be possible to help human to synthesing a summary but it is too complex to automate this process	1	1
6.6	That is a problem we don't have answer to and it is important for quality programs in US	1	1
6.7	There is a paper that says only 20 percent of predicted value of all systems is useful	1	2
6.7.1	We have to review how we define alerts and other functionalities because many of them add noise rather than relevan	1	1
6.8	Two set of categories	1	4
6.8.1	Decision support capabilities time-driven that are able to notify clinicians important things happening to the patient	1	1
6.8.2	Standard reporting	1	2
6.9	We use special databases for research, data analysis and statistics purposes	1	1
6.10	Why limit the information. Is there economic or technical reasons that support losing data. All data forever	1	1

Figure 34. Classification of tags and extracts associated with summarising information over time

4.3.3.18 Alignment with latest clinical evidence

Experts indicated that health providers cannot always be aligned with the very latest clinical evidence, since it takes a while for a sufficient body of evidence to accumulate to justify changing clinical practice, and consequently to justify changing the clinical information structures within EHR systems. Moreover CIMs and EHR systems were recommended to be

able to support the documentation of legacy practices for some time, since there is a gradual adoption of clinical evidence. The input sources to CIM design must therefore combine existing with best practice.

The starting point for clinical modelling was usually clinical guidelines and current clinical practice. It is not always possible to adhere to clinical guidelines, since these are sometimes only updated infrequently and newer improved practices may emerge after their publication. In some large healthcare providers the people responsible for defining regional guidelines will be included in the modelling design team in order to ensure that a guideline is correctly adopted, and that any issues arising during this process will be incorporated in the next review of the guideline. A clinical modelling expert can bring clinical models and guidelines that are internationally available as an input for the core team of domain experts to verify if they are applicable to their local environment.

A second way of incorporating new clinical evidence is from users, obtaining new requirements when the system is implemented or in the model validation stage.

Mechanism to improve the alignment

Rather than multiple clinical communities each developing models that conform to a national or European guideline, it was recommended by the experts that clinical models be developed according to guidelines at a regional or national or European level. Health care providers would then become users of such models, rather than developers of them, and could make demands for their regular updating as guidelines are updated, in the same way that EHR system vendors are required to regularly update a knowledge database of drug interactions. Another proposal was to provide incentives to healthcare providers to adopt established evidence in a similar way to the US “Meaningful Use” program.

Table 28 includes some of the most representative quotes from the performed interviews associated with the alignment with latest clinical evidence. Figure 35 details the classification of tags obtained in the performed inductive content analysis.

Interviewee role	Representative Quote
Expert clinical modeller	“Latest clinical evidence is not always right, it certainly has a long lead time, it comes out and then it takes many many years for it to be implemented in systems. So whatever was the legacy evidence has to be supported for some time.”
Member of health informatics organisation	“Best evidence clinical guidelines and best evidence practice should be part of that initial step of working out what it is you are trying to support. Then we would make sure that the data supports whatever those best practised things are.”

Table 28. Representative quotations about the alignment with latest clinical evidence

	Name	Sources	References
	15.1 How are you aligned	12	22
1	Alignment with evidence	7	7
1.1	Best evidence guidelines are practice should be initial step in defining requirements and models	1	1
1.2	Check clinical guidelines	1	1
1.3	For creating a model checking evidence base is the first need	1	1
1.4	Increase clinician awareness	1	1
1.5	It is important to involve clinician becuase they are likely to have links with the research fields	1	1
1.6	Modellers need to facilitate it	1	1
1.7	We check evidence as part of the academic medical center conferences where we receive world leading experts to	1	1
2	At system deployment you have to wonder if collect this information will work for individual patient or population	1	1
3	Clinical evidence is not easily available	1	1
4	Legacy evidence must be supported for some time	1	1
5	Our models should be able to represent the practice applied by our clinicians	5	6
5.1	Experts participating in functional requirement definition are those who participate in regional guideline definition	1	1
5.2	Our healthcare professionals have the knowledge to identify the latest clinical evidence	1	1
5.3	This is a clinical issue	4	4
6	We had feedback from users	1	1
6.1	Even in most sophisticated places such as Veteran's Health Administration they don't have a process it is ad hoc pe	1	1
7	You can't afford to be aligned with latest clinical evidence	3	5
7.1	e.g. the blood pressure archetype is updated with the european hypertnsion guideline for 24h monitoring but this pa	0	0
7.2	For healthcare providers can't incorporate the latest clinical evidence because it is safer to wait a little bit longer unti	1	1
7.3	Latest clinical evidence is relative since it is not the same comply with national guidelines than participate in the dev	1	1
7.4	Latest evidence is not always right	1	1
7.5	Takes years to implement it in the systems	1	1
8	15.2 Improve the alignment	8	10
8.1	Clinical discussions about guidelines should be in an earlier stage than functional requirement definition	1	1
8.2	Difficult to align since clinicians dont have time for meeting more than once each month and for many decisions you ca	1	1
8.2.1	They are mostly organisational problems and you have to work on provisory decisions	0	0
8.2.2	we have a strong clinicaly driven structure	1	1
8.3	Establish a fixed schedule for yearly updates help users to collect the requirements	1	1
8.4	Healthcare providers should garantee that their prescription systems are actualised with the updated information about	1	1
8.4.1	IT providers such as MEDICMECUM or Boot have updates every 2 or 3 months	1	1
8.5	In the ontology field once they will be required to define processes and knowledge	1	1
8.6	It is required to identify how archetypes are going to be maintained and who will be responsible	1	1
8.6.1	In 10 years archetypes are likely to be owned by SDOs to be trusted or will obtain quality assurance by national org	1	1
8.7	Links to references in journals	1	1
8.8	Scale the process at regional or national level	2	2
8.8.1	It will be possible to reduce cost by scalling this process at regional and national level	1	1
8.8.2	Not scalable for small groups it has to be done by European and national professional bodies	1	1
8.9	Since the cost is high and revenew is low increasing incentives from instance from the US goverment could be way to i	1	1

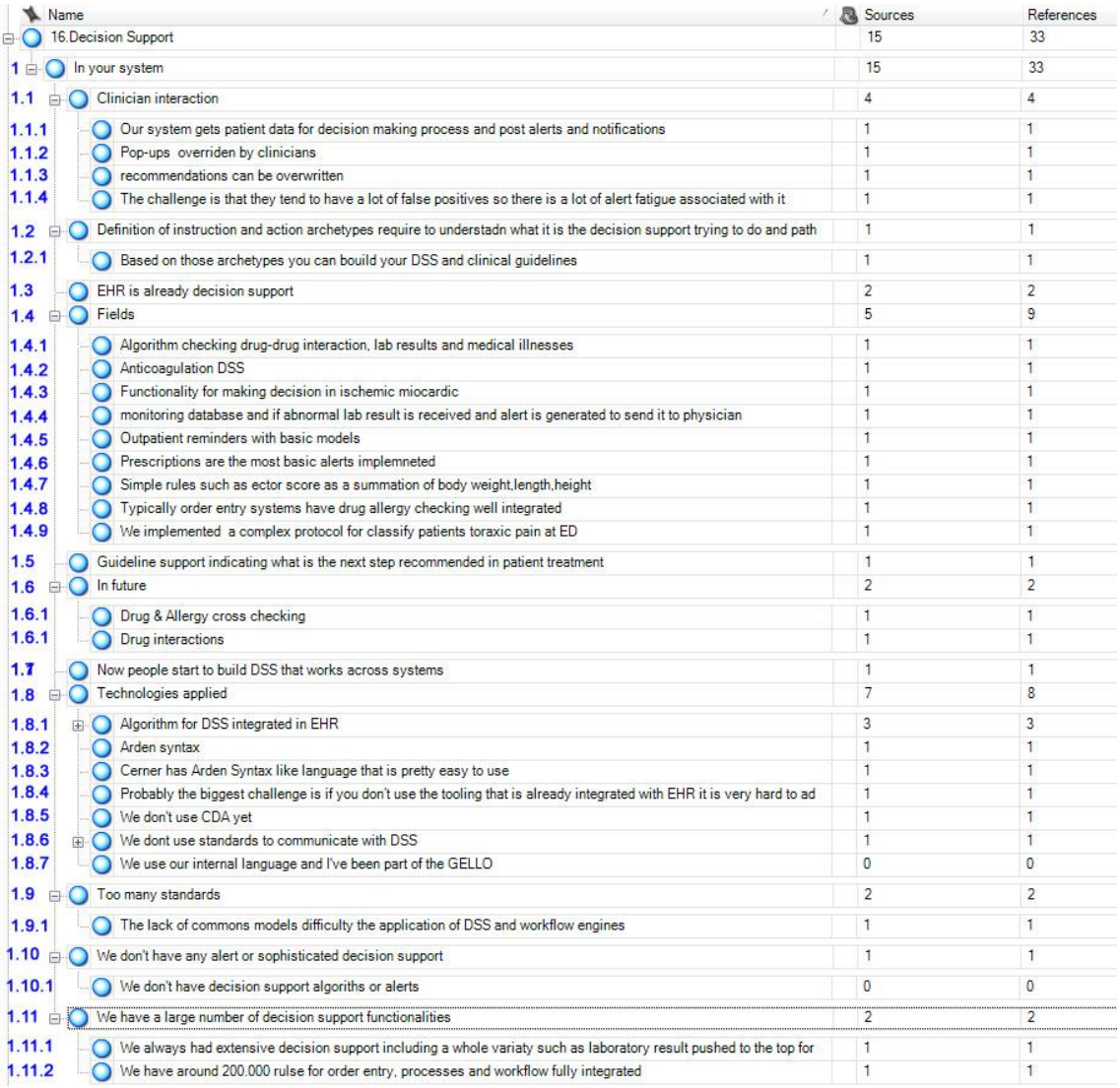
Figure 35. Classification of tags and extracts associated with the alignment with the latest clinical evidence

4.3.3.19 Decision support

Although it was recognized that EHR systems are already largely Decision Support Systems, not all interviewed experts had additional decision support functionalities implemented in their systems. A couple of interviewed experts indicated that their system had a large number of decision support functionalities implemented.

Their experiences were based on using Arden Syntax (Hripcsak, Ludemann et al. 1994), GELLO (Sordo, Boxwala et al. 2004), ontologies or proprietary solutions. The experts with decision support experience believed that the lack of common clinical models had contributed to the proliferation of large numbers of incompatible decision support rules, applications and engines.

Figure 36 details the classification of tags obtained in the performed inductive content analysis associated with modelling information for clinical decision support systems.



Name	Sources	References
16.Decision Support	15	33
1 In your system	15	33
1.1 Clinician interaction	4	4
1.1.1 Our system gets patient data for decision making process and post alerts and notifications	1	1
1.1.2 Pop-ups overriden by clinicians	1	1
1.1.3 recommendations can be overwritten	1	1
1.1.4 The challenge is that they tend to have a lot of false positives so there is a lot of alert fatigue associated with it	1	1
1.2 Definition of instruction and action archetypes require to understadn what it is the decision support trying to do and path	1	1
1.2.1 Based on those archetypes you can bouild your DSS and clinical guidelines	1	1
1.3 EHR is already decision support	2	2
1.4 Fields	5	9
1.4.1 Algorithm checking drug-drug interaction, lab results and medical illnesses	1	1
1.4.2 Anticoagulation DSS	1	1
1.4.3 Functionality for making decision in ischemic miocardic	1	1
1.4.4 monitoring database and if abnormal lab result is received and alert is generated to send it to physician	1	1
1.4.5 Outpatient reminders with basic models	1	1
1.4.6 Prescriptions are the most basic alerts implemneted	1	1
1.4.7 Simple rules such as ector score as a summation of body weight,length,height	1	1
1.4.8 Typically order entry systems have drug allergy checking well integrated	1	1
1.4.9 We implemented a complex protocol for classify patients toraxic pain at ED	1	1
1.5 Guideline support indicating what is the next step recommended in patient treatment	1	1
1.6 In future	2	2
1.6.1 Drug & Allergy cross checking	1	1
1.6.1 Drug interactions	1	1
1.7 Now people start to build DSS that works across systems	1	1
1.8 Technologies applied	7	8
1.8.1 Algorithm for DSS integrated in EHR	3	3
1.8.2 Arden syntax	1	1
1.8.3 Cerner has Arden Syntax like language that is pretty easy to use	1	1
1.8.4 Probably the biggest challenge is if you don't use the tooling that is already integrated with EHR it is very hard to ad	1	1
1.8.5 We don't use CDA yet	1	1
1.8.6 We dont use standards to communicate with DSS	1	1
1.8.7 We use our internal language and I've been part of the GELLO	0	0
1.9 Too many standards	2	2
1.9.1 The lack of commons models difficulty the application of DSS and workflow engines	1	1
1.10 We don't have any alert or sophisticated decision support	1	1
1.10.1 We don't have decision support algoriths or alerts	0	0
1.11 We have a large number of decision support functionalities	2	2
1.11.1 We always had extensive decision support including a whole variaty such as laboratory result pushed to the top for	1	1
1.11.2 We have around 200.000 rulse for order entry, processes and workflow fully integrated	1	1

Figure 36. Classification of tags and extracts associated with modelling information for clinical decision support systems

4.3.3.20 Clinical workflows

Further research is needed in how business processes should incorporate archetypes, and how clinical models should be harmonized with the CONTSYS standard. Experts recommended focusing on modelling actions that will have an impact on patient risk rather than all the clinical actions to be performed during healthcare. The representative of one large IT company explained that they have moved towards providing a default flow of screens according to the clinical process, but allowing freedom to clinician to override this flow. One expert from a standardization body claimed that there has not been much effort in standardizing workflow syntax, probably because this is not as high priority obtaining common representation of

processes such as sharing the EHR information structures. Among the specifications applied by the interviewees were BPMN, archetypes, the HL7 framework or proprietary solutions. Figure 37 details the classification of tags obtained in the performed inductive content analysis associated with modelling clinical workflows.

	Name	Sources	References
	17.Clinical Workflows	14	35
1	Actions can be triggered by actors or time	1	2
1.1	Workflows related to time functionalities	1	1
2	Avoid excessive restrictions	5	6
3	CONTSYS	2	2
3.1	Contsys models as the least clinical activity	1	1
3.2	In the CONTSYS meeting it will be discussed the relationship among clinical workflow and documentation needs fullfiled	1	1
4	Fields	2	3
4.1	We have implemented for transversal proceses in our hospital test order, medication prescription, nurse process and sur	1	1
4.2	We have some experience modeling the intake process for breast cancer patients but the tool was not purchased by the	1	2
5	Framework to make possible for the user to jump from module to module	1	1
5.1	Go from medication administrations to procedure making all the screens easily available for user	1	1
6	Modeling Clinical workflows	6	9
6.1	Clinicians define a process taking a long time to be defined and they want it implemented the day after they decided it	1	1
6.2	Harmonise the complete path is a heavy effort	1	1
6.3	Identifying experts	1	1
6.4	Lots of different ways	1	1
6.5	OpenEHR has action and instruction archetypes but how they will be implemented can not be solved by them	1	1
6.6	Similarities with information modeling	1	1
6.7	Some scenarios have many exceptions	1	1
6.8	Start with simple paths in future they will become longer	2	2
7	Roles	1	1
7.1	Clinical care role	0	0
7.2	System Administrator	1	1
8	Technologies	3	3
8.1	HL7 framework	1	1
8.2	They are programmed into the applications we are working to create a general workflow tool	1	1
8.3	We have JBPM and it is a great advantage because it is able to satisfy the needs for modifications just when clinicians w	0	0
8.4	We used archetypes to give instructions to the workflow tool	1	1
9	This effort waits for us in the next decade	3	3
9.1	Standarize Workflow syntax is not high on my list	1	1
9.2	Workflow is the most under-researched area on health IT	1	1
10	Useful for national guideline publication	1	1
11	We dont use automatic workflows	2	2
11.1	Currently we don't define clinical workflows	1	1
11.2	System menus allow clinician freedom	1	1
11.3	We define the clinical process without any tool	1	1
12	We have moved towards defeult flows of screens	1	1
12.1	Previously we had tabs to facilitate clinician navigation	1	1
12.2	screens secquence themselve	1	4
12.3	Step by step workflow where if you want to deviate just have to press the tab but in most of cases it is not required	1	1

Figure 37. Classification of tags and extracts associated with modelling clinical workflows

4.3.3.21 Summary of key findings about the clinical information modelling process

Table 29 details the main findings identified as part of the inductive content analysis from the data collected within the interviews associated with the CIMP.

Recommendations for improving the clinical information modelling process		
Description	KF1. Agile deployment plus continuous improvement cycles are the recommended processes to ensure the fulfilment of system requirements. They could be combined with methods for evaluation success based on questionnaires and screen feedback buttons	Sources ▪ Continuous improvement 1@figure16 ▪ Evaluation of development 4@figure16 ▪ Feedback button 2.1@figure20
Recommendation	KF2. Improving tools and educational material to facilitate clinician participation and mitigate problems associated with a lack of understanding of modelling and system requirements. KF3. Involvement of professional medical associations and bodies KF4. Collaborative tools to support knowledge evolution at large scale. KF5. Define formal clinical information modelling process in order to be able to verify if defined CIMs were appropriately developed KF6. Improve tools with syntactical and semantic validation capabilities to support clinical information modellers	Sources • Improving tools 1@figure21 • Educational material 5@figure25 • Medical bodies 1.9@figure21 • Collaborative tools 1.4.2@figure21 • Define a formal process 1@figure21 • Tools with semantic check 1.7@figure21
Domain experts team composition		
Description	KF7. Involving teams of domain experts for supporting the process of collecting sources of information and requirements. They are required to review the definition of screens and clinical information models to verify the fulfilment of the requirements and validate the EHR system.	Sources: ▪ Collecting sources 4@figure20 ▪ Review screens and models 6@figure20 ▪ Validation 7@figure20
Recommendation	KF8. Compose a multidisciplinary team with at least doctors and nurses and any user groups who will access/analyse the data KF9. Include more than one expert from the same field to avoid personal dependences	Sources: ▪ Multidisciplinary team 5.2@figure20 ▪ Personal dependences 7.2@figure18
Clinical information modelling process phases		
Prioritisation & Scope definition:		
Description	KF10. Analysis of management, economic, logistic, regulatory, medical and nursing needs to define scope	Sources: ▪ Prioritisation 3@figure20
Recommendation	KF11. Any changes in scope should be accompanied by full analysis of the requirements of the system	Sources: ▪ Scope changes 5.9@figure22
Collecting sources of information for system definition		
Description	KF12. Clinical guidelines provide information about the recommended best practice KF13. Existing patient records both in paper or electronic form provide information about the current practice KF14. Technological specifications and CIMs provide guidance about how to structure the information	Sources: ▪ Clinical guidelines 4@figure20 ▪ Patient records 4@figure20 ▪ Technological specifications 4@figure20

Recommendation	KF15. Additional guidance when terminologies have overlapping scope is recommended	Sources: ▪ Terminology guidance 3@figure26
Collecting requirements from health and IT professionals		
Description	KF16. Definition of requirements for information collection, exploitation, transference and processing. Usually carried out at the same time that EHR system functionalities are defined	Sources ▪ Collecting requirements 5@figure20
Recommendation	KF17. Commercial, economic and administrative issues are commonly found and should be identified	Sources ▪ Commercial, economic and administrative issues 3@figure17
Defining prototype screens of the system		
Description	KF18. Defining prototype screens and system mock-ups are able to simulate the future implemented system	Sources ▪ Defining prototype screens 6.2@figure20
Recommendation	KF19. Early involvement of end users with prototype validation is recommended as mechanisms to fulfil requirements because is a mechanism easily understood by clinicians for detailing value sets and entries	Sources ▪ Early involvement of end users 6 @figure18
Defining implementable clinical information models		
Description	KF20. The information defined to be communicated and processed in the EHR system is structured according to formal EHR specifications and standards.	Sources ▪ Defining implementable clinical information models 6.1@figure20
Recommendation	KF21. Mapping to international terminologies requires the support of terminology experts to guide in the application of a consistent methodology for management pre-coordinated and post-coordinated terms. KF22. The definition of structured data should be guided by the processing and exploitation capabilities that the system aims to provide KF23. Common reference able to be specialized for local context in order to support sharing information with other domains or locations	Sources ▪ Terminology experts 2.2@figure26 ▪ Structuring information only when is going to be exploited 6@figure24 ▪ Specialise models for local context 1@figure28
Validation stage		
Description	KF24. Review the defined clinical information models, screens and final system through online or face-to-face meetings and workshops to collect feedback about possible missing requirements	Sources ▪ How to organise meetings 5.7@figure20
Recommendation	KF25. Domain experts not involved in the definition should be included in the validation stage to reduce the chances of missing or wrong requirement definition KF26. This stage could conduct usability testing processes with end users	Sources ▪ Defining implementable clinical information models 6.1@figure20 ▪ Usability testing 7.1@figure20
Implementation stage		
Description	KF27. Agile software development process is carried out by IT professionals with the	Sources ▪ Defining implementable

	coordination of leading team	clinical information models 6.1@figure20
Recommendation	KF28. According to the incremental releases it is recommended to collect users feedback from piloting the system in controlled scenarios	Sources ▪ Release 14.1@figure25
Governance and maintenance		
Description	KF29. Process for receiving feedback or issues relating to the adoption and use of the standards it publishes	Sources ▪ Maintenance 12.4@figure25
Recommendation	KF30. Monitoring and analyse how data is collected to identify errors in data collection to analyse possible strategies for preventing them KF31. Monitor relevant eHealth projects within the region to coordinate and harmonise specifications KF32. Promoting the use of reporting and analysis functionalities for the collected data increases the clinician's perception of usefulness of information and their acceptance towards high quality documentation	Sources ▪ Monitor data and exploitation 5.7@figure22 ▪ Monitor eHealth projects in the region 6@figure25 ▪ Increase clinician perception of usefulness 2@figure22

Table 29. Summary of key findings about the clinical information modelling process

4.3.3.22 Checklist for clinical information modelling process

In order to provide guidance for CIM developers the identified recommendation, requirements and metrics associated with the human & organisational factors were applied to develop a checklist. Table 30 presents the checklist that aimed to verify that the identified best practices are adopted as part of the CIMP according to a set of quality metrics identified for this domain.

Checklist for clinical information modelling process	
Understanding	
CL1. Has the scope (domain coverage, purpose) of the Clinical Information Models been shared and understood by all user stakeholders and additional relevant experts? (this is recommended to reduce the chances of a lack of common understanding between participants) CL2. Were the exploitation benefits communicated? (formalizing how these clinical models will deliver value to nominated stakeholder groups: it is recommended to explain benefits for end users to increase acceptance, and to document these intended benefits for future verification)	Sources: ▪ Changes in scope 5.9@figure22 ▪ Lack of common understanding 12@figure17 ▪ Explain benefits 11@figure18
Teams	

CL3. Has a multidisciplinary team participated in the modelling process? (it is recommended to include at minimum doctors and nurses, but often other user groups and those who will access/analyse the data) CL4. Has more than one expert per field participated in the modelling process? (it is recommended to have more than one expert from the same field to avoid personal dependences) CL5. Have experts from more than one location participated in the modelling process experts? (it is recommended to have more than one expert from the same field to avoid personal dependences, even if the eventual models are only to be implemented and used in one care location) CL6. All professional specialties and medical fields who will use the Clinical Information Models were consulted before the models were finalised? (it is recommended to have more than one expert from the same field to avoid personal dependences and include representatives from all the professional specialties and medical fields that will use the CIM)	Sources: ▪ Multidisciplinary team 5.2@figure20 ▪ Personal dependences 7.2@figure17 ▪ Other locations 3@figure28 ▪ Multiple domains 6@figure29 ▪ Prototype screens 6.2@figure20
Sources of knowledge	
CL7. Have existing published sources of clinical knowledge been consulted (e.g. pre-existing clinical information models, interoperability standards, national or international data sets). (it is recommended to use technical examples defined through a review process and to be standards based) CL8. Has the CIMP examined or developed the clinical examples in the form of scenarios or EHR screens to help communicate and gain consensus on the design of the models? (it is recommended to provide additional inputs to clinicians to ensure a good understanding of the implications of the model features, and to reduce dependency on the understanding of a small number of experts) CL9. Have the clinical models been examined according to their level of agreement with relevant regional, national or local guidelines? (this will allow verification of the clinical validity of the produced Clinical Information Model)	Sources: ▪ Check guidelines 4.2@figure20 ▪ Sources 4.2@figure20 ▪ Prototype screens 6.2@figure20 ▪ Level of agreement 13@figure25
Validation	
CL10. Has a methodology been applied for CIM validation? (E.g. discussion at a multi-stakeholder workshop, testing against previously-recorded patient data, etc.) (it is recommended to validate with a larger group of clinical experts than those who participated in the CIM design) CL11. Did the CIMP have more than one iteration process to allow for clinical review the models? (it is recommended to establish an iterative process that helps to tune the Clinical Information Models)	Sources: ▪ Validation 7@figure20 ▪ Feedback and iterations 2@figure20
Clinical Information models	

CL12. Have the final clinical information models been approved by consensus? (it is recommended to establish an iterative process that helps to tune the CIM till consensus between end users is achieved) CL13. Can the clinical models be shared with other clinical domains? (it is recommended to define models that are able to be applied in multiple domains to the best extent possible, to maximize consistency of clinical documentation) CL14. Has provision been made in each of the defined sections to record free text comments, unless it has been agreed that this is not appropriate? (it is recommended to allow recording free text comments associated to most relevant structured and coded concepts) CL15. Is each entry mapped to an international terminology? (it is recommended to have each Clinical Information Model concept mapped to an international terminology) CL16. Has the mapping to terminology been made by an expert in that terminology? (this is recommended to ensure that clinical information models do not have wrong maps to terminologies) CL17. Are all nodes of the medication, problem, allergy and test clinical information models mappings with terminologies? (this is recommended to ensure exploitation of at least the most relevant information included in patient summary) *CL18.* In order to allow a broad range of clinical situations that are intended to be covered by the model, does the model provide for all of the different kinds of clinical information that may need to be documented?*(it is recommended to identify and model all concepts required by relevant stakeholders in an inclusive process)* CL19. Has been specified which are the priorities to those items included in the CIM?(it is recommended to identify those concepts that won't be included in the final system because either budget or usability constraints) CL20. Have the mandatory items been specified? (it is recommended to identify the level of quality of care recording agreed by experts)	Sources: ▪ Consensus 5.4@figure22 ▪ Multiple domains 6@figure29 ▪ Information preferred as free text 5@figure24 ▪ Adding termsets to clinical information models 1@figure27 ▪ Terminology experts 2.2@figure26 ▪ Prioritising @section 4.1.2.3.16 ▪ Scope 3@figure20 ▪ Example of methodologies 5.4@figure20 ▪ Define mandatory data 8.2@figure23
Knowledge Evolution & Governance	
CL21. It is clear how and when the defined models will be updated? (it is recommended to define the process for updating the models) CL22. Have the eHealth projects that will adopt these models been specified?(it is recommended to identify which projects and systems will use the models, at least initially to monitor how they are applied) CL23. Have the defined CIMs been made available to the interested parties?(it is recommended to make CIMs available to support its adoption and revision)	Sources: ▪ Continuous update process 1.2.1@figure31 ▪ Monitor eHealth projects 6@figure25 ▪ Publish 9.2@figure20

Table 30. Checklist for clinical information modelling process

4.3.4 Discussion

This section analyses how the results of the international survey of modelling initiatives presented in the previous section could contribute towards the establishment of good modelling practices and scaling up those processes associated with clinical information modelling.

4.3.4.1 Establish good modelling governance practices

Based on the qualitative content analysis of 20 experienced EHR experts, this research has identified a representative sample of practices and needs for CIMPs in large EHR infrastructures. Collected results did not show differences in the modelling processes adopted based on the different EHR standards and specifications applied. As a result, it could be inferred that CIMP for EHR systems could be harmonized.

These results complement the previously published literature by providing a more detailed description of the CIMPs and providing recommendations for multiple steps of this process like organisation of teams or terminology binding. The information extracted from interviews can be useful to provide a wider spectrum of CIMPs and the proposed steps and roles can help to palliate the lack of common nomenclature in this area. For instance different experts applied many different terms for the person leading CIMP. (e.g. medical informatician, information analyst, clinical information modeller and expert in methodology). This contributes to a lack of understanding and different perspectives on the clinical information modelling tasks. Likewise, the definition of a detailed methodology and educational materials that address the multiple steps of the CIMPs could be an appropriate instrument to overcome some of the barriers identified.

Clinical information modelling tools were identified as a relevant area for further research in order to improve the CIMP. New functionalities for these modelling tools were identified: interviewed experts suggested improving tool capabilities for creating CIMs and user-interfaces as a mechanism for accelerating the CIMP and make easier to obtain wider clinician participation. They can be combined with new functionalities that will guide the participation of different actors in the CIMP. The collected information was applied to identify new requirements for tools presented in section 4.4.

Aligned with the analysis of literature previously performed, the obtained results indicate that it is possible to define a common CIMP to be applied with multiple EHR specifications. Results obtained from experts experienced in heterogeneous EHR communication technologies were consistent between them, making it possible to identify common recommendations to improve the establishment of good modelling governance practices. The obtained modelling process in this research has a strong level of similarity with the results from the literature. The most relevant difference is the emphasis on combining CIMP with iterative software development techniques such as agile technology. This will allow providing updated version of defined CIMs

aligned with EHR system evolution. In addition, aligned with the analysis of the literature, interviewed experts did not include as a recommended step in the CIMP publishing the final models in order to share them with others. Although sharing the defined models is not mandatory, it could lead to increased feedback resulting in improved quality of the definitions and will help the harmonisation from multiple groups developing CIMs and in the same domain (increasing semantic interoperability of EHR information).

4.3.4.2 Scaling up the resource development process

Existing collaborative tools allow the participation of relevant stakeholders but it is recommended that this is complemented by a regulatory endorsement, as well as a practical strategy for eHealth semantic interoperability. Monitoring and collaborating with other eHealth projects within a region/nation (but with a reduced or local scope) should enable promotion of a gradual harmonization of CIMs within a region. Defining CIMs based on a maximally inclusive data set (i.e. including a superset of the data items nominated across all relevant stakeholders) was identified as an easier approach to obtaining consensus. Existing recommendations to define CIMs as maximally inclusive data sets (Buck, Garde et al. 2009) could incorporate data items required by localised eHealth projects (centred on a hospital or city) into a regional or national governance process. Local eHealth projects would thereby have more resources in the form of recommended CIMs, and they could use their limited budget by working with regional/national recommendations for clinical information modelling and then applying prioritisation mechanisms to select the most relevant information that they will require locally for their final screen forms and to share within the regional infrastructure. Even though a clinical information modelling approach will result in reduced costs, there is an initial need for substantial funding for monitoring and coordinating the eHealth semantic interoperability strategy. The SemanticHealthNet project conducted further research in this area to identify approaches that could increase coordination in the development of semantic interoperability resources on a large scale. This project aimed to provide the methods, the cooperation and recognition of the different semantic resources developed by multiple European projects and international initiatives including relevant information about their quality and their potential for reuse in the trustworthy and consistent manner. The definition and eventual implementation of a large scale process for discovery, review and reuse of semantic interoperability resources is expected to accelerate a continuous improvement cycle.

On the other hand, the involvement of professional bodies needs to be promoted and this will make it easier to obtain wider clinician participation in the CIMP. New functionalities should be incorporated into these modelling tools: interviewed experts suggested improving tool capabilities for creating clinical information models and suggested user-interfaces as a mechanism for accelerating the CIMP. Moreover, they can be combined with new functionalities that will guide the participation of different actors in the CIMP.

4.3.4.3 Limitations of the study

Although the sample selection of experts was made in an attempt to obtain international coverage and a large experience about CIMP using different EHR technologies, it was difficult to ensure representation across the full spectrum of clinical information modelling expertise and processes, and so some approaches may have been missed. Despite such limitations, the results obtained are proposed as useful to guide the development and test of a formal CIMP.

4.4 Requirements for Clinical Information Modelling Tools

4.4.1 Research Objective

Based on the reported limitation of existing CIMTs, this study sought to identify consensus on the requirements for a clinical information modelling environment in order to be able to support modelling tasks in medium/large scale institutions. Rather than identify which functionalities are currently available in existing tools the study aimed to identify functionalities that should be provided by good quality tools in order to provide guidance about how to evolve existing tools.

4.4.2 Methodology

This study was conducted according to the Delphi methodology: a technique designed to obtain the most reliable consensus amongst a group of experts to obtain the basis for defining technical quality criteria. (Dalkey and Helmer 1963) This is a method for structuring a group communication process to deal with a complex problem. There are multiple variants of Delphi techniques, and this study has been conducted according to the classical Delphi paradigm (Van Zolingen and Klaassen 2003).This is characterised as an anonymous process that can be achieved by sending the questionnaire either in paper form or online to the identified experts. They can provide their answers without being influenced by the social pressure of a group or differences in status within a group.

Through an iterative process experts are able to revise their opinion based on the controlled feedback provided in the second or successive questionnaire.

4.4.2.1 Sample of Experts

Starting from the set of experts participating in the SemanticHealthNet project a snowballing methodology (Emerson 1981) was applied to obtain a representative sample of experts with international coverage of tools developers and advanced users in the clinical information

modelling field. Each person contacted was requested to suggest additional experts. In addition the survey was distributed through the mailing lists of relevant organizations such as openEHR and HL7 as well as other more generic health informatics forums like the Linkedin groups of the Journal of American Medical Informatics Association and the European Federation of Medical Informatics.

4.4.2.2 First Round

The first round of the study was conducted between 10th November 2013 and 5th of December 2013. A total of eighty one experts were invited via an email detailing the aims of the study and its methodology. The questionnaire was developed based on the published information available in the literature about the tools presented in Section 2.4, and using results obtained in previous interviews conducted as part of a survey of 20 international recognized experts about how they implemented clinical information modelling processes addressing the current limitations and needs (Section 4.3.3.).

The first round of this study was focused on classifying and prioritizing requirements according to the experts' answers. The questionnaire included a request for some personal information to determine if the answers were influenced depending on respondent background. A total of fifty three requirements for CIM tools (CIMT) were organised under the following sections:

- Tool objectives
- Reference Model, formal syntax and technical implementations
- Semantic requirements
- Terminology binding
- Repository capabilities
- Clinical information modelling process
- Guiding clinicians in the development process
- Governance & Quality criteria

In order to be able to rate responses, all requirements were measured with the 5 point Likert Scale except for 2 open questions that had the possibility for multiple responses.

The Likert scale allows one to determine if respondents either 1-Strongly disagree; 2-Disagree; 3-Neither agree nor disagree; 4- Agree or 5-Strongly agree. Figure 38 gives an example question. The survey was conducted through a Google online questionnaire tool with a total of 59 questions that required around 30 minutes to be completed (a link to access the questionnaire is provided in Appendix C). Before distributing the online questionnaire, a group

of five experts were consulted to review the questions and to test the tool (i.e. to pilot the instrument). Their opinions and recommendations were focused mostly in rephrasing some of the questions.

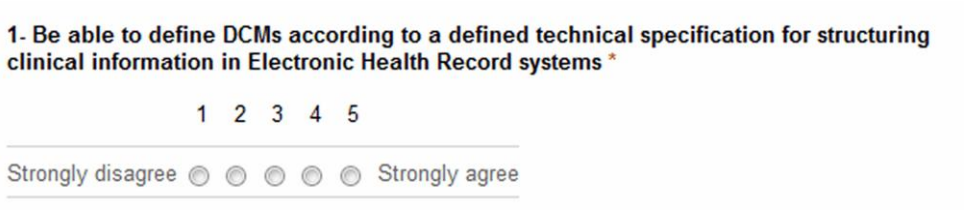


Figure 38. Example of a first round question

4.4.2.3 Classification of Requirements

The methodology included thresholds for respondents to prioritize each proposed requirements as essential, recommended or optional. This made it possible to identify the subset of most relevant requirements. The collected answers were classified, after collecting first round results, according to the following rules:

- **Essential requirements**: requirements that must be met by any tool that claims to be for clinical information modelling, and if we one day have a certified tools list, any tool that does not meet the essential criteria will be excluded. Requirements were considered to be essential when they obtained more than 70% of global agreement (4 or 5 point answers) and also had more than 50 % of respondents asserting strong agreement. These requirements are identified as the most basic capabilities that should be fulfilled by all future clinical information modelling tools.

- **Recommended requirements**: requirements that may be met by tool developers offering a superior product (e.g. a freeware version meeting only essential requirements, and a paid-for one meeting also recommended ones), or may be the recommended requirements are only needed in certain modelling situations, by specialised tools. Requirements were considered to be recommended when they obtained more than 70% of global agreement (4 or 5 point answers). These requirements were identified as recommended capabilities, based on the level of agreement, should be fulfilled by clinical information modelling tools but have a lower level of criticality

- **Optional requirements:** Requirements with a level of global agreement between 50% and 70% (4 or 5 point answers). These requirements didn't obtain the minimum level of consensus to be recommended and it will be decision of tool developers to incorporate them in case that they are suitable for their specific scenario.

- **Not recommended requirements:** Requirements with less than 50% agreement (4 or 5 point answers) were considered as not recommended.

4.4.2.4 Final Round

The final round of the study was conducted between 21th December 2013 and 5th of February 2014. This round aimed to validate the classification of requirements made. In this round a second online questionnaire was developed with the Limesurvey survey tool (a link to access the questionnaire is provided in Appendix C). This questionnaire asked experts if they agree with the proposed classification of requirements defined according to the first round results. The questionnaire asked experts if they agreed with those requirements which were identified as essential and recommended in the first round. If experts disagreed with any requirement, they were encouraged to explain why the requirement should not be covered. Figure 39 and 40 include screenshots of the essential and recommended requirement questions.

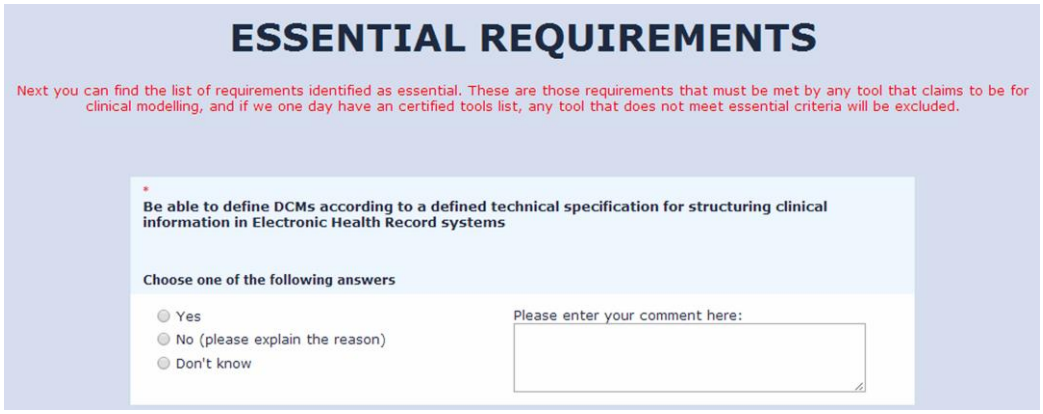


Figure 39. Example of essential requirement questions

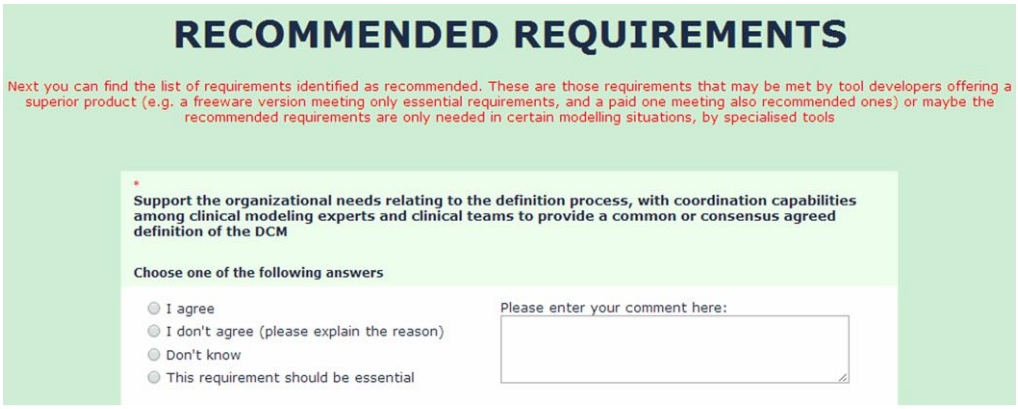


Figure 40. Example of recommended requirement questions

4.4.2.5 Checking for variability of results

In order to evaluate differences in responses to an item on the survey after two rounds, the *Wilcoxon* signed-rank *test* was applied (Wilcoxon and Wilcox 1964). This test is commonly used in this situation, and was applied here to check that there was no difference between the ranks of the responses of the experts from the two rounds (Kalaian and Kasim 2012). The test provides the sum of each of the positive and negative ranks of the differences between any consecutive rounds of Delphi survey responses (e.g., ratings) with a Z statistic and its asymptotic p-value. This makes it possible to evaluate how each person is influenced in the final round based on the classification made from the whole set of experts consulted. A p-value threshold of 0.05 was used to determine the comparison between the two round answers.

Given that questions in first round had 5 possible answers and in final round there were 3 possible answers for essential requirements and 4 for recommended requirements, a variable was created in order to being able to map answers provided to each round in a harmonized framework that could be analysed. This variable had the following values to express: disagreement (0 point), don't know (1 point) and agreement (2 points). According to this assignation, positive variations will represent increasing the level of agreement (e.g. one expert changing from disagreement to don't know or agreement). The negative variations are the opposite variations. The analysis included all the questions that have closed answer, Table 31 details how it was value assignation was applied for each question from the possible answers contained in first round or final questionnaire.

Round	Answer	Assigned value
First round	1	0
	2	0
	3	1
	4	2
	5	2
Final round: Essential requirements	No	0
	Don't know	1
	Yes	2
Final round: Recommended requirements	I don't agree	0
	I don't know	1
	I agree	2
	This requirement should be essential	2

Table 31. Assignment of values to questionnaire answers for Wilcoxon test

4.4.2.6 Research team

This research study was carried in collaboration with a team of three researchers (including the thesis supervisor). They collaborated with the author reviewing the results of survey and performing the Wilcoxon analysis. They contributed and approved the interpretation of the obtained results.

4.4.3 Results

Next are detailed the results of the Delphi study carried out to obtain consensus about the essential functional requirements for CIMTs. As was described in the methodology section, this study included two rounds based on specifically designed online questionnaires. The first round of this study was focused on classifying and prioritizing requirements and the final round aimed to first prioritise the list of requirements identified and finally aimed to validate the previous classification.

4.4.3.1 Delphi Study: First Round Results

Of the 81 experts directly invited to participate, 57 experts (63%) participated in the first round questionnaire. Only five people joined the study through the publicly available information in the specialised mailing lists and online groups.

This study only sought to include experts who had a minimum level of experience with clinical information tools, either as end users or developers. Three respondents who declared not being familiar enough with CIMT were therefore excluded from the study. The question about expert background provided for multiple answers because participants could be identified with both developer and end-user roles. Nine participants identified as end-users with basic modelling skills were considered to have the minimum level of understanding of the field based on their declared familiarity with multiple CIMT, and their length of experience in health informatics. Figure 41 shows the skills declared by questionnaire participants.

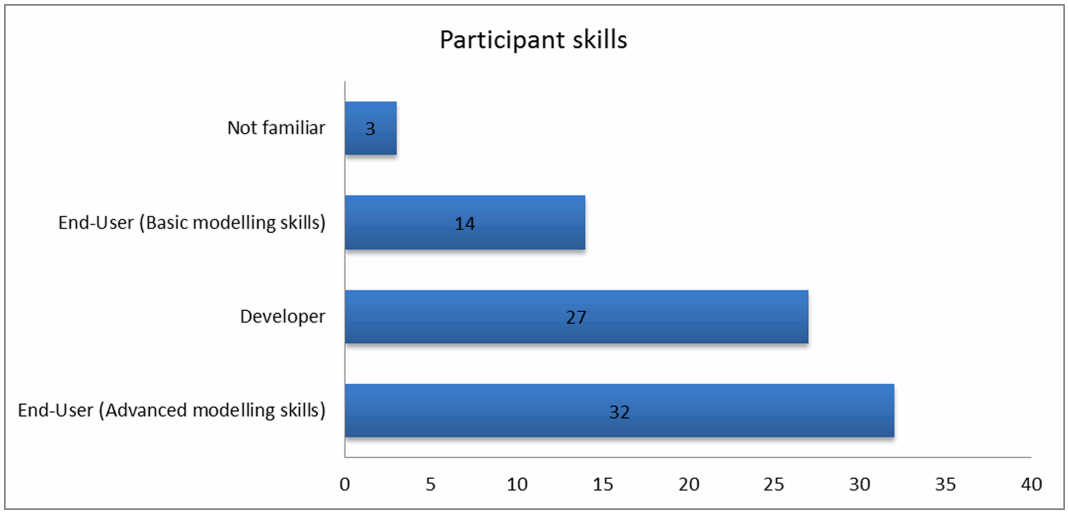


Figure 41. Participant skills

Most of the experts included in the study are active in more than one organization, with a high proportion of involvement of academia, industry and SDOs. This was helpful as it was intended to obtain international coverage aiming to collect answers from multiple backgrounds. Table 32 details the distribution of experts between countries.

Continent	Number of experts	Countries
Europe	41	Spain, Austria, Slovenia, France, Netherlands, UK, Norway, Denmark, Germany, Italy, Sweden and Ireland
America	7	US and Brazil
Oceania	3	Australia
Africa	1	Kenya

Table 32. Distribution of experts between countries

Figure 42 and 43 detail how the sample of experts was involved with multiple organisations and their experience with existing CIMTs.

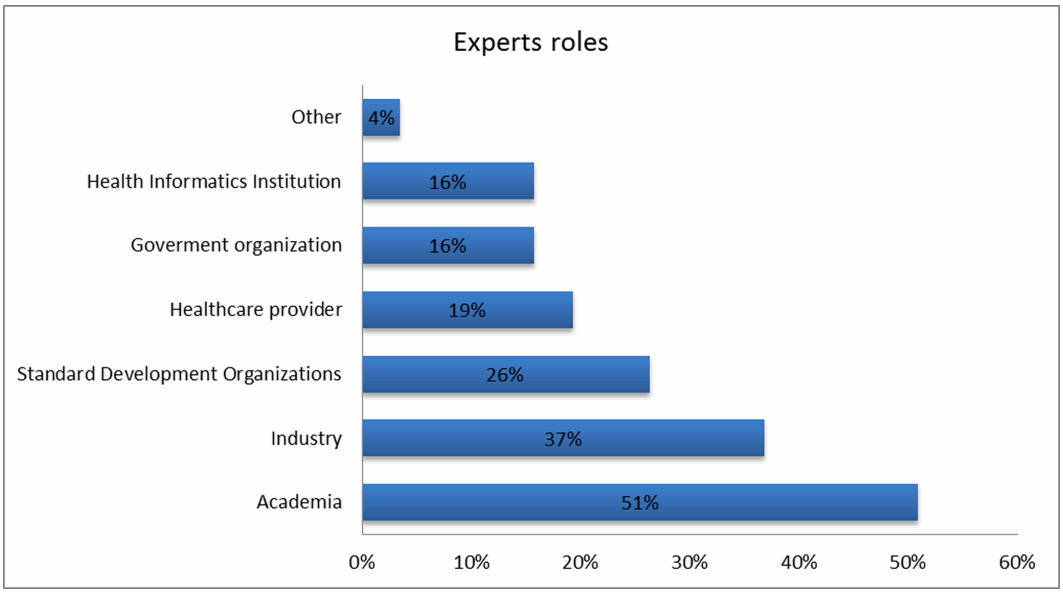


Figure 42. Expert involvement in organizations

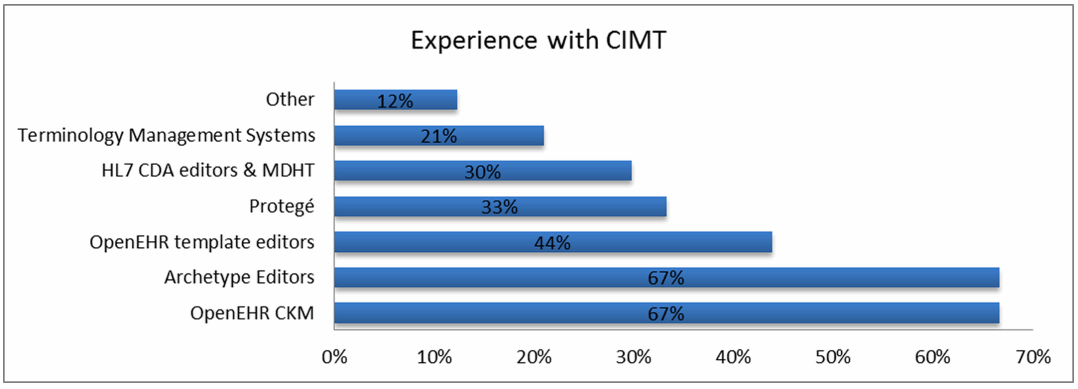


Figure 43. Expert experience with CIMT

Table 33 details the number of requirements classified either as essential, recommended or optional according to the first round of the Delphi study.

Requirements Classification	
Essential	22
Recommended	21
Optional	13
Not recommended	0

Table 33. Classification of requirements from first round questionnaire results

4.4.3.2 Delphi Study: Final Round Results

All the experts who answered the first questionnaire were invited to participate in the final round by email. A total of 38 experts (67%) participated in the final round to verify that they agreed with the classification of requirements made in the first round. Table 34 details the results obtained in the final round for essential and recommended requirements.

Type of requirements	Total	Approved	Rejected
Essential	22	20	2
Recommended	21	21	0

Table 34. Classification of requirements from final round questionnaire results

To be approved as essential or recommended each requirement had to obtain over 70% agreement in the final round. Although first round showed balance between those who declared to be developers (51%) and those who declared being only end-users (49%), in the final round developers were by 13% more participative than end users. The distribution between agreements and disagreements was similar in both groups of experts in the first and final round surveys.

4.4.3.3 Essential requirements

In general the level of agreement was very high and only one essential requirement R21 didn't obtain the minimum of 70% of agreement. It was also identified that R18 (enabling the formal definition of clinical content by domain experts without the need for technical understanding) had a 21% disagreement. Given that 73% of respondents agree to support this requirement the authors agreed to include this requirement as essential. The authors understand that in addressing the comments from those disagree with this requirement, this statement could be approved only after making clear that "no technical understanding" means having no previous knowledge about CIM specifications but still there could still be a need for support by a health informatician during the CIMP.

An open question determined the importance of the ability to import and export CIMs in multiple formats (R5). The results indicated that it is essential for CIMT to support XML and ADL

representations. In contrast, an OWL representation (R22) obtained 63% of agreement. This requirement was below the threshold but it is close enough to be considered an optional requirement, and is candidate to be included in the recommended group in future.

4.4.3.4 Recommended requirements

For some of those identified as recommended requirements, a few respondents claimed that they should be promoted to essential level, but the number of respondents claiming this promotion was in each case less than those who agreed with the proposed classification. As a consequence, it was determined that none of those proposed as recommended requirements had obtained the minimum level of consensus to be promoted to essential.

4.4.3.5 Resultant classification of requirements

The exhaustive list of requirements included in this study is presented in table 35 indicating if they were classified after the final round either as Essential (E), Recommended (R) or Optional (O). This classification was the resultant classification of the Delphi study based on the responses provided by the sample of experts participating in the multiple surveys. Additional information with the complete statistics of the results collected to each question in the multiple rounds of this Delphi study can be found in Appendix C.

Req. Number	Type	Description
R1	E	Be able to define clinical information models according to a defined technical specification for structuring clinical information in EHR systems
R2	E	Support the semantic interoperability of EHR systems
R3	E	Ensure consistency of information collected by enabling the definition of clinical information models generic enough to be compatible in multiple scenarios through specialization mechanisms for the additional constraints of each local scenario
R4	E	Definition and validation of the clinical information models according to a formal syntax
R5	E	Import and Export clinical information models according to the following formal syntaxes: XML and ADL
R6	E	Represent data types according an accepted data type standard (e.g. ISO 21090 standard or a subset of this)
R7	E	Support for version management, tracking changes and past history for each clinical information model
R8	E	Provide an automatic parser for the defined clinical information model
R9	E	Tools will verify that clinical information model and their instances are semantically and syntactically consistent
R10	E	The tool allows the author to create term bindings by connecting with Terminology Servers using (e.g. using CTS2) or another suitable terminology server communication specification
R11	E	Should include an intuitive graphical user interface for navigating large taxonomies
R12	E	Allows the user to assign one or multiple terminology/ontology concept to each node of the clinical information model structure
R13	E	Should include mechanisms that enable users and find a clinical information models in the repository by searching on any of its structured information properties

R14	E	Should export its clinical information model in at least one format that conforms to a published international standard or specification
R15	E	The repository and its services shall maintain a complete and audited version history for all of its clinical information models
R16	E	Should allow collaborative authoring of clinical information models according to the established roles. As well as recording experts and organisation participating in this process
R17	E	Should provide mechanisms to support multiple language translations of a clinical information model
R18	E	Should enable the formal definition of clinical content by domain experts without the need for technical understanding
R19	E	Should ensure the definition of purpose, appropriate description of usage, and precise mention of clinical information model domain
R20	E	Generate documentation for clinician review as MindMaps and Prototype Screens
R21	O	Facilitate the implementation of EHR systems that meet clinical requirements
R22	O	Import and Export clinical information models according to Web Ontology Language (OWL)
R23	R	Support the organizational needs relating to the definition process, with coordination capabilities among clinical information modelling experts and clinical teams to provide a common or consensus agreed definition of the clinical information model
R24	R	Support the implementation of governance mechanisms to allow the establishment of an agreed editorial policy, process and quality criteria
R25	R	Promote the clinician adoption with a simplified and guided view well understood by them that guide their participation in the modelling process
R26	R	Define semantic and syntactic patterns in the form of constraints to on the selected Reference Model
R27	R	Provide an automatic testing environment for systems using the defined clinical information model
R28	R	Should allow the definition and import of Semantic patterns
R29	R	Should include Visualization components for viewing complex term relationships
R30	R	Should facilitate the use of the clinical information model to transform/map from existing data
R31	R	Should allow to define transformations of the clinical information models to/from other specifications
R32	R	A repository service should provide a notification service to experts and systems about clinical information model updates, additions and backwards compatibility
R33	R	Where more than one format is supported, requester user or system will be able to nominate the preferred retrieval format
R34	R	Requesters of obsolete versions of an clinical information model shall be provided with a notification that an update (or updates) exist and be able to nominate the version(s) to be returned
R35	R	Allows to subscribe to clinical information model and terminology repositories from national/international regulatory bodies to ensure that is contained version of the clinical knowledge is updated
R36	R	Provide mechanisms for backward compatibility
R37	R	Should provide mechanisms to assign the following roles to experts participating in the Clinical information modelling process and document this information in the final clinical information model produced: editor, author and reviewer
R38	R	Should provide mechanisms for document sharing, discussion and wiki with 2.0 capabilities to support the collaborative development
R39	R	Should provide the means to define the clinical and usage scope of the

		clinical information model in a structured and coded format, in order to be able to check for possible scope overlap with other clinical information model
R40	R	Should implement clinician understandable mechanisms for a guided process for local specialisation and validation purposes
R41	R	Should be able to create prototype screens for domain expert validation of the defined clinical information model auto-generates example GUIs to test the creation of example instances
R42	R	User friendly interface for clinicians including drag & drop capabilities to be able to manage multiple clinical information models easily
R43	R	Editorial role can examine changes, and accept or reject changes
R44	O	Should be easily adapted to using alternative types of (or new versions of) a Reference model
R45	O	Import/select the reference model that will lead underpin the definition
R46	O	Should be able to compare 2 clinical information models covering a similar clinical domain and highlight differences
R47	O	Should allow to rank similar clinical information models
R48	O	Tools should suggest clinical information modellers with candidate terminology/ontology terms based on their semantic underlying model.
R49	O	Should request the items to be included in the generic definition of clinical information models according to the maximal data set approach
R50	O	Should provide mechanisms for prioritising data items to be included in local implementations based on minimal data set approach and multiple user needs
R51	O	Should integrate or link to educational material to teach clinicians how to participate either in core and validation domain expert group
R52	O	Should allow to assign or edit the GUI presentation capabilities for local purposes, making possible that clinician/administrator edit the local presentation
R53	O	Tools for ongoing monitoring level of use and acceptance of clinical information models
R54	O	Provide mechanisms for generalization capabilities
R55	O	Ensure conformance to any relevant licenses or restrictions for use of clinical information models and provide appropriate means to inform potential users
R56	O	Should include checkbox to verify that the resultant clinical information model quality has been developed according to the quality metrics defined by editorial role

Table 35. Classification of requirements for Clinical Information Modelling tools. E=Essential; R=Recommended; O=Optional

4.4.3.6 Checking Variability of responses

According to Wilcoxon signed-rank test only two requirements had a result below the previously defined minimum threshold. Firstly, it was confirmed that R21 should not be approved as essential since this requirement obtained a result (p=0.012) below the threshold and was not appropriated to be approved as essential. As a result it was determined that it was not essential that CIMT should facilitate the implementation of EHR systems. Based on the high level of agreement (68.5%) in the second round, it was determined that it could be considered as an optional requirement which is a candidate to be included in the recommended group in the future. Secondly, R32 was the only requirement that obtained a result below the threshold (p=0.033) within the Wilcoxon test due improved perception in the second round questionnaire.

Although 24% of respondents had an improved perception (positive rank in second round), the number of people claiming the requirement as recommended was so much higher (78%) than those claiming to promote the requirement to essential (13%).

Table 36 displays the results from the analysis of variability of answers. Data is presented indicating the number of people and their average as n (%) that either reduced the level of agreement (negative), increased their level of agreement (positive) or kept the same answer (draw). The p value was calculated through Wilcoxon signed-rank test and the threshold for this variable was (p=0.05).

Req. Number	Negative rank	Positive rank	Draw rank	p
R1	1 (3.0)	8 (22.0)	28 (76.0)	0.075
R2	4 (11.0)	3 (8.0)	30 (81.0)	0.792
R3	2 (5.0)	4 (11.0)	33 (89.0)	0.330
R4	1 (3.0)	3 (8.0)	33 (89.0)	0.317
R6	4 (11.0)	2 (5.0)	31 (84.0)	0.330
R7	3 (8.0)	2 (5.0)	32 (86.0)	0.655
R8	4 (11.0)	4 (11.0)	29 (78.0)	0.557
R9	2 (5.0)	2 (5.0)	30 (81.0)	0.340
R10	3 (8.0)	0 (0.0)	34 (92.0)	0.083
R11	8 (22.0)	6 (16.0)	23 (62.0)	0.628
R12	3 (8.0)	2 (5.0)	32 (86.0)	0.783
R13	5 (14.0)	1 (3.0)	31 (84.0)	0.084
R14	1 (3.0)	2 (5.0)	34 (92.0)	0.564
R15	1 (3.0)	3 (8.0)	33 (89.0)	0.317
R16	4 (11.0)	3 (8.0)	30 (81.0)	0.603
R17	2 (5.0)	4 (11.0)	31 (84.0)	0.915
R18	5 (14.0)	4 (11.0)	28 (76.0)	0.902
R19	2 (5.0)	6 (16.0)	29 (78.0)	0.473
R21	10 (0.27)	2 (5.0)	25 (68.0)	0.012
R23	9 (24.0)	5 (14.0)	23 (62.0)	0.175
R24	5 (14.0)	4 (11.0)	28 (76.0)	0.623
R25	8 (22.0)	2 (5.0)	27 (73.0)	0.103
R26	7 (19.0)	3 (8.0)	27 (73.0)	0.166
R27	11 (30.0)	5 (14.0)	21 (57.0)	0.236
R28	6 (16.0)	5 (14.0)	26 (70.0)	0.963
R29	4 (11.0)	6 (16.0)	27 (73.0)	0.222
R30	6 (16.0)	9 (24.0)	22 (59.0)	0.854
R31	4 (11.0)	7 (19.0)	26 (70.0)	0.285
R32	2 (5.0)	9 (24.0)	26 (70.0)	0.033
R33	3 (8.0)	8 (22.0)	26 (70.0)	0.088
R34	4 (11.0)	8 (22.0)	25 (68.0)	0.153
R35	2 (5.0)	8 (22.0)	27 (73.0)	0.124
R36	6 (16.0)	6 (16.0)	25 (68.0)	0.614
R37	3 (8.0)	3 (8.0)	31 (84.0)	0.999
R38	2 (5.0)	8 (22.0)	27 (73.0)	0.052
R39	6 (16.0)	6 (16.0)	25 (68.0)	0.796
R40	7 (19.0)	7 (19.0)	23 (62.0)	0.816
R41	3 (8.0)	3 (8.0)	31 (84.0)	0.739
R42	5 (14.0)	5 (14.0)	27 (73.0)	0.791
R43	2 (5.0)	4 (11.0)	31 (84.0)	0.414

Table 36. Non-parametric analysis results

4.4.4 Discussion

This is the first study that has analysed requirements for CIMT based on the opinion of a representative sample of experts. The sample of experts in the study included members from industry, academia, SDOs and the most relevant health informatics organizations with an international coverage. The study tried to be open to collect answers from any experts from the field and the snowballing invitation process resulted in a far more effective process than dissemination through specialised forums.

Experts were advised that agreed requirements should be fulfilled by tools in a reasonable time for adjustment (e.g. two years time). This was effectively addressed by their responses obtaining consensus on more basic capabilities that are common in tools but at the same time promoting the adoption of functionalities that still need to increase adoption such as requesting that tools should connect with terminology servers according to formal specifications. The research method was designed to ensure the confidentiality of respondents' identities and of their current involvement in the field, which should have minimised the "halo effect" commonly associated with Delphi studies, allowing respondents to be honest in supporting or disagreeing with the statements proposed in the questionnaire.

Given that both groups, developers and end-users, had similar distributions of agreement and disagreement, it could be inferred that technical limitations for satisfying the requirements are reasonable. Given that many of the existing tools will need to be modified to satisfy the supported requirements, this study appears to have overcome any potential difficulties associated with obtaining consensus amongst users that have existing products in the field.

4.4.4.1 Classification of requirements

According to the high level of acceptance provided in the first round of the study, the definition of a threshold to determine the classification of requirements and obtain agreement needed to be highly sensitive. Although initially the 70% threshold level requiring a strong level of agreement might appear restrictive, the results obtained in the final round confirmed that experts agreed with the final classification. Moreover, the evaluation of the existing tools against the defined essential requirements performed in section 4.4.3 shows that all the requirements were able to be implemented and most of them were widely implemented. As a result, it is confirmed that the defined threshold was not low.

4.4.4.2 Essential Requirements

These are the requirements that must be met by any tool that claims to be for clinical information modelling. They effectively cover the full spectrum of the clinical information modelling processes including definition, version management and, repository capabilities. These tools should be adapted for use by modelling experts and by clinicians with a simplified

view, such as a mind map and prototype screens that allow clinician engagement without the need for technical (information modelling) understanding. On the technical capabilities, experts agreed on the need to include standard data types, connect with terminology servers, verify syntactic and semantics. The essential specifications for importing clinical information models were XML and ADL.

Although this study does not include a detailed evaluation about how existing tools satisfy the set of requirements agreed in this study, some of the requirements identified as essential are not adopted by any existing tools or representative initiatives. An example requirement that is presently unsupported is the definition of clinical information models in an XML format, since some of the CIM specifications with wide acceptance use other formats such as ADL (R5). This requirement reflects a desire among tool developers and experts for making it possible to define constrains over the RM in XML format, which is not currently supported by CIMI, openEHR or EN ISO13606.

It is important to note that although most of the effort in CIM tools development has traditionally been focused only on technical developers as users, the results of this study suggest that tools should also take into account the participation of clinical experts, providing them with mind-maps and screen forms for validation, and enable their participation in the formal definition of clinical content without the need for technical understanding (R18, R20). Today most CIM Editors are designed and expected to be used by software developers. It is recommended that tools allow collaborative development of clinical information models based on multiple (collaborating) user roles (R16).

4.4.4.3 Recommended Requirements

These are the requirements that may be met by tool developers offering a superior product or one that is only needed in certain modelling situations, for example by specialised tools. These requirements included additional capabilities mostly linked with design governance, the modelling process (workflow) itself, model adoption and implementation. In addition, advanced functionalities were identified such as the definition and import of semantic patterns as guidance for clinical information modelling and the ability to map information models to multiple specifications.

4.4.4.4 Optional Requirements

Those identified as optional requirements include more complex semantics such as being able to work with multiple reference models, suggest candidate terminology/ontology concepts, identify semantic overlaps and rank similarities between models as well as support generalization capabilities rank. In addition to the increased difficulties associated with the development of tools with increased semantics, it was recognised that tools could satisfy user needs being compliant with just one specification.

Requirements based on clinical information modelling process such as specific steps for identifying items according to the maximal data set approach, prioritizing them and including a checkbox to verify metrics did not obtain the minimum level of agreement to be considered recommended. The lack of available published material at the time of this survey about best practices in clinical information modelling could impact on obtaining consensus on these requirements.

The first round results showed that all the requirements included in each category had a high level of relevance, obtaining at least 60% of acceptance for all of them. Given that some requirements were derived from previously implemented systems and suggestion made by previously interviewed experts, it could be inferred that they were perceived as requirements that were able to be successfully implemented and desirable to be included in any tool.

4.4.4.5 Limitations of the study

Although the sample of experts was representative by including highly active experts from leading health informatics communities, there may be potential future users of CIMT who were not identified as they are not connected with the field at present. For example, patients are not presently engaged in the design of most EHR systems, but will increasingly access EHR data and contribute to their provider held EHR. Their views on the shape of clinical information structures and terminology will become increasingly important.

The tool functions that were reflected in the initial list of candidate requirements were drawn from the existing literature, which has largely been authored by those active in the field already and therefore has the risk of having reinforced at least some of the functions that are already largely perceived as relevant.

There are multiple (usually independent) tools that currently support different parts of the CIMP life cycle, and this research did not seek to distinguish which kinds of tool will be required to satisfy each requirement. In future any organisation that intends to develop CIMP may be able to choose from a range of tools the one that will best satisfy their requirements. This may be a single tool (e.g. a CIM editor integrated with a repository in the cloud) or multiple tools that work together as an ecosystem for clinical information modelling.

For both types of limitation, the diversity of survey respondents from different backgrounds, countries and initiatives offers some mitigation. It is in practice very difficult to engage completely novice individuals in appraising the need for tools in such a niche area of health informatics as this. A more broad survey of potential future clinical information model developers would have needed an extensive educational process before their views could have been obtained.

Although it was attempted to collect answers at an international level including dissemination of the questionnaire within organisations not based on Europe such as AMIA, HL7 and openEHR, most of respondents were based in European countries. Additional dissemination within mailing lists from non-European organisations such as IMIA could have provided a wider representation from multiple continents.

4.5 Evaluation of Clinical Information Modelling Tools

4.5.1 Research objective

This research study aimed to define an evaluation framework for CIMTs based on the consensus obtained from experts in the field about the definition of essential requirements for CIMTs. The proposed conformance criteria were tested with a representative sample of existing tools in order to identify current needs that are not fully supported for defining, validating and managing CIMs used by large healthcare providers.

4.5.2 Methodology

4.5.2.1 Questionnaire Development

Fifty conformance criteria were developed based on those 20 functional requirements identified as essential in the previously-described research. Conformance criteria were developed specifying the set of questions needed to verify that each requirement has been met. They were agreed between 4 experts in the field and tested with a group of 3 tool developers. These conformance criteria were incorporated within a self-evaluation questionnaire sent to relevant tools developers. Possible answers to each question were “Yes”, “No” and “Don’t know”. Table 37 details the main domains covered by the questionnaire. The full version of the questionnaire is included in the Appendix D.1.

▪ Data types & specifications ▪ Support for testing and validation process ▪ CIM Metadata ▪ Support for CIM evolution and specialization ▪ Collaboration	▪ Clinician involvement ▪ Searching capabilities ▪ Terminology and ontology binding process ▪ Semantic relationships ▪ Communication with Terminology servers

Table 37. List of domains covered by functional requirements for CIMTs

4.5.2.2 Identification of tools

Based on the results from a systematic literature review (section 4.2), an international survey about clinical information modelling processes (section 4.3) and answers provided by experts interested in CIMT as part of a Delphi study (section 4.4), the authors sought here to identify CIMT that were able to manage recognized international standards and specifications that can support the semantic structures (in the form of CIMs) for EHR communication. The specifications studied include:

- EN ISO 13606 standard (ISO13606 2008-2010)
- openEHR specifications (OpenEHR 2014)
- HL7 Clinical Document Architecture standard (ISO/HL7 27932 2009)
- HL7 version 3 standard (Beeler 1998)
- Detailed Clinical Model standard (ISO/DTS 13972 2015)
- Clinical Element Model specification (Coyle, Heras et al. 2008)

As part of this research, tools were excluded if they focused only on HL7 v2 messages (HL7 v2 2003) since this specification is not able to support the scalable management of semantics for comprehensive EHR communication (Mead 2006). Likewise, although tools emerging from the Clinical Information Modeling Initiative could have been candidates to be included in this research, we were not able to include them because these tools are still at an early stage of development.

4.5.2.3 Collection of questionnaire responses

The self-evaluation questionnaire was distributed to those teams involved in the development of the identified CIMTs. One definitive response, to be internally agreed, was requested from each organization responsible of the development and maintenance of each tool. Each tool self-assessment response was reviewed by the team of authors in order to verify that collected results appropriately correspond to the tool functionalities.

4.5.2.4 Research team

This research study was carried in collaboration with a team of three researchers (including the thesis supervisor). They collaborated with the author reviewing the results of survey performed. They contributed and approved the interpretation of the obtained results.

4.5.3 Results

Next are detailed the results obtained from the evaluation of a representative sample of tools against the defined evaluation framework for CIMTs. This evaluation aimed to test and validate the defined quality framework and also to identify current needs that are not fully supported for defining, validating and managing CIMs. As was described in the methodology section, this research applied a self-evaluation questionnaire that contained a set of quality metrics based on the previously-identified essential requirements for CIMT.

4.5.3.1 Evaluated tools

The self-evaluation questionnaire was distributed to development teams of the 11 identified initiatives working on CIMTs, a total of 9 tools were evaluated according to their performance to the defined evaluation survey tool. The other two initiatives were not possible to be contacted in order fill the questionnaire. The period of time for collecting these results started in August 2014 and finished in December 2014. Table 38 details the identified tools that satisfied the selection criteria to be included in this research and additional information is included in the Appendix D about all the identified tools not suitable for this research. As was explained in the methodology section, tools were excluded when they do not comply with those specifications to support the scalable management of semantics for comprehensive EHR communication.

Name of tool	Summary description	Supported specification	Evaluated	Examples of relevant projects
LinkEHR (LinkEHR-Ed 2015)	This platform is designed for modelling, normalization and semantic interoperability of health data. It has capabilities for transforming data into the most relevant EHR standards	Any specification based on reference model	Yes	Spanish National EHR specifications, Uruguayan National EHR specifications and several healthcare providers.

openEHR suite: archetype editor, template editor and clinical knowledge manager (OpenEHR Modelling Tools 2016)	Archetype editor is a software tool that defines clinical information models in the form of archetypes according to the openEHR specification. Template editor is a system that is able to combine multiple archetypes and specify additional semantics to be applied in a specific domain. This tool includes capabilities for defining how the specific form will be display on screen. Clinical Knowledge Manager is designed to act as repository for archetypes, templates and value sets	openEHR specifications	Yes	Australian, Swedish, Norway and UK national eHealth projects
Aruchi pattern tool (Lea 2015)	This editor software developed by University College London is able to define clinical information models and implement forms in EHR systems based on the defined models	Any reference model or without reference model	Yes	EHR4CR project
DCM Modeller suite (DCM-ModelCreator 2014)	The suite addresses different clauses from ISO 13972 by using the following set of tools: DCM Content Creator, DCM Model Creator, DCM Validator, DCM Composer and DCM Repository.	ISO 13972: Detailed Clinical Models	Yes	Dutch National Perinatology, National Epilepsy Register
Trifolia (Trifolia 2016)	Trifolia Workbench supports standards authors, developers and implementers in reviewing HL7 Clinical Document Architecture templates.	HL7 CDA templates	Yes	USA Office of the National Coordinator Longitudinal Care Coordination, Standards and Interoperability Framework

Model Driven Health Tools(MDHT 2016)	This open source platform promotes shared artefacts between related healthcare standards and standards development organizations, and works to develop localized specifications. Benefits of MDHT: provides automated publication of Implementation Guides and validation tools, delivery of a consistent format of published documents and reuse of existing templates to republish Implementation Guides for future initiatives	HL7 CDA Templates	Yes	US Semantic & Interoperability Framework project
OntoCR (Lozano-Rubi, Munoz Carrero et al. 2016)	OntoCR is a Clinical Repository that is based on metamodel and ontology technologies representing both the reference and the archetype models. They apply archetypes as building blocks for clinical applications	EN ISO13606	Yes	Hospital Clinic health informatics projects
openCEM (OpenCEM 2016)	Repository of defined clinical element model instances from Intermountain Healthcare.	Clinical Element Model	Yes	Intermountain Healthcare EHR projects
ART-DÉCOR (Art-Decor 2016)	Open-source tool that supports comprehensive collaboration of team members within and between governance groups. It allows separation of concerns and different views on a single documentation for different domain experts to support creation and maintenance of HL7 templates, value sets and data sets.	HL7 CDA Templates and HL7 v3 Templates	Yes	Perinatal Registry, Lithuania eHealth project
LiU archetype editor (LiU Archetype Editor 2007)	One of the earliest Archetype editors that was developed by the Linköping University Project. This project didn't have activity in recent year. Last release of this tool was from 2007. . It could be considered as obsolete.	openEHR specification	Not evaluated Not possible to collect feedback	Research projects from the Linköping University
openMapping software (OpenMapping 2016)	Model-based mapping tool defined complex integration projects, in healthcare and other domains.	GreenCDA and HL7 v3	Not evaluated because it was not possible to collect feedback	UK National Health Service Spine project

Table 38. List of the CIMT identified.

4.5.3.2 Domain specific results

The rest of this section presents the self-assessment results for each category of conformance criteria, and relating them to the specific question numbers of the questionnaire. Tables 39-41 present the detailed data about the performance of the evaluated tools against the metrics evaluated.

4.5.3.3 Data types & Specifications

All tools were able to represent data types according to standard specification (Q1), supporting the most common of them: Boolean, Integer, Double, date, date-time, URI, Multimedia, Concept Descriptor, Physical Quantity, String with Language (Q2). They were able to define CIMs according to a formal syntax that conforms to an open (published) specification (Q3)

Given that main purpose of the evaluated tools was to support clinical information modelling based on EHR interoperability specifications, all the tools included functionalities to detail the EHR specification and the version supported (Q4). Tools were able to demonstrate their conformance to each supported EHR through multiple mechanisms such as importing of models into other conformant tools, or through parsing tests against the published specification (Q5). 66.7% of them allowed exporting and importing according to a specified international standard for CIM representation (Q6). The same percentage supported more than one specification, providing capabilities to select which one to use when designing a new model (Q7). In order to avoid misunderstanding, they always displayed clear information about which CIM specification is satisfied by the selected CIM (Q8). The most common format for importing/exporting CIMs in CIMTs was XML (77.8%) (Q9). In second place was Archetype Description Language (ADL) format that was adopted by 44.4% of tools (Q10)

4.5.3.4 Support for testing and validation process

All the tools were able to validate that a defined or imported CIM was conformant to the selected specification (Q11), but validation errors were only fully detailed by 55.6% of them (Q12). The other conformance criteria in this category focused on support for more advanced testing processes, but these did not reveal a high level of adoption. The ability to export an XML Schema based on the defined CIM, against which instances of it may be validated (Q13) or library code by which valid instances in XML Schema may be parsed into a common object-oriented programming environment (Q14), were supported by 55.6% and 44.4% respectively.

4.5.3.5 Metadata of the CIM

All the evaluated tools are designed to record information about the expected purpose of use for each specific CIM (Q15). Most of the tools (77.8%) also allowed recording of the recommended usage (Q16) and clinical domains or clinical users (Q17)

Domain	ID	Description of tool capabilities	Adoption (%)
Data types & specifications	1	Representation of data types according to a specified data type standard	100.0
	2	Definition and management of the following data types: Boolean, Integer, Double, date, date-time, URI, Multimedia, Concept Descriptor, Physical Quantity, String with Language	100.0
	3	Definition of CIMs according to a formal syntax that conforms to an open (published) specification	100.0
	4	Show which CIM specification and which version of that specification is supported by the tool	100.0
	5	The tool has demonstrated a process of verifying that the CIMs produced or modified using the tool do conform to each CIM specification	100.0
	6	Exportation/importation according to a specified international standard for CIM representation	66.7
	7	Users can select between more than one CIM specification when designing a new model	66.7
	8	Tool supports more than one specification and it clearly displays when opening (viewing or editing) a CIM conformant specification	66.7
	9	Importation/exportation of CIMs in XML format, according to a publicly accessible XML schema	77.8
	10	Importation/exportation of CIMs in ADL format	44.4
Support for testing and validation process	11	Validation that a defined or imported CIM is conformant to the selected specification	100.0
	12	Shows any validation errors a specific CIM has according to the selected specification	55.6
	13	Emit an XML Schema based on the defined CIM against which instances of it may be validated	55.6
	14	Emit library code by which valid instances in XML Schema (or other, as above) may be parsed into a common object-oriented programming environment	44.4
CIM metadata	15	Define for which purpose a CIM is recommended to be applied	100.0
	16	Define for which usage a CIM is recommended to be applied	77.8
	17	Define for which clinical domain or clinical user a CIM is recommended to be applied	77.8

Table 39. Percentage of tools that satisfy functional requirements related with testing and validation processes, CIM metadata, data types and specifications.

4.5.3.6 Supporting CIM evolution and specialization

Although all CIMTs were designed to support the development of new versions of a previously defined CIM (Q18), the management of changes and previous versions was only supported by a subset of tools mostly corresponding to those that aim to act as CIM repositories. Only 55.6 % of tools allowed displaying previous versions of a CIM, detailing the changes made in the current version (Q19) and provided links to or direct access to the previous versions (Q20). 66.7% of CIMTs were able to detail all the tracked changes from a previous version (Q21).

In order to allow different levels of granularity, it is common that tools allow the definition of generic CIMs. There are functions that have been designed to support the management of specialization relationships between CIMs. 77.8% of tools included capabilities for defining further constrains making it possible to specialize a definition for a local scenario whilst ensuring compatibility with the generic definition (Q22). 88.9% of tools are able to include a reference in the specialized CIM to the more general version that it is based on (Q23). 66.7% of tools could identify all the specialized versions of a CIM defined for generic purposes (Q24).

4.5.3.7 Collaboration

To support collaboration between multiple participants many tools (77.8%) support the registration of multiple users so that the actions of different users on the same CIM can be attributed to each user (Q25). A lower number of tools (44.4%) provided a more specific support for processes associated with revision of CIMs, through functionalities that allow creating profiles for modelling experts such as an author, editor or reviewer and their respective organizations (Q26).

4.5.3.8 Clinician involvement

In order to promote the participation of clinicians as part of the CIMP for defining, reviewing and validating CIMs, some tools include simplified views specifically for clinical experts. 66.7% of tools are able to display CIM nodes and value set in the form of prototype screens (Q27) (Q28-29). Another common validation mechanism is based on mind map representations that were offered by 54.5% of tools (Q30).

Domain	ID	Description of tool capabilities	Adoption (%)
Supporting CIM evolution and specialization	18	Allow the creation of new versions of a previously defined CIM	100.0
	19	Display previous versions of a CIM, detailing the changes made in the current version	55.6
	20	Contain or link to a repository of all previous versions of any particular CIM	55.6

	21	Contain, reference, or generate a track of changes between all previous versions of a particular CIM	66.7
	22	Define further constrains on an existing CIM making possible to specialize its definition for local scenario ensuring compatibility with the generic definition	77.8
	23	When a specialized version of a CIM is created it includes a reference to the more generic version	88.9
	24	Identify all those specialized versions of CIM defined for local scenario from a CIM defined for generic scenario	66.7
Collaboration	25	Support the registration of multiple users and ensure each contribution to a CIM can be attributed to each user	77.8
	26	Include profiles for modeling experts such as author, editor or reviewer and their organizations	44.4
Clinician involvement	27	Include a simplified view for clinical experts to define or review clinical concepts that should be included as CIM nodes	66.7
	28	Include a simplified view for clinical experts to define or review clinical concepts that can be bound, or are bound, to CIM nodes	66.7
	29	Display a simplified representation of CIM nodes and value sets in form of a Prototype screen form	66.7
	30	Display a simplified representation of CIM nodes and value sets in form of a MindMap	55.6

Table 40. Percentage of tools that satisfy functional requirements related with collaboration in the modelling process, clinician involvement, CIM evolution and specialization

4.5.3.9 Searching capabilities

Many of the evaluated CIMT were able to support the management of multiple CIMs, acting as a repository. All tools allowed searching CIMs based on their name (Q31). More advanced searching functionalities were based on the concept codes and attributes associated with CIM nodes (66.7%) (Q32), clinical domain or value sets and terms bound to nodes (44.4%) (Q33-34).

4.5.3.10 Terminology and ontology binding process

All the evaluated tools allowed mapping each node of a CIM to a term (Q35), as well as creating, reviewing and binding a value list from an international terminology (automatically, or by end users manually, or a combination of these) (Q36-Q39). 88.9% of tools support multiple languages and have capabilities for mapping each node name and each term in a value list from more than one terminology (including multiple language translations of each term, if

relevant) (Q40-42). Moreover, the same percentage of tools allows mapping nodes to one or multiple ontology concepts. (Q43)

Other functionalities designed for supporting terminologist participation in CIMP had lower adoption. 66.7% of tools are able to incorporate terms and any relevant child concepts for the definition of value lists (Q44) and the same percentage allow searching in large taxonomies that can be bound to CIM nodes (Q45)

4.5.3.11 Semantic relationships

Although experts in our previous research claimed that displaying the semantic relationships between concepts could be beneficial for definition and review purposes, only 44.4% of CIMTs are able to display these. This subset of tools is able to show relationships between node names within a CIM according to their concept relationships within a published international terminology and relationships between a node name and its value list (Q46-47).

4.5.3.12 Communication with Terminology servers

66.7% of CIMTs are able to connect with remote (online) terminology servers that conform to published standards and specification (e.g. Common Terminology Services 2 Technical Specification (OMG CTS2 2012) (Q48). But their compliance is not full since functionalities included in CTS2 such as terminology service administration or search & query capabilities are only supported by 22.2% of tools (Q49-50).

Domain	ID	Description of tool capabilities	Adoption (%)
Searching capabilities	31	Searching CIMs based on CIM name	100.0
	32	Allow searching CIMs based concept codes and attributes associated with CIM nodes	66.7
	33	Allow searching CIMs based on domain	44.4
	34	Allow searching CIMs based on value sets and terms bound to nodes	44.4
Terminology and ontology binding process	35	Each node of a CIM could be mapped automatically or by end users manually to a term within a published international terminology	100.0
	36	Defined or reviewed value sets created or reviewed by a user can be drawn from or mapped to terms from a published international terminology	100.0
	37	Allow user to define value sets that will be bounded to CIM nodes	100.0
	38	Allow mapping nodes to one or multiple terminology concepts	100.0

	39	Terminology bindings are defined according to the chosen specification	100.0
	40	Allow a user to enter language translations of terms and concepts used within a CIM definition	88.9
	41	Allow mapping each node name to more than one terminology (including multiple language translations)	88.9
	42	Allow mapping each term in a value set to more than one terminology (including multiple language translations)	88.9
	43	Allow mapping nodes to one or multiple ontology concepts	88.9
	44	Allow user to identify one or more suitable terms from a published international terminology and incorporate such terms and any relevant child concepts to a defined value set	66.7
	45	Allow searching in large taxonomies that will be bound to CIM nodes	55.6
Semantic relationships	46	Show the semantic relationships between node names within a CIM by reference to their concept relationships within a published international terminology	44.4
	47	Show the semantic relationships between a node name and its value set if this is a terminology value set	44.4
Communication with terminology servers	48	Connection with remote (online) Terminology servers that conform to published standards and specification	66.7
	49	Connection with terminology servers based on specifications for terminology service administration (e.g. load, export, activate and retire terminologies).	22.2
	50	Connection with terminology servers based on specifications for search & query concepts	22.2

Table 41. Percentage of tools that satisfy functional requirements related with searching capabilities, communication with terminology servers, semantic relationships, terminology and ontology binding process.

4.5.3.13 Overall results of CIMTs in the evaluated domains

Figure 44 details the level of fulfilment of the multiple tools for each domain. For each domain it was calculated the number of metrics satisfied and divided by the total number of metrics contained in this domain. As a result, the presented is able to show that the evaluated domains could be classified in three levels of adoption:

- **Domains with high adoption level:** (more than 80%) tools fulfil those metrics and functionalities related with management of data types and EHR specifications. Moreover the capabilities for recording CIM metadata and defining terminology or

ontology bindings are widely adopted. This set of functionalities could be identified as the core set in the evaluated collection.

- **Domains with medium adoption level:** (between 50 and 80%) could be found about functionalities supporting the CIMP and associated processes. It involves tasks related with CIM search, CIM evolution and specialization or including capabilities to coordinated collaboration between CIMP participants, promoting clinicians involvement with personalized views or supporting testing and validation processes.

- **Domains with low adoption level:** (less than 50%) Last there are functionalities that were identified as essential such as displaying semantic relationships between concepts and communication with terminology servers that are only adopted in a few of the evaluated tools.

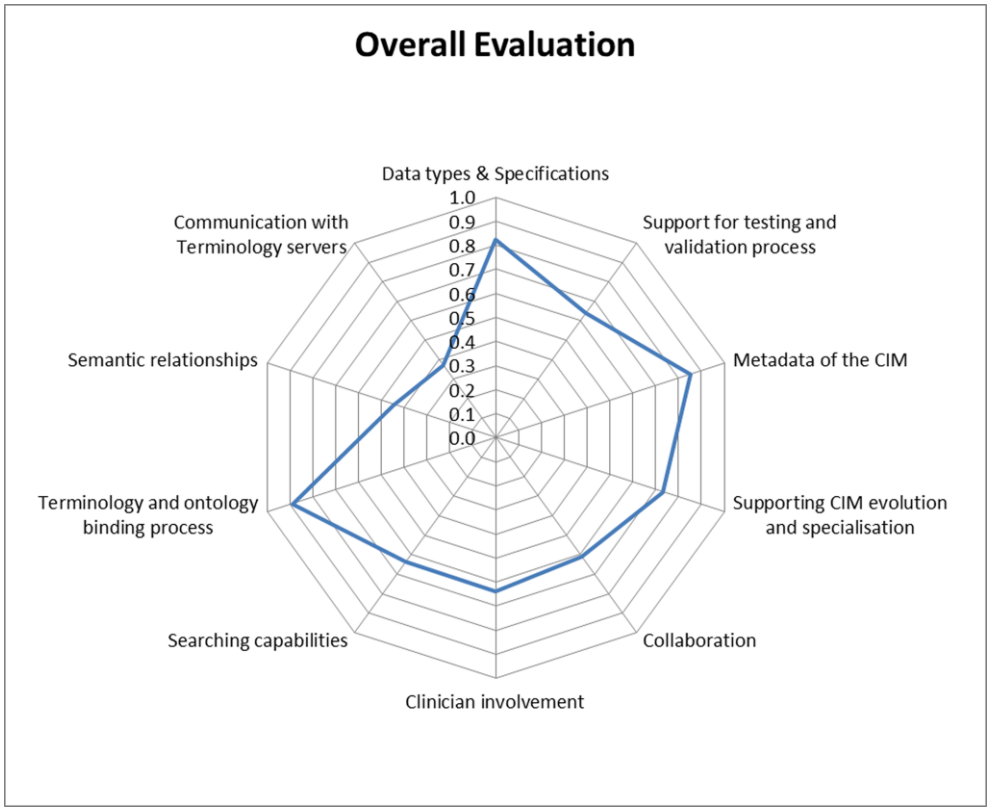


Figure 44. Graphical representation of the overall results of CIMTs in the evaluated domains

Figure 45 details how each evaluated tool performed according to the categories of conformance criteria. Similarly to the previous image, the presented charts show the level of fulfilment of each tool for the defined categories. The score for each category was calculated based on the number of metrics satisfied and divided by the total number of metrics contained in the evaluated domain. Results show that traditional classification of tools based on repository, CIM editors, screen definition tools, testing and validation tools, etc. are not clearly identified

since most of the tools fulfil a wide range of requirements. Moreover, it was observed that each tool's performance in the multiple domains was not associated with the specification supported. Appendix D details how the performance of the evaluated tools according to each of the metrics defined.

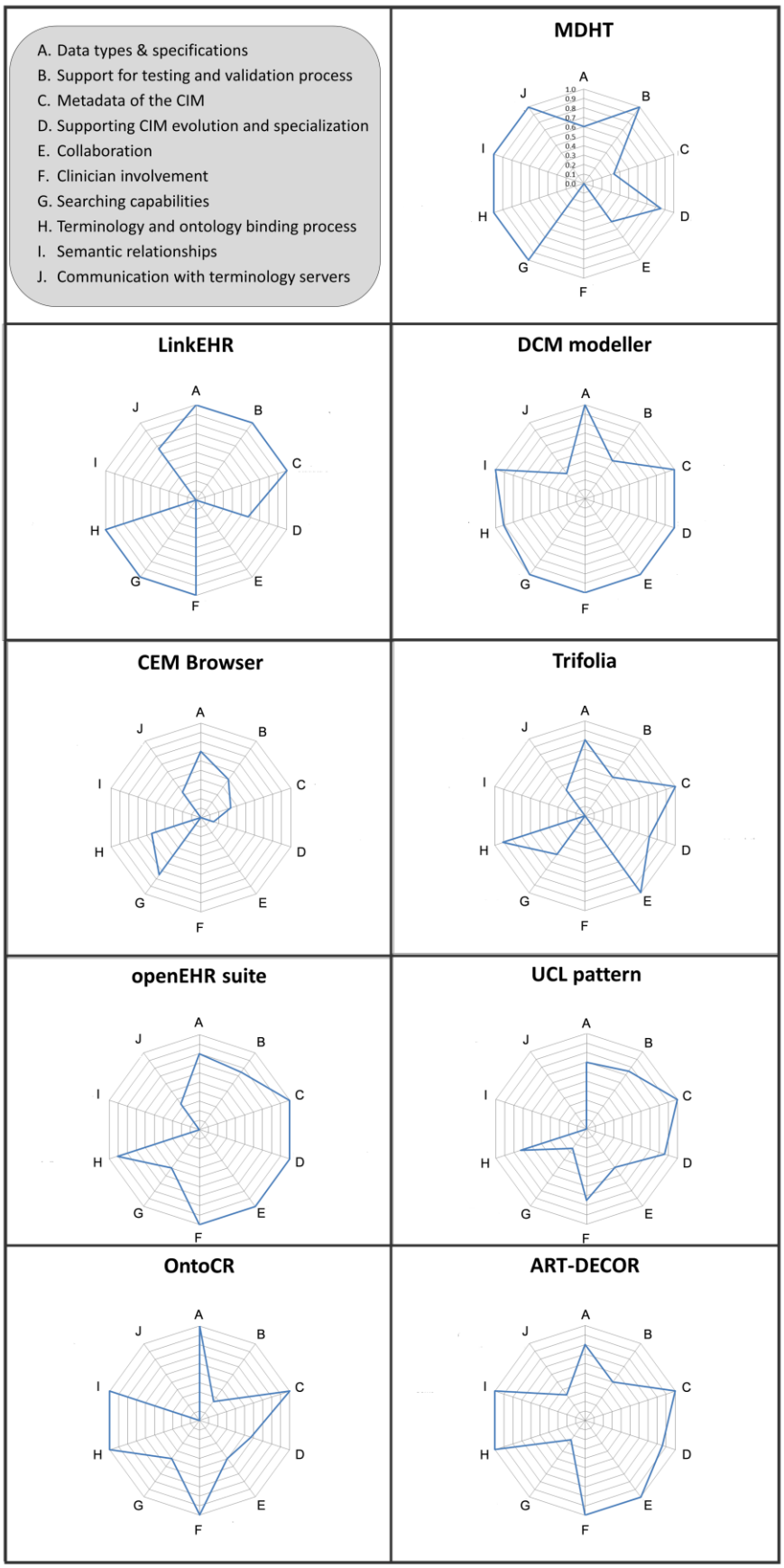


Figure 45. Graphical representation of the individual evaluation of CIMTs

4.5.4 Discussion

Based on the evaluation results, it is proposed that the defined CIMT evaluation framework is generic enough to be applied to multiple EHR interoperability standards and specifications. The framework should be applicable even if these interoperability specifications evolve. The evaluated tools show a large number of similarities in functionalities in the definition of CIMs, suggesting that tools applied in this field could benefit from common strategies and approaches resulting in more consistent CIMPs.

The evaluated set of essential requirements and criteria had been defined based on an open consultation with multiple developers and end users. They had prioritized the most relevant requirements that should be implemented by existing tools in a reasonable time for adaptation. All of these prioritized (essential) requirements and metrics proved to be implementable because each criterion was met by more than one of the evaluated tools.

This evaluation framework has the potential to guide the evolution of CIMT in the near future, as well as highlighting the current limitation of existing tools.

4.5.4.1 Areas to improve in Clinical Information Modelling Tools

Although tools in general fulfil the management of specifications, data types, terminology binding and CIM metadata, this evaluation shows that support to CIMP could be improved in the following areas:

- **Governance support:** Although all tools allow creating new versions of a previously defined CIM, 27% of tools don't support CIM evolution and specialization. These functionalities are required in order to establish governance in the CIMP through consistent management of CIMs that are able to be adapted to the needs of multiple projects and systems. This process is fundamental for healthcare providers to allow the correct management and evolution of the defined CIMs.

  This governance process usually establishes an editorial process designed to collect inputs from multiple experts for definition, validation and feedback about CIMs. Although editorial modelling processes can be established through face to face meetings and emails, the level of management effort required has clear limitations when scaling up these processes. As a result, incorporating these functionalities in CIMTs is recommended to reduce the efforts and costs associated with obtaining an open and transparent editorial processes for clinical information modelling, especially in large organizations. With only 44.4% of tools incorporating specific support for editorial process (Q26) it is recommended that this is one area where tools could promote the participation of a larger number of experts in CIMP, increasing the quality of the resultant models.

- **Clinical participation:** Aligned with the participation of experts in the editorial process, a lack of common understanding has been identified as one of the most relevant barriers associated with the CIMP (section 4.3.3.3). Collaboration between IT professionals, information modellers, terminologists and clinicians is not always straightforward, due in part to their different backgrounds. If the only available tools have been designed just for IT professionals, clinicians have difficulty becoming involved in the CIMP because the process is not friendly or flexible enough to become widely incorporated into their practice. The results show that improvements in 36.1% of tools defining simplified views personalized for clinical experts could help to reduce this problem.

- **Technical Validation & Testing:** Although technical validation & testing are not considered essential in CIMPs, optimizing the mechanisms associated with the implementation of defined CIMs should reduce the costs of development and adoption of these technical specifications.

- **Searching capabilities:** Given that all tools allow searching CIMs by name, incorporating functionalities to search by additional attributes should not be difficult to implement. On the other hand, benefits will only be seen in those organizations that have already defined a large collection of CIMs.

Considered next are those domains that were found to have a low level of adoption in existing tools.

- **Semantic relationships:** displaying the semantic relationships between concepts and value sets will allow users to easily determine the most appropriate concepts according to their hierarchies. The lack of fulfilment could be associated with the lack of adoption of medical ontologies in healthcare. Tools avoid implementing this functionality because local value sets are more often demanded by healthcare providers. With the expected increased ontologization of medical terminologies and the improved semantic interoperability level of quality of CIMs, it is expected that this functionality will become more relevant in the coming years.

- **Communication with terminology servers:** Although 66.7% of tools support communication with terminology servers based on standard specifications, only a few support communications related with load, export, activate, retire terminologies or query terminologies based on concept associations or search criteria. Since terminology servers are highly relevant to support the management and maintenance of multiple terms and mappings across multiple systems and organizations, their adoption is expected to grow. The results show that not all functionalities defined for communicating with terminology servers might have the same level of acceptance

because some of them might be implemented in terminology management systems that are external to a CIMT. As a consequence, healthcare providers are not able to benefit from synchronized management of multiple local and international terminologies to be applied in both new defined CIMs and the multiple systems deployed in their infrastructure. Moreover, the application of queries and search capabilities based on association impacts on the usability and validation capabilities that CIMTs could bring to the modelling process.

4.5.4.2 Limitations of the study

Ideally the assessments would each have been made by 3 or 4 experienced users not directly involved in a tool's development since external evaluation is the most secure mechanism to avoid bias. In contrast, for this study it was felt important to involve the development team directly, to make sure that all functionalities were evaluated since even experienced users might not be familiar with all the possible capabilities that each tool has. The author of this research is not currently CIMT developer, but is familiar enough with most of them. They acted as external referees who reviewed the answers from each tool development team. Ideally, though, the results of this kind of evaluation would be published openly in an online environment where the user communities of each tool could critique the responses, endorse or modify them based on their real usage experience

As a possible example of discrepancy, answers obtained through the self-evaluation identified that most of the tools have a high level of usability. These results do not align with the results obtained from interviews with experienced clinical information modellers who emphasized the need for improving tool usability (section 4.3.3). This could be a consequence of different perceptions of the required level of usability. Although developers could have expended a larger effort in solving usability issues, this is an area that could still be expected to improve in the future by incorporating easier to use interfaces combined with advanced semantic functionalities in the background, to provide a more relevant role for clinicians in the modelling process.

4.6 Definition and assessment of the Interoperability Asset Quality Framework

4.6.1 Research objective

This research study aimed to identify those relevant characteristics for the quality in use model which is considered here as the degree to which interoperability assets can be used by end users and developers to meet their needs to achieve specific goals with effectiveness, efficiency, freedom from risk and satisfaction in specific contexts of use (ISO/IEC 25010 2011). The research aimed to be able to collect the opinion from decision makers, healthcare professionals and health informaticians about the relevant factors that influence the decision when they need to evaluate in their organisation which technology might be the most appropriate to be incorporated as part of their eHealth infrastructure.

4.6.2 Methodology

In order to classify the interoperability assets useful to support the existing European eHealth Interoperability Framework and its foreseen evolution towards the cross border transference of eHealth information, the process carried out for defining the quality metrics associated with this domain was based on interactions with representatives from the leading eHealth initiatives from multiple EU Member States and international organisations.

The methodology applied integrated feedback from experts with the results from the research studies previously described. The process combined face to face workshops and online meetings and surveys in order to maximise the number of experts involved. This methodology was defined according to the following steps:

- Identification of interoperability assets for cross border care
- Collection of requirements for interoperability asset quality criteria
- An iterative process for definition of the detailed quality criteria descriptors and graphical representation
- An assessment of the interoperability asset quality criteria

As a result, the defined quality metrics and graphical representation were defined and assessed based on the feedback and opinion of a representative sample of potential end users. According

to the information collected, it was possible to identify requirements for providing a detailed set of metrics to evaluate the (technical and semantic) interoperability capabilities of the multiple resources contained.

4.6.2.1 1st Workshop

In the first exploratory stage, a first workshop coordinated by the EXPAND project took place on 15th May 2014 in Athens with the active participation of 43 attendees representing 20 EU projects. In particular, the 1st workshop explored the following questions:

- What kinds of interoperability asset are appropriate to collate and signpost at a European level? What are the interoperability assets most frequently reused, sought after?
- On what basis should assets emerging from standards and specification bodies, European research projects, industry, professional societies and other initiatives be included within our collection? What should be our relationship with standards bodies and/or user groups?
- What are the main metadata headings and quality criteria that a potential asset user would most need, in order to have trust in an asset and make the most appropriate use of it?

4.6.2.2 Second Workshop

A second workshop was held on November 3rd 2014, in Brussels. It was attended by 35 participants representing 16 EC projects, SDOs and other initiatives, together with representatives from three Directorate-Generals of the European Commission:

- Directorate General for Communications Networks, Content & Technology.
- Directorate-General for Health and Consumers.
- Directorate-General for Informatics.

The information collected in the first workshop was applied to create the first prototype online web register that aimed to contain semantic resources and associated information. This Interoperability Asset Register was reviewed, starting with an overview explanation and a brief demonstration of it. Each group contained an expert or nominee who had reasonable knowledge about the asset, and acted as the “interviewee”. The rest of the group acted as collective interviewers, who were expected to ask questions about the asset – using the Register descriptors as their interview guide, and acting in the role of potential re-users of that asset. The aim of this activity was to determine which descriptors (and any that were missing) were most helpful at assisting them to determine the quality and fitness for purpose of the asset.

4.6.2.3 Definition of the detailed quality criteria descriptors and graphical representation

After consolidating the results of both workshops, and further consultations with experts, an asset descriptor spreadsheet tool was developed as a second prototype of the quality criteria. The spreadsheet form was designed between 6th of April and 5th of June 2015 aiming to support the evaluation of the proposed domains, descriptors and graphical representation, before being implemented as an online register and database. This prototype included a detailed classification in order to be able to easily test this framework for asset evaluation. The designed spreadsheet form could allow users to evaluate their assets by using Microsoft Excel, a familiar software application to all the participant experts.

4.6.2.4 Iterative feedback process

In order to provide an understandable version of the detailed quality descriptors for interoperability asset, an iterative testing process was conducted through direct email consultation and/or teleconferences with 18 experts involved either in EXPAND and SemanticHealthNet projects or other relevant eHealth interoperability initiatives. This testing stage was conducted between 9th of June and 13th of October 2015.

The quality metrics for interoperability assets and the associated graphical representation were tested by the development team and these external users through the evaluation of a sample of interoperability assets. They evaluated a total of 8 diverse interoperability assets with the proposed framework in order to test if the metrics were appropriate for the different kind of resources.

4.6.2.5 Assessment of interoperability asset quality criteria

The assessment stage was based on an online survey that requested participants to review the defined descriptors, value sets and graphical representation. This survey was divided into three sections:

- **The first section** requested information about the participant's personal background and the kinds of interoperability asset that they would have interest to access.
- **The second section** provided the full list of descriptors defined as part of the interoperability asset quality assessment framework. Participants were requested to evaluate how clearly they had been defined and the level of importance that they perceived from the multiple framework domains for decision making.
- **The third section** included the evaluation results of three examples of interoperability assets against the quality framework. As part of this section there were presented these asset evaluation results via their associated graphical representation. The examples

chosen covered the three categories of interoperability assets that register aimed to contain. Moreover, this section requested information about how likely participants would be to use this framework and if they would recommend its use to their colleagues.

This survey was disseminated through those experts that participated in previous surveys related with this thesis and those experts involved in the SemanticHealthNet and EXPAND projects. The survey was conducted between 15th of October and 15th of December 2015.

4.6.2.6 Analysing and prioritising domains

The questionnaire applied the 5-point Likert scale to determine the participants' opinions about multiple domains, the graphical representation and the acceptability of the framework. The Likert scale was applied to prioritise between the multiple domains according to their perceived importance. This prioritisation was made based on the score association provided in Table 42.

Association between answer and priority weight					
Answer	Strongly disagree	Disagree	Neutral	Agree	Strongly agree
Prioritisation weight	-2	-1	0	1	2

Table 42. Weight association for prioritisation analysis

4.6.3 Results

4.6.3.1 Definition and assessment of Interoperability Asset Quality Framework

Table 43 details the list of interoperability assets identified as result of the Athens workshop described in the section 4.6.2.1. The multiple interoperability assets were classified under three categories including: i) evidence used, ii) legal & organisational and iii) technical and semantic assets.

Category	Type of asset	
Evidence used	1. Use case 2. Methodology	3. Requirements specification 4. Design guidelines
Legal, organisational	1. Policy 2. Operational guidelines 3. License or contract, specimen contract 4. Procurement template	5. Educational or training resource 6. Safety or risk assessment 7. Governance or audit framework 8. Benchmarking data
Technical, Semantic	1. Standards, Specifications 2. Information model 3. Knowledge model	12. Implementation guidelines 13. Engineering artefact (software) 14. Source code

	4. Data set specification 5. Terminology resource 6. Mappings 7. Architecture specification 8. Message or interface model 9. Component engineering specification 10. Specification guidelines 11. Interoperability profile	15. Software service (e.g. hosted) 16. Conformance specification 17. Conformance guidelines 18. Test plan 19. Test data set 20. Test guidelines 21. Benchmarking data 22. Deployment guidelines

Table 43. Identified categories and types of interoperability assets

4.6.3.2 First Prototype of the Interoperability Asset register

The defined first prototype of the interoperability asset register included an initial proposal for descriptors that aimed to be able to collect the relevant information about interoperability assets to allow end users to determine their suitability to be reused in their local projects and organisations. At this initial stage, descriptors were just collected in free text form without distinguishing if they are applied for quality assessment or searching purposes. The initial free text forms were included to test if the identified descriptors were suitable to characterise interoperability assets. Based on the examples uploaded by a set of experts included in the EXPAND project, the descriptors were redefined including structured data values. The final descriptors developed through this research are given in section 4.6.3.5.7. Figure 46 shows a screenshot of the first prototype of the IA register.

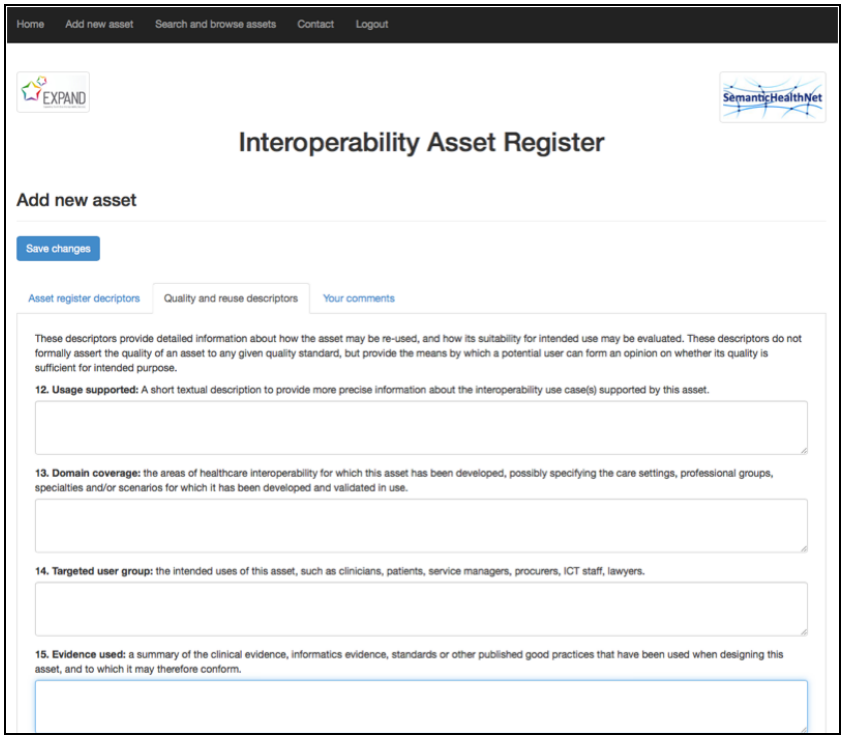


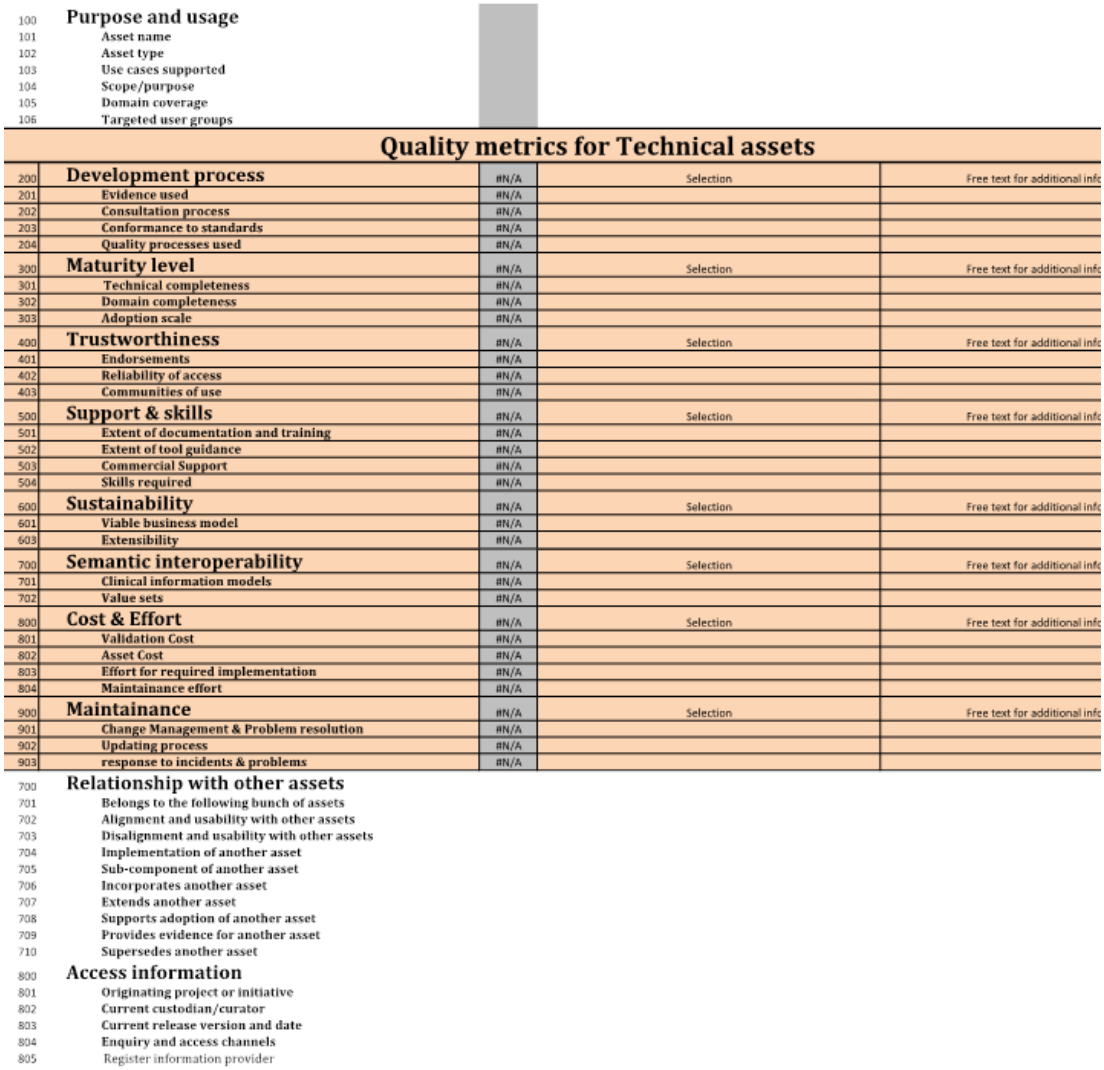
Figure 46. First prototype of the IA register

4.6.3.3 Asset descriptor spreadsheet tool

The defined spreadsheet tool included the first proposal of value sets for each of the interoperability asset descriptors (Figure 47). The defined value sets were based on the previous prototype and were ordered according to their level of fulfilment of the evaluated descriptor. Moreover, this spreadsheet organised the multiple descriptors in 11 domains that were classified into two groups:

- **Domains to support asset discovery and provenance information.** This group included three domains, represented in a white background colour in the spreadsheet. They were used for describing the purpose and recommended usage of an interoperability asset, enabling new users external to the asset's development team to determine if the specific asset is likely to be suitable to be reused in their projects and systems. Additionally, these descriptors provided information about how to access each interoperability asset, detailing the organisation that developed the asset and the one that now hosts the asset. Lastly, it recorded information about its relationship with other assets contained in the register.

- **Quality metrics.** This set of domains was presented on a pink background colour. They were designed for evaluating the most relevant characteristics associated with the measurement of the quality of the interoperability resources analysed. Some of these metrics evaluated the robustness of the development process, the level of maturity, trustworthiness based on the level of endorsement, the size of the supporting community and the semantic interoperability capabilities. They were complemented with an evaluation of the impact for an organisation adopting the asset based on the available level of support, skills required, cost & effort foreseen and maintenance requirements.



100	**Purpose and usage**			
101	Asset name			
102	Asset type			
103	Use cases supported			
104	Scope/purpose			
105	Domain coverage			
106	Targeted user groups			

Quality metrics for Technical assets

200	**Development process**	#N/A	Selection	Free text for additional info
201	Evidence used	#N/A		
202	Consultation process	#N/A		
203	Conformance to standards	#N/A		
204	Quality processes used	#N/A		
300	**Maturity level**	#N/A	Selection	Free text for additional info
301	Technical completeness	#N/A		
302	Domain completeness	#N/A		
303	Adoption scale	#N/A		
400	**Trustworthiness**	#N/A	Selection	Free text for additional info
401	Endorsements	#N/A		
402	Reliability of access	#N/A		
403	Communities of use	#N/A		
500	**Support & skills**	#N/A	Selection	Free text for additional info
501	Extent of documentation and training	#N/A		
502	Extent of tool guidance	#N/A		
503	Commercial Support	#N/A		
504	Skills required	#N/A		
600	**Sustainability**	#N/A	Selection	Free text for additional info
601	Viable business model	#N/A		
603	Extensibility	#N/A		
700	**Semantic interoperability**	#N/A	Selection	Free text for additional info
701	Clinical information models	#N/A		
702	Value sets	#N/A		
800	**Cost & Effort**	#N/A	Selection	Free text for additional info
801	Validation Cost	#N/A		
802	Asset Cost	#N/A		
803	Effort for required implementation	#N/A		
804	Maintainance effort	#N/A		
900	**Maintainance**	#N/A	Selection	Free text for additional info
901	Change Management & Problem resolution	#N/A		
902	Updating process	#N/A		
903	response to incidents & problems	#N/A		

700	**Relationship with other assets**
701	Belongs to the following bunch of assets
702	Alignment and usability with other assets
703	Disalignment and usability with other assets
704	Implementation of another asset
705	Sub-component of another asset
706	Incorporates another asset
707	Extends another asset
708	Supports adoption of another asset
709	Provides evidence for another asset
710	Supersedes another asset
800	**Access information**
801	Originating project or initiative
802	Current custodian/curator
803	Current release version and date
804	Enquiry and access channels
805	Register information provider

Figure 47. Spreadsheet tool for interoperability asset quality evaluation

All domains included the descriptors that had been strongly supported by experts through the various workshops described in section 4.6.2. They were considered to be the metrics most useful to support an adoption decision between the different assets contained in the IA register. Users could select the value for each descriptor based on the corresponding drop-down list. The drop-down list options were ordered according to the level of fulfilment of the descriptor. Each option was assigned a weight with a range between 0 and 1. For instance, if a question had five possible answers, these were ordered depending on the level of importance and weight is distributed uniformly (increasing 20% the weight between answers). Figure 48 shows an example of dropdown list with five values and Table 44 details how weights were assigned between the multiple answers.

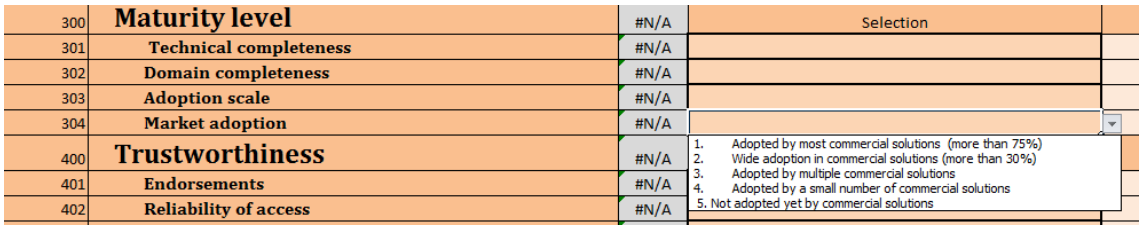


Figure 48. Dropdown menu in the evaluation spreadsheet tool

Market adoption descriptor	Weight
1. Adopted by most commercial solutions (more than 75%)	1
2. Wide adoption in commercial solutions (more than 30%)	0.75
3. Adopted by multiple commercial solutions	0.5
4. Adopted by a small number of commercial solutions	0.25
5. Not adopted yet by commercial solutions	0

Table 44. Example of weight assignation for descriptor answers

4.6.3.4 Graphical representation

A radius diagram representation was automatically calculated according to the answer weights to display the quality of the selected asset in each of the defined quality domains. This representation was chosen because it allows end users to review the multiple quality domains at the same time. The radius diagram showed the average fulfilment of the selected asset for each descriptor included in the corresponding domain. It is recognised that the weighting applied to the different members of each descriptor value list were equally spaced between a range of 0 to 1.The proposed assignation of weights could be improved in the future but it will first be necessary to collect feedback on the use of the IA register to identify additional evidence before establishing a different assignation of weights. Figure 49 shows how the multiple quality domains are represented in the graphical representation.

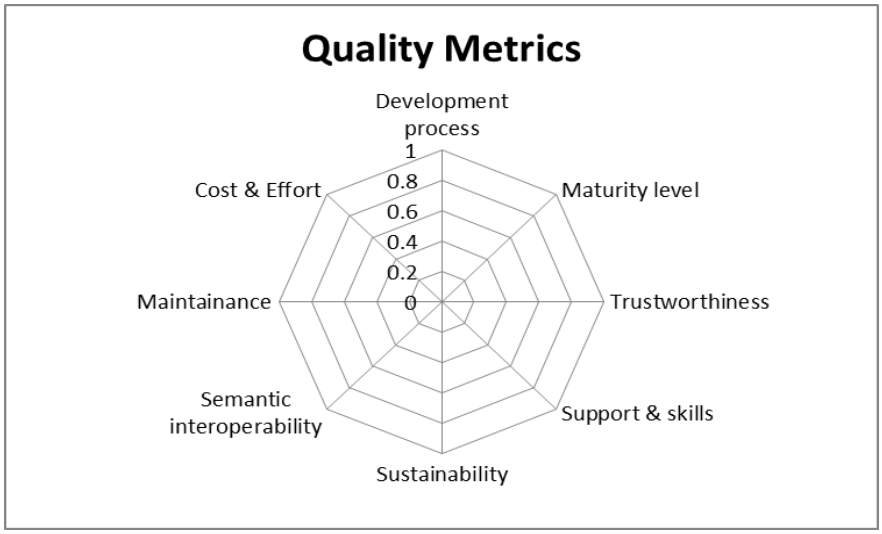


Figure 49. Graphical representation of the quality metrics domains

Appendix D provides examples of the evaluation results of a set representative specifications developed by projects focused on cross-border, national or regional interoperability against the quality in use framework.

4.6.3.5 Assessment of the proposed Interoperability Asset Quality Framework

Next are detailed the results obtained as part of the online survey defined for collecting feedback about the defined description, value sets and graphical representation. As was previously described, the defined survey requested information about each participant's personal background. Moreover, participants were able to review the full list of descriptors included in the interoperability asset quality framework and the evaluation results of three examples of interoperability assets.

4.6.3.5.1 Sample of experts

A total of 20 experts participated in the survey. They had 17.20 ± 8.65 years of experience in their field. Most of them were considered health informatics experts (85.00%) that could be combined with complementary roles such as IT developer, business analyst, terminologist or decision maker. In addition, 3 of the participants had the following roles clinician, eHealth Strategist and decision maker without being recognised as health informatics expert. Figure 50 details the percentage of participants associated with the multiple reported roles.

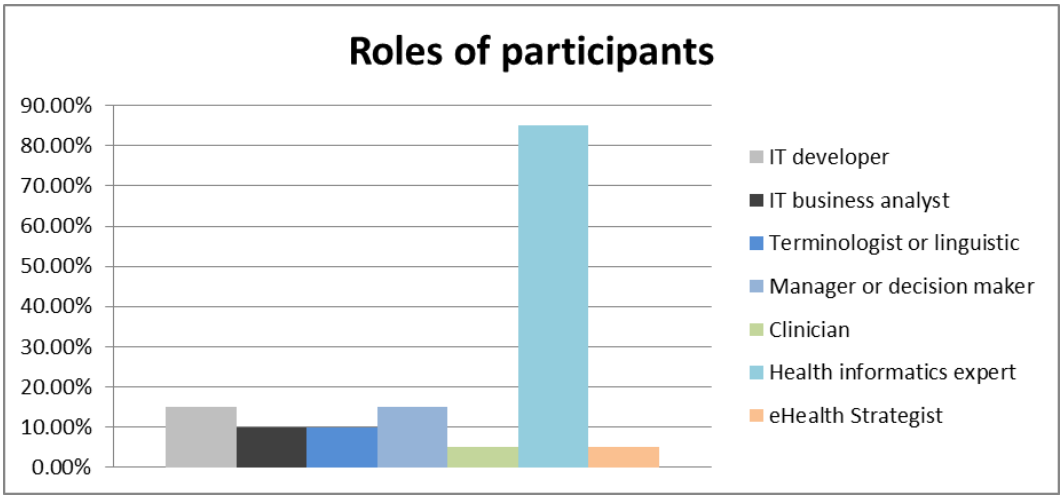


Figure 50. Roles associated of the survey participants

4.6.3.5.2 Expected access to multiple kinds of asset

Figure 51 shows the results of how much those experts participating in this survey expected to access multiple asset types. The analysis of this result highlights that technical assets are identified as the most relevant ones for reuse. Technical & interoperability asset were expected

to be accessed by 95% of participants. Moreover, a broad sample of participants (60-70%) also indicated that they would be interested to access legal, organisational and general assets. There were a small number of participants (between 10 to 5%) who declared that they didn't expect to access this latter group of assets.

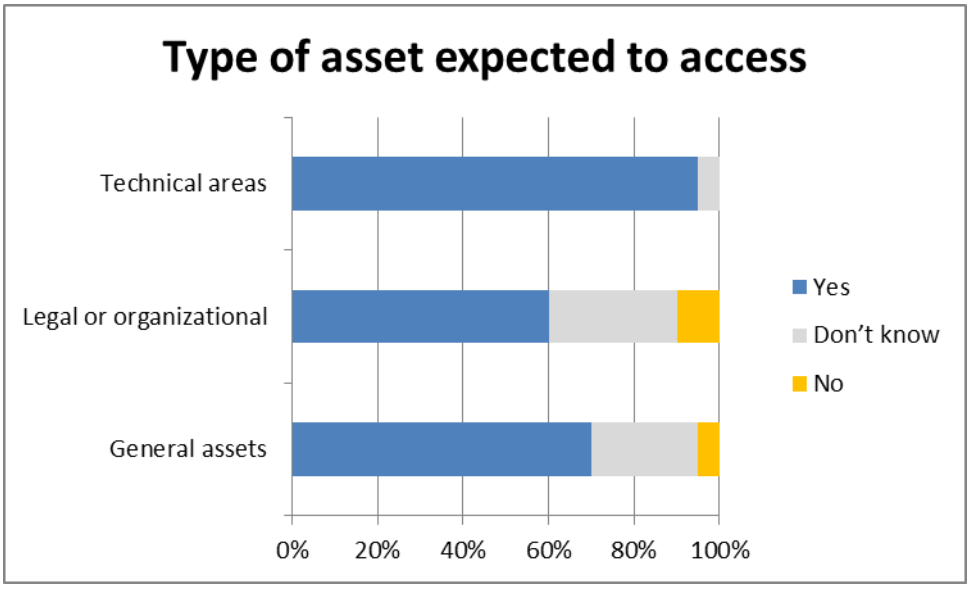


Figure 51. Graphical representation of the type of assets that end users expect to access

4.6.3.5.3 Perception of description clarity in quality domains

These results show that most of the domains were perceived by the experts who participated in the survey as being clearly defined, with and acceptance by more than 75% of experts. Moreover, most of the evaluated domains had only a small proportion of experts (5% or less) who disagreed with their description. Only the cost & effort domain obtained slightly less support with 70% of acceptance and 10% of disagreement. The collected comments indicated possible improvements for the description of this domain. Figure 52 details the results obtained about how clearly each domain is defined, ordered according to the prioritisation technique described in the methodology section (section 4.6.2.5).

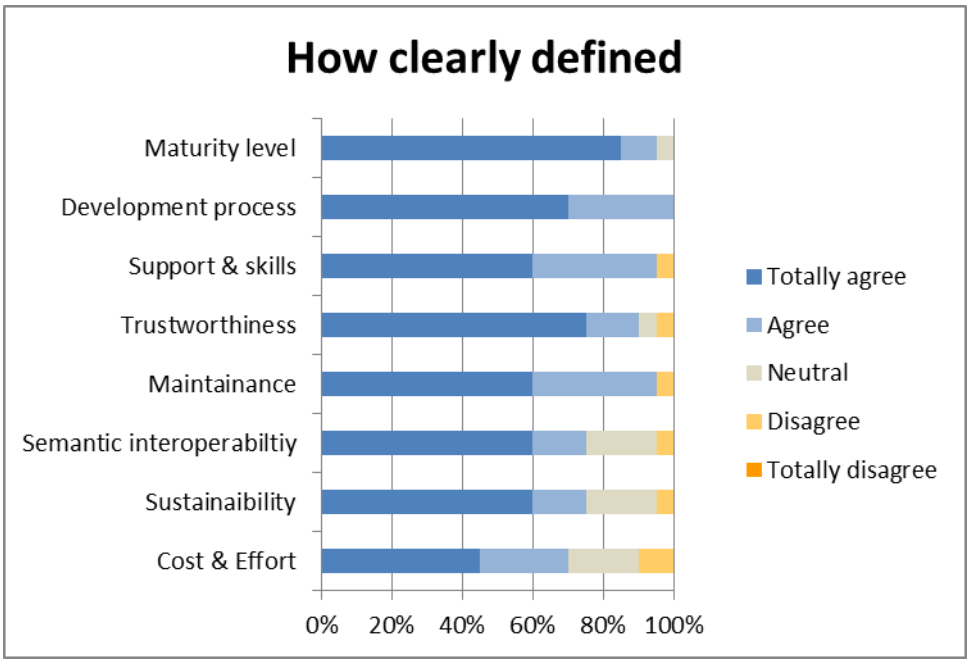


Figure 52. Clarity of the quality domains

4.6.3.5.4 Perception of importance for the proposed quality domains

Most of the domains were considered as important for decision making by the survey participants.

- The majority of users (more than 75%) considered as important the Trustworthiness, Semantic Interoperability, Support & Skills and Maintainance domains.
- A broad number of users (between 65-70%) identified as important the Cost & Effort, Maturity level and Development Process domains.
- The sustainaibility domain was considered important by only 45% of users. In addition the number of users that disagreed about the importance of this domain was 20%.

As was described in the methodology section (section 4.6.2.5.), the multiple domains were ranked according to the participants' responses. Figure 53 shows the prioritised list of domains according to the perception reported by the participant experts.

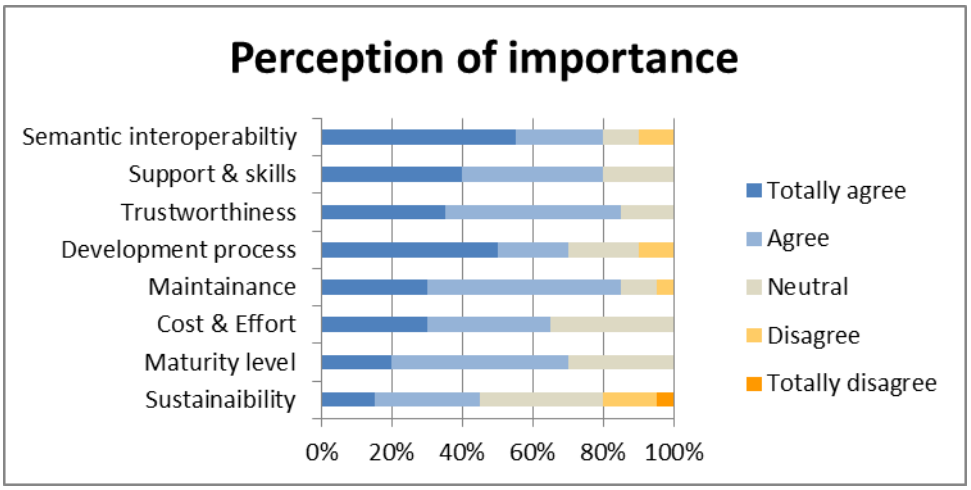


Figure 53. Perception of importance of the proposed domains

4.6.3.5.5 Acceptance of graphical representation

Most of the users (80%) declared that the graphical representation was perceived as useful for the technical asset provided. In addition, the acceptance of the graphical representation was good for the example of operational guidelines but only half of the users declared it to be useful for the example provided of a legal asset. Figure 54 details the reported level of acceptance for graphical representation associated with each type of asset.

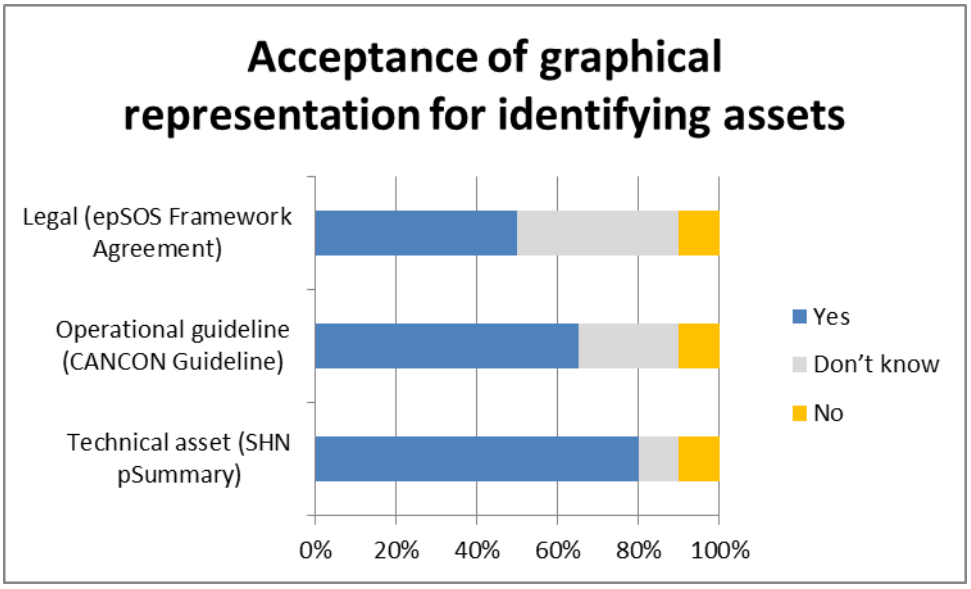


Figure 54. Chart with the acceptance of the graphical representation for multiple asset tipes

4.6.3.5.6 Overall evaluation

Figure 55 details the overall evaluation of the interoperability asset quality framework. 70% of participants declared that they would recommend the use of the register based on the quality in use framework to their colleagues. Only a small proportion of experts declared that they would not recommend the register (5%). Moreover, the same percentage (70%) of experts declared that this proposed register would be useful for discovering interoperability assets with a greater number of disagreements (20%).

Last, slightly more than half of the participants (55.56%) declared that this register would be important for them in order to decide which assets they might reuse. In this latter question, there were 25% of experts that disagreed with the statement that this proposed framework would be important to supporting decisions about choosing assets. They provided the following arguments:

- A clinician claimed that the proposed approach won't have impact on clinical practice.
- A health informatics expert indicated that the register descriptors might be too broad and that it will be necessary to have a more exhaustive common understanding of interoperability concepts to avoid misinterpretations.
- Moreover, there were two experts who claimed that there is not enough evidence that the interoperability asset register would be able to support real decisions or the discovery of assets.

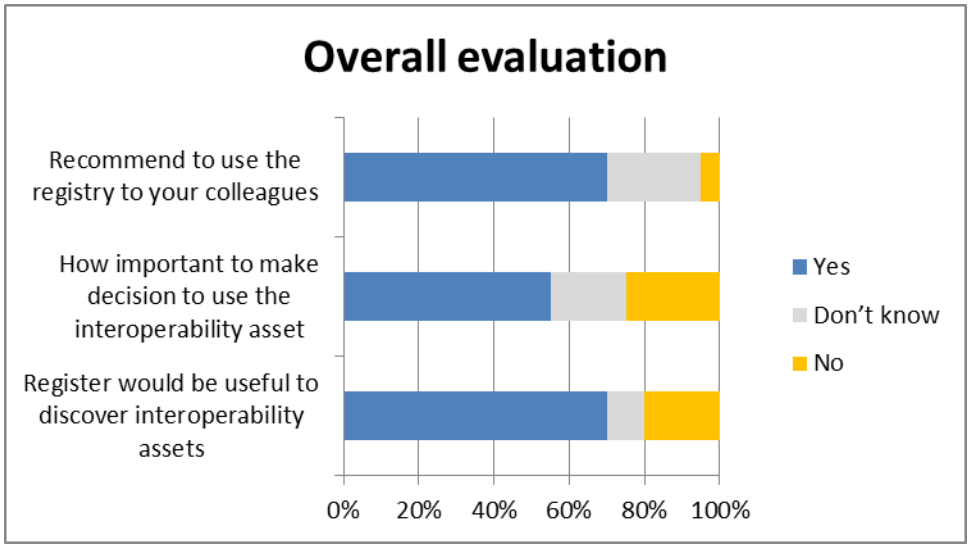


Figure 55. Chart with the overall evaluation of the interoperability asset framework

4.6.3.5.7 Defined quality domains for interoperability asset

The collected survey results included a set of suggestions that led to minor adjustments in the proposed quality descriptors. More information about the modifications performed is included in Appendix E. This section details the resultant final definition of the eight quality domains and associated descriptors.

4.6.3.5.7.1 Development process:

This domain refers to the process of defining and validating the evaluated asset according to stakeholder engagement activities, quality assurance practices, evidence adopted and alignment with other assets and standards. Table 45 details the multiple options for each of the descriptors included as part of the development process quality domain.

1. Development process		
Evidence used	1. Guideline (complies with or aligns with one or more specified evidence based clinical guidelines or equivalent good practice publications) 2. Literature review and meta-analysis (design or content has been informed by published evidence, in the literature)	3. Regional/National practice (design or content reflects the consensus of existing practice within a health region or country) 4. Local practice (design or content reflects the consensus of opinions or practices within a participating community such as a single care setting, a research consortium, an advisory board or a focus group). 5. No evidence
Consultation process	1. An open access consultation process was used, resulting in >50 respondents spanning multiple relevant stakeholder groups 2. A wide multi-organisation and multi-stakeholder consultation process was adopted at some point in the development life-cycle (resulting in >20 respondents)	3. At least one representative from most stakeholder groups who might be users or impacted by the asset's use were consulted on requirements or to peer review the design or completed asset 4. <5 independent domain experts were consulted on requirements or to peer review the design or completed asset 5. Only those experts directly engaged in the asset development were consulted
Conformance to standards	1. Fully conforms to the following standards: 2. Has drawn on and complies to some extent to the following standards: ….	3. Conform to, or aligns, with the following other assets: … 4. Has not adhered to any standards 5. Not relevant
Quality processes used	1. External quality management process based in ISO9000 or other recognised methodologies 2. External quality assessment process	3. Internal quality assessment process 4. No verified quality assessment process 5. Not relevant

Table 45. Detailed list of descriptors and value sets for the development process domain

4.6.3.5.7.2 Maturity level:

This domain refers to evaluating the readiness of an asset for operations in the specified scenario with a final objective of transitioning it to the user. This is evaluated according to the technical and domain completeness, the scale of asset application and market adoption.

As part of this domain the Technology Readiness Level (TRL) of each individual Interoperability Asset is included. This indicator "provides a method of estimating technology maturity of Critical Technology Elements (CTE) of a program during the acquisition process. They are determined during a Technology Readiness Assessment (TRA) that examines program concepts, technology requirements, and demonstrated technology capabilities. TRL are based on a scale from 1 to 9 with 9 being the most mature technology. The use of TRLs enables consistent, uniform, discussions of technical maturity across different types of technology" (Wikipedia 2016). Table 46 lists the multiple options included as part of the descriptors contained in the maturity level domain.

2. Maturity level		
Technical completeness	1. TRL 9. Actual system proven in operational environment (competitive manufacturing in the case of key enabling technologies) 2. TRL 8. System complete and qualified 3. TRL 7. System prototype demonstration in operational environment 4. TRL 6. Technology demonstrated in relevant environment (industrially relevant environment in the case of key enabling technologies)	5. TRL 5. Technology validated in relevant environment (industrially relevant environment in the case of key enabling technologies) 6. TRL 4. Technology validated in lab 7. TRL 3. Experimental proof of concept 8. TRL 2. Technology concept formulated 9. TRL 1. Basic principles observed 10. Not relevant
Domain completeness	1. Full coverage for multiple domains 2. Full coverage of the stated domain	3. Partial (incomplete) coverage of the stated domain 4. Not relevant
Adoption scale	1. Multiple countries for cross border care 2. National healthcare provider	3. Regional healthcare provider 4. Local healthcare provider 5. Not deployed yet
Market adoption	1. Adopted by most commercial solutions (more than 75%) 2. Wide adoption in commercial solutions (more than 30%)	3. Adopted by multiple commercial solutions 4. Adopted by a small number of commercial solutions 5. Not adopted yet by commercial solutions

Table 46. Detailed list of descriptors and value sets for the maturity level domain

4.6.3.5.7.3 Trustworthiness

This domain refers to the evaluation of the level of confidence and reliability of the asset according to the organisations endorsing it, or committed to implement it and make it more widely available, as well as the volume of users supporting the asset implementation. Table 47 specifies the multiple descriptors and associated value sets contained in the trustworthiness quality domain.

3. Trustworthiness		
Endorsement	1. Governmental policy or strategy or law 2. National Healthcare provider 3. European scientific or international scientific society 4. National Scientific society 5. National or European Patient Association	6. Regional Healthcare provider 7. Regional Scientific society 8. Small/Medium healthcare provider 9. Non-profit organization 10. Company customer or research project testimonials 11. Not relevant
Reliability of access	1. The asset is held and made available by an organisation that has committed to making it available indefinitely. 2. The asset is held and made available by an organisation that has committed to making it available for at least the next three years.	3. The asset is held and made available by an organisation that has committed to making it available for at least the next year. 4. The asset is being held by a temporary body, and plans are in place for it to be transferred to a long-term source. 5. The asset is being held by a temporary body, and there are no plans as yet in place for it to be transferred to a long-term source.
Communities of use	1. This asset has both user and developer communities, available online, to provide support in how to use the asset and to receive new requirements that might be incorporated into future versions of it. 2. An online community exists, and may be contacted, to provide advice and to share experiences and how best to use the asset. 3. Apart from other asset users, it is possible to find and seek advice from experts who have substantial knowledge about how the asset may best be used, and any localisation issues that may be required (not necessarily free of charge).	4. It is possible to find and contact other asset users, who may be able to share their experience and offer advice, on an informal basis. 5. The original development group, or the present asset holder, is available to provide support and guidance to downstream users of the asset (not necessarily free of charge). 6. Not relevant

Table 47. Detailed list of descriptors and value sets for the trustworthiness domain

4.6.3.5.7.4 Support & skills

This domain refers to the evaluation of the required skills to apply the asset according the background that end users requires and the level of available support from documentation,

training, tools and external commercial companies. Table 48 shows the descriptors and value sets included as part of the Support & skills quality domain.

4. Support & skills		
Extent of documentation and training	1. Technical documentation and certified training program based on the technical specification with a large volume of examples for adapt the proposed implementation in multiple scenarios 2. Technical documentation and training program based on the technical specification with a large volume of examples for adapt the proposed implementation in multiple scenarios	3. Technical documentation based on the technical specification with a large volume of examples for adapt the proposed implementation in multiple scenarios 4. Technical documentation only, based on the technical specification 5. Not relevant
Extent of tool guidance	1. There are available tools able to support the definition, validation and certification of this class of assets 2. There are available tools able to support the definition and validation of this class of assets	3. There are available tools able to support the definition of this class of assets 4. There are not tools to support the use of this class of asset 5. Not relevant
Third party Support	1. There is available third party support 24/7 2. There is available third party support on office hours	3. There is not third party support for the implementation 4. Not relevant
Skills required	1. There are not previous skills required 2. General background in the asset field 3. Specialised background associated with the asset field	4. Specialised background that have some previous knowledge about those related assets and specifications/regulations 5. Professionals with specialised training program and expertise in those related assets and specifications/regulations 6. Not relevant

Table 48. Detailed list of descriptors and value sets for the support & skills domain

4.6.3.5.7.5 Sustainability

This domain refers to the evaluation of how the asset contributes business value to the achievement of the targeted interoperability use cases, and what evidence exists for the size of the actual and potential market and extensibility capabilities. Table 49 includes the descriptors and value sets associated with the sustainability quality domain

5. Sustainability		
Viable business model	1. The asset has an established adoption model, evidenced by its uptake and business success. 2. The organisation holding or productising the asset has a formal business plan for its sustainability and maintenance. 3. A business model has been developed to define the market for this asset, including a financial model for purchasers and providers, for products or services that incorporate this asset.	4. An outline business model has been developed for this asset, giving some confidence of its viability. 5. Multi-stakeholder value propositions have been developed for this asset, indicating why it should be successfully adopted. 6. Some basic work has been undertaken to indicate why this asset provides a useful business purpose. 7. No formal work has yet been done to establish the business case for the wide-scale adoption of this asset. 8. Not relevant
Extensibility	1. Designed to be extended by others including feedback from open consultation into review cycles and yearly maintenance 2. Designed to be extended by others including feedback from open consultation into review cycles	3. Designed to be extended by others without including feedback from open consultation into review cycles with maintenance 4. Relevant example of implementation of the selected domain that could be reused or adapt in other implementations 5. Not relevant

Table 49. Detailed list of descriptors and value sets for the sustainability domain

4.6.3.5.7.6 Semantic interoperability

This domain refers to the evaluation of the capabilities of the asset to be computable by computer systems and exchange data with unambiguous, shared meaning. This is evaluated according to the technical specifications adopted and the level of adoption of international terminologies for the structured data and metadata. Table 50 includes the descriptors and value sets associated with the semantic interoperability quality domain.

6. Semantic Interoperability		
Clinical information model specification	1. Based on standard specification 2. Based on open specification	3. Based on proprietary solution 4. Not relevant
Clinical information model Terminology Binding	1. All of the nodes defined in the clinical information models have been mapped to international terminologies 2. Some of the nodes defined in the clinical information models have been mapped to international terminologies	3. All of the nodes defined in the clinical information models have been mapped to local terminologies 4. None of the nodes have been mapped to international or local terminologies 5. Not relevant

Value sets	1. All the terms were mapped to international terminologies 2. Some the terms were mapped to international terminologies	3. The terms were mapped to local terminologies 4. There is not terms mapped to terminologies 5. Not relevant

Table 50. Detailed list of descriptors and value sets for the semantic interoperability domain

4.6.3.5.7.7 Cost & Effort

This domain refers to the evaluation of the resources required for asset implementation, maintenance, validation and use. Table 51 lists the quality descriptors and value sets included as part of the Cost & effort quality domain.

7. Cost & effort		
Validation Cost	1. The validation and certification program is based on third party organization 2. Certification and validation is partially supported by third party organization and there are validation tools and example of models (e.g. schematrons) available to support validate the local implementation	3. There are validation tools but there is not example of models (e.g. schematrons) available to support validate the local implementation 4. There is not validation tools 5. Not relevant
Asset Cost	1. The selected asset is free of charge for any purpose 2. Free for non-commercial use 3. Costs are covered by a framework contract (e.g. governmental)	4. It is needed to pay in order to use the selected asset 5. Not relevant
Effort for required implementation	1. The selected asset is free of charge for any purpose 2. Free for non-commercial use 3. Costs are covered by a framework contract (e.g. governmental)	4. It is needed to pay in order to use the selected asset 5. Not relevant
Maintenance effort	1. Minimal maintenance effort is required foreseen to adopt this asset 2. It is recommended that adopters assign resources to implement new releases regularly that could be automatized to be incorporated in their system	3. It is recommended that adopters assign resources to implement new releases regularly that might impact on their system 4.Not relevant

Table 51. Detailed list of descriptors and value sets for the cost & effort domain

4.6.3.5.7.8 Maintenance

This domain refers to the evaluation of the processes adopted to support the evolution of the asset according to an updating process, a problem resolution methodology and the expected response time to incidents and problems. Table 52 shows the multiple descriptors and value sets associated with the Maintenance quality domain.

8. Maintenance		
Problem resolution by the asset custodian	1. Change management process based on prioritisation according to team leader and open consultation for evaluating complexity, gravity and feasibility of change	2. Change management process based on prioritisation according to team leader for evaluating complexity, gravity and feasibility of change 3. Not implemented process for change management 4. Not relevant
Updating process	1. The update process has a regular updating process with new releases every 6 months or less 2. The update process has a regular updating process with new releases every year or less	3. The update process has not planed regular updates but new releases are foreseen in the future 4. There is not update process defined 5.Not relevant
Response to incidents by asset custodian	1. Critical incidents and problems have a maximum allowed time to be addressed 2. There are enough resources to address incidents and problems in a reasonable time	3. There are not resources to address incidents and problems in short period of time 4. Not relevant

Table 52. Detailed list of descriptors and value sets for the maintenance domain

4.6.3.5.8 Classification of quality descriptors for type of assets

According to the broad kind of interoperability assets that will be contained in the IA register, the defined quality descriptors were primarily defined to fully characterise technical and semantic interoperability assets. Based on the performed research was primarily directed towards CIMs and value sets, it is expected that the defined metrics will be able to indicate the interoperability capabilities of the multiple kind of technical and semantic interoperability assets that could be included in the register.

Moreover, a subset of these descriptors was found to also apply to general purpose, legal or organisational assets. Table 53 shows the relevant descriptors for each category of asset based on the evaluation of the different examples and agreed with experts participating in the definition of the interoperability asset quality framework. In this table, it can be seen that all the defined descriptors are applied to technical and semantic interoperability type of assets. In addition, it is

recognised that further research is recommended to identify possible additional quality descriptors for evaluating general, legal and organisational assets.

Quality Descriptors	General	Legal, organisational	Technical, semantic
1.Development process			
1.1. Evidence used	X	X	X
1.2. Consultation process	X	X	X
1.3. Conformance to standards	X	X	X
1.4. Quality processes used	X	X	X
2.Maturity level			
2.1.Technical completeness			X
2.2.Domain completeness			X
2.3.Adoption scale	X	X	X
2.4. Market adoption	X	X	X
3.Trustworthiness			
3.1. Endorsements	X	X	X
3.2.Reliability of access	X	X	X
3.3.Communities of use	X	X	X
4. Technical Support & Skills			
4.1.Extent of documentation and training	X	X	X
4.2. Extent of tool guidance			X
4.3. Commercial Support			X
4.4. Skills required	X	X	X
5. Sustainability			
5.1. Viable business model	X	X	X
5.2. Extensibility	X	X	X
6. Semantic interoperability			
6.1. Clinical information model specification			X
6.2. Clinical information model binding			X
6.2. Value sets			X
7. Costs & efforts			
7.1. Validation Cost			X
7.2. Asset Cost	X	X	X
7.3. Effort for required implementation			X
7.4. Maintenance effort	X	X	X
8. Maintenance			
8.1. Problem resolution by the asset custodian	X	X	X
8.2. Updating process	X	X	X
8.3. Response to incidents by asset custodian	X	X	X

Table 53. Association the asset types with the quality descriptors

4.6.4 Discussion

4.6.4.1 Definition stage

The process carried out benefited from the collaboration with the SemanticHealthNet and EXPAND projects to engage the participation of a broad sample of experts interested in semantic interoperability. Moreover, additional active experts identified from previous disseminations through the mailing list of relevant initiatives such as HL7, EN13606 Association and openEHR complemented the sample of participants. As a result, it was possible to collect feedback from representatives of healthcare providers, academia and SDOs at an international level.

Lessons learned about the multiple mechanisms applied for obtaining consensus as part of the clinical information modelling processes (section 4.2.3 and 4.3.3) were used for defining the IA descriptors. The iterative feedback process with multiple prototypes allowed the development of a relatively mature definition of these descriptors. Moreover, the IA descriptors were tested through the assessment of multiple project results, by EXPAND project participants and external experts.

4.6.4.2 Preferred types of assets

The sample of experts participating in this research identified technical & semantic assets as those assets more interesting to be widely accessed. This seems reasonable since these interoperability assets are considered as relevant material, along with documentation to support the implementation of interoperability projects.

Moreover, as the quality framework is intended to be applied to a broad sample of interoperability assets, the sample of users was not restricted to health informatics experts. The analysis of the results did not show major differences in the levels of acceptance between those experts with non-technical roles compared with experts in health informatics.

4.6.4.3 Assessment of the proposed framework

4.6.4.3.1 Asset descriptors

The obtained assessment results showed a good level of acceptance by a broad range of stakeholders for the defined quality descriptors. During the assessment all of the proposed domains were declared to be clearly defined by more than 70 % of participants and small modifications were proposed for improving end user readability. The level of disagreement was low and the comments provided were useful to improving the definitions of domains, but only with small modifications. Given the broad sample of types of interoperability assets, this result suggests that end users should be able to use the quality framework as defined.

The classification of domains according to their importance shows that most domains have been evaluated as important by a high percentage of participants. Only the sustainability domain had a medium acceptance rate (45%) and users with a neutral position (30%). The increased focus that the European Commission is supporting towards incorporating sustainable measurements in health informatics (with a specific call in this area last year) suggests that this domain might become more relevant in the coming years.

As has been previously stated, the described methodologies were applied to consensus building, for defining the assessment framework for interoperability assets. The adopted methodology is a representative example that shows how long it could take and the amount of effort required to obtain consensus amongst large samples of heterogeneous stakeholders. After carrying out two workshops with a total of 78 participants, direct consultation with 18 internal experts and the survey with 20 end users, it is now consideredthat the level of acceptance and support has been sufficient. The low level of disagreement is not perceived as a risk of failure for the proposed metrics.

4.6.4.3.2 Graphical representation

A graphical representation was proposed as a mechanism for quickly reviewing the overall assessment of an interoperability asset against the eight quality framework domains. The results of the evaluation showed that the graphical representation was widely accepted for technical interoperability assets, 80% of participants agreed with a low level of disagreement (10%). Interoperability assets focused on guideline and legal information received less support with an increased number of experts in a neutral position and a small number disagreeing with the use of this representation. This result was aligned with the sample of experts declared to be more likely to be interested in technical interoperability assets. Likewise, it coincides with this thesis work that was primarily focused on researching how to describe and classify technical assets. Future research is recommended to identify possible improvements on how to evaluate general, organisational and legal assets, which is outside the scope of the present work.

4.6.4.3.3 Overall evaluation

When participants were requested to evaluate the overall quality in use framework, an acceptable number of participants (70%) reported that they would recommend using the register to their colleagues, with minimal disagreement. This result provides promising feedback about the possible good acceptance of the proposed framework by the eHealth community.

Moreover, a high proportion of participants identified that the register could provide relevant benefits such as discovering new assets (70%) and supporting decision making between multiple assets (55%). Nevertheless, there were between 20-25% of participants who were reluctant to believe that the IA register could provide these benefits. They claimed that there is

not enough evidence about the possible benefits of the register and the broad scope could impact on their acceptance.

Although there were promising results through expert support, and a perception of the IA register benefits, it is recognised that the adoption of the proposed new methodology will require it to be implemented in real practice and on a large scale in order to obtain the required evidence. Multiple factors such as the availability of valuable interoperability assets would impact on the capability of the register to demonstrate these the desired benefits. The community will only use the register if they can find useful assets to be incorporated in their projects and organisations. Providing educational material about the use of the register with a special effort on system usability are vital to obtain the desired impact.

Moreover, it is recommended to monitor how users are using this quality framework once it is implemented, to detect possible improvements that could guide its evolution. The definition of the IA register, as the first instrument that defines a framework for classifying the quality of semantic interoperability resources, will be the first attempt focused on promoting the improvement of European interoperability through supporting multiple eHealth actors on decisions about which assets to reuse.

4.6.4.3.4 Limitations

Since the previous research was mainly conducted in the field of EHR interoperability and CIMs, it is recognised that the proposed descriptors have been primarily oriented to address the needs of the technical and semantic interoperability assets. Other kind of asset descriptors related to general purpose and to legal & organisational asset types might be improved with future research in these fields. Moreover, it is recognised that there could be a selection bias towards people who are involved in developing assets. This was inevitable since the majority of the people participating in the related projects and health informatics initiatives work on the definition of interoperability assets. It is possible that new insights might be gained when a wider range of asset users provide feedback on the usefulness of the different descriptors. This cannot be done until the register has many more assets in it, and it has been widely promoted, so this is a limitation that could not properly be addressed during the time interval of this thesis research.

It was claimed by some of the survey participants that it is not possible to confirm to what extent the quality in use proposed framework is likely to benefit the eHealth community. Although representatives from multiple organisations such as IT development companies, vendors, healthcare providers, health informatics organisations and SDOs participated during the development process, the final implemented register will be affected by external factors that include political decisions and self-interest of the organisations involved. The defined interoperability asset register aims to become a mechanism that will gradually support the

harmonisation and evolution of eHealth in Europe, but it is not possible to determine how long it might take to gain wide acceptance. As a result, rather than focusing on demonstrating the acceptance of this register, this research was focused on establishing an novel methodology for classifying and assessing the quality of those interoperability assets relevant for the European healthcare domain.

4.7 Comparison with quality metrics for clinical information models defined in ISO 18864

4.7.1 Research objective

The definition of objective requirements for meta-data, data elements and terminology bindings in a CIM allows determining to what level one could achieve semantic interoperability. This research aimed to compare the requirements identified as part of the technical and human factors associated with the development process quality models and quality in use models with the work carried out as part of the current draft standard ISO 18864 Quality Metrics for detailed clinical models.

4.7.2 Methodology

The multiple quality metrics defined as part the current draft standard ISO 18864 Quality Metrics for detailed clinical models were compared with the quality metrics and requirements identified in:

- The analysis of the published literature and international survey of modelling initiatives associated summary of key findings (Table 29) and checklist (Table 30) about the CIMP
- Requirements and quality metrics for Clinical Information Modelling (Table 35)
- Interoperability Asset Quality Framework defined in section 4.6.3.5.7.

The analysis applied was focused on determining the level of alignment between multiple metrics and identify new metrics that could be incorporated as part of the ISO18864 standard to improve the capabilities of evaluating the quality of CIMs.

4.7.2.1.1 Research team

This research study was carried by the thesis author in collaboration with the thesis supervisor.

4.7.3 Results

Next is detailed the results of the comparison between the quality metrics included in the current draft standard ISO 18864 with the findings obtained in the multiple research studies carried out in this thesis. As was previously detailed, this comparison mapped each quality metric to the requirements identified as part of the technological, human and organisational factors of the development process quality model and the quality in use model.

The quality metrics defined in the ISO18864 draft standard are interlinked with the previous requirements identified as part of the development process quality model and quality in use model. This standard proposes evaluating each individual CIM based on the adopted development process, structure of information and metadata. Each individual ISO18864 quality metric verifies specific characteristic of the CIM according to the data and metadata that it contains. They describe the evaluation target, method and possible results from the evaluation. Each quality metric has only two possible results “pass” if the CIM is compliant with the evaluation method or “fail” in case that the requirement was not fully met. Table 54 includes an example of quality metric included in the ISO 18864 draft standard.

8.1.1 Clinicians participated in the development (or design) of CIM
1) Definition: Were there any non-technical clinicians involved in the development or design of the DCM, who helped incorporate data user requirements 2) Evaluation Target: DCM content, metadata 3) Evaluation Method: Check to see if any clinicians have participated in the DCM development/design 4) Evaluation Result: ‘fail’: No participating clinician (s), or their participation is unknown, ‘pass’: Clinician(s) have participated

Table 54. Example of ISO18864 quality metric

Moreover, the comparison performed shows that many of the requirements identified for structuring EHR information for CIMT are shared with this specification. Next is detailed how each of the sections of this draft standard are mapped with the findings obtained as part of this research thesis. Each section includes a table that details if the individual quality metrics of the ISO 18864 draft standard are aligned with the quality domains that were defined as part of this research.

4.7.3.1 Design and development domain

Metrics proposed in this domain verify the clinician involvement as part of the development and approval of CIMs. These metrics are aligned with the identified steps of the CIMP. Moreover the definition of semantic relationships between CIMs and CIM translations are covered as part of the CIMT requirements and the Interoperability Asset Quality Framework.

Additional metrics associated with the team composition, testing the models with examples of patient data and ensuring the common understanding of experts participating in this process are recommended to be incorporated. Table 55 shows how the multiple metrics associated with the ISO 18864 standard are aligned with the quality models defined as part of our proposed SIQF.

Quality metrics	Relationship with other Quality Models
8.1.1 Clinicians participated in the development of CIM	▪ Checklist for CIMP (CL3@table30) ▪ Requirements for CIMT(R18@table35) ▪ Interoperability Asset Quality framework (Consultation Process@table45)
8.1.2 Clinicians participated in the verification/approval of CIM	▪ Checklist for CIMP (CL10@table30) ▪ Requirements for CIMT(R8@table35) ▪ Interoperability Asset Quality Framework (Consultation Process@table45)
8.1.3 Translations, only if applicable	▪ Requirements for CIMT(R17@table35) ▪ Interoperability Asset Quality Framework (Consultation Process@table45) (1.8 Language@table72)
8.1.4 Semantic Relationship between CIMs	▪ Requirements for CIMT (R9@table35)

Table 55. Relationship between ISO18864 quality metrics for design and development domain with SIQF quality models

4.7.3.2 Compliance to standard evaluated per clinical information model

Table 56 shows that most of the defined metrics defined for evaluating compliance to standard in ISO 18864 are aligned with the identified requirements for CIMTs. Moreover, it was identified that all of the evaluated CIMTs are able to satisfy these metrics. Moreover, the defined CIMP and the Interoperability Asset Quality Framework incorporate some of the metrics included in ISO 18864.

Quality metrics	Relationship with other Quality Models
8.2.1.1 Formal Syntax	▪ Requirements for CIMT (R4@table35) ▪ Interoperability Asset Quality framework (conformancetostandards@table45)
8.2.1.2 Use of international standard terminology	▪ Checklist for CIMP (CL15@table30) ▪ Requirements for CIMT(R12@table35) ▪ Interoperability Asset Quality framework (terminologybinding@table49)
8.2.1.3 Use of international standard data types	▪ Requirements for CIMT (R6@table35)
8.2.1.4 Use of international standard units of measures	▪ Not directly identified
8.2.1.5 Name of the data element	▪ Requirements for CIMT (R5@table35)
8.2.1.6 Identification of the data element	▪ Requirements for CIMT (R5@table35)
8.2.1.7 Description of the data element	▪ Requirements for CIMT (R5@table35)
8.2.1.8 Description of the data element	▪ Requirements for CIMT (R5@table35)
8.2.1.9 Coding of data elements	▪ Requirements for CIMT (R5@table35)
8.2.1.10 Identification of the terminological or classification	▪ Requirements for CIMT (R5@table35)

system by name and/or the OID	

Table 56. Relationship between ISO18864 metrics for clinical information model compliance to standard with SIQF quality models

4.7.3.3 Metadata per detailed clinical model

CIM metadata is associated with supporting the appropriate management, discovery and application of the CIM. Table 57 details that most of the ISO18864 quality metrics for metadata are included in the Interoperability Asset Quality Framework. The development process quality model includes, as well, some of the metrics proposed.

Furthermore, our research suggests defining metrics associated with the identification of sources of knowledge that guided the definition of the CIM. Specific metric associated with this evaluation is recommended to be incorporated as part of the ISO18864 standard.

Quality metrics	Relationship with other Quality Models
8.2.2.1 DCM Version	▪ Check list for CIMP (CL15@table30) ▪ Requirements for CIMT (R5@table35) ▪ Interoperability Asset Quality framework (1.1currentrelease@table72)
8.2.2.2 Purpose of DCM	▪ Check list for CIMP (CL1@table30) ▪ Requirements for CIMT (R19@table35) ▪ Interoperability Asset Quality framework (1.4scope/purpose@table72)
8.2.2.3 Appropriate description of application target of DCM	▪ Requirements for CIMT (R5@table35) ▪ Interoperability Asset Quality framework (1.10. expected revision@table72)
8.2.2.4 Purpose described multiple uses	▪ Check list for CIMP (CL1@table30) ▪ Requirements for CIMT (R19@table35) ▪ Interoperability Asset Quality framework (1.4scope/purpose@table72)
8.2.2.5 Appropriate description of discipline of DCM user	▪ Requirements for CIMT (R5@table35) ▪ Interoperability Asset Quality framework (1.6.targetuser@table72)
8.2.2.6 Author(s) of DCM	▪ Requirements for CIMT (R19@table35) ▪ Interoperability Asset Quality framework (1.4scope/purpose@table72)
8.2.2.8 Date of modification	▪ Interoperability Asset Quality framework (1.4scope/purpose@table72) (11.1currentreleasedate@table72)
8.2.2.9 Initial review round date	Not included
8.2.2.10 Number of review rounds	Not included
8.2.2.11 Last review round date	Not included
8.2.2.12 Status of content publication	▪ Interoperability Asset Quality framework (technicalcompletness@table46)
8.2.2.13 Mention of reference(s) used in DCM development, only if applicable	▪ Interoperability Asset Quality framework (evidenceused@table45)

Table 57. Relationship between ISO18864 metrics for metadata with SIQF quality models

4.7.3.4 Correctness per data element

Table 58 details how most proposed quality metrics associated with data elements were included in the requirements for CIMTs. Just the use of cardinalities was not directly identified in our research. Based on our research, the need for specifying mandatory items is recommended to be incorporated as part of the ISO18864 standard.

Quality metrics	Relationship with other Quality Models
8.3.1.1 Valid value of DCM	▪ Requirements for CIMT (R5@table35)
8.3.1.2 Terminology Binding	▪ Check list for CIMP (CL15@table30) ▪ Requirements for CIMT (R10@table35) ▪ Interoperability Asset Quality framework (terminologybinding@table50)
8.3.1.3 Appropriate use of data type	▪ Requirements for CIMT (R6@table35)
8.3.1.4 Appropriate use of cardinality	▪ Not specifically detailed

Table 58. Relationship between ISO18864 metrics for data elements with the SIQF quality models

4.7.3.5 Governance

The ISO 18864 proposed metrics associated with governance were aligned with the requirements identified in this research. Table 59 details how the proposed Interoperability Asset Quality Framework includes all the metrics identified in this standard and strong alignment exists with the development process quality model.

Moreover, quality metrics associated with monitoring how well CIMs are applied are recommended to be incorporated in the ISO18864 standard.

Quality metrics	Relationship with other Quality Models
8.4.1 Maintenance organisation of DCM	▪ Interoperability Asset Quality framework (11.1.currentcustodian@table72)
8.4.2 Existence of user feedback mechanism for DCM	▪ Check list for CIMP (CL21@table30) ▪ Requirements for CIMT (R3@table35) ▪ Interoperability Asset Quality framework (maintainance/problemresolution@table52)
8.4.3 Realm-Specific Specialisations and Extensions	▪ Check list for CIMP (CL13@table30) ▪ Requirements for CIMT (R3@table35) ▪ Interoperability Asset Quality framework (extensibility@table49)
8.4.4 Multiple Outputs, with no change to the meaning (e.g. mapping to CDA, HL7 v3, XML Schema)	▪ Not specifically identified
8.4.4.2 Quality Management System for DCM development (QMS-DCM)	▪ Interoperability Asset Quality framework (extensibility@table45)
8.4.4.3 Search/access criteria for DCMs	▪ Requirements for CIMT (R13@table35) ▪ Interoperability Asset Register Functional Requirements (FR30searching@section5.2)
8.4.4.4 Clear Accountability	▪ Requirements for CIMT (R16@table35) ▪ Interoperability Asset Quality framework (extensibility@table49)

8.4.4.5 Architectural/model flexibility and scalability	▪ Check list for CIMP (CL20@table30) ▪ Requirements for CIMT (R5@table35)
8.4.4.6 Certification level of DCM	▪ Requirements for CIMT (R16@table35) ▪ Interoperability Asset Quality framework (1.9.certification@table72)
8.4.4.7 Change notification mechanism	Interoperability Asset Register Functional Requirements (FR39notification@section5.2)
8.4.4.10 Clear statement of copy right or licensing restriction	▪ Interoperability Asset Quality framework (1.7.license@table72)

Table 59. Relationship between ISO18864 metrics for governance domain with the SIQF quality models

4.7.3.6 Representing information

This domain includes the requirements for structuring clinical information in EHR systems. These metrics are mostly associated with the specifications applied for this purpose. Table 60 specifies how just two of the ISO18864 quality metrics were included as part of the requirements identified for CIMTs. There were no identified specific recommendations for this domain.

Quality metrics	Relationship with other Quality Models
8.4.4.8 Expression of outcome of a calculation	▪ Not included
8.4.4.9 Expression of applied calculations algorithms or heuristics	▪ Not included
8.4.4.11 Specification of atomic attributes	▪ Not included
8.4.4.12 Fixed set of predefined data type	▪ Requirements for CIMT (R6@table35)
8.4.4.13 Specify the occurrence of an attribute	▪ Not included
8.4.4.14 Specify the attribute related no data	▪ Not included
8.4.4.15 Specify the allowed scalar range of value	▪ Not included
8.4.4.16 Specify the allowed quantity range of value	▪ Requirements for CIMT (R6@table30)
8.4.4.17 Specify the expression of a moment in time	▪ Requirements for CIMT (R6@table30)

Table 60. Relationship between ISO18864 metrics for information representation with the SIQF quality models

4.7.3.7 Representing specialisation and constrains

Table 61 shows that all of the defined SIQF quality models are aligned with the ISO18864 metrics identified in this domain. There were no identified specific recommendations for this domain.

Quality metrics	Relationship with other Quality Models
8.4.4.18 Representing specialization	▪ Check list for CIMP (CL23@table30) ▪ Requirements for CIMT (R3@table35)

	▪ Interoperability Asset Quality framework (extensibility@table49)
8.4.4.19 Overridden of the constraints	▪ Check list for CIMP (CL23@table30) ▪ Requirements for CIMT (R3@table35) ▪ Interoperability Asset Quality framework (extensibility@table49)
8.4.4.20 Overridden occurrence constraints on attributes and relationships	▪ Check list for CIMP (CL23@table30) ▪ Requirements for CIMT (R3@table35) ▪ Interoperability Asset Quality framework (extensibility@table49)
8.4.4.21 Overridden occurrence constraints on attributes and relationships	▪ Check list for CIMP (CL23@table30) ▪ Requirements for CIMT (R3@table35) ▪ Interoperability Asset Quality framework (extensibility@table49)
8.4.4.22 Allow a specialized type to constrain coded attributes	▪ Check list for CIMP (CL23@table30) ▪ Requirements for CIMT (R3@table35) ▪ Interoperability Asset Quality framework (extensibility@table49)

Table 61. Relationship between ISO18864 metrics for representing specialisation and constrains with the SIQF quality models

4.7.4 Discussion

The draft standard ISO18864 has been analysed according to the requirements identified as part of this research. The analysis shows that some improvements could be made to it, including additional metrics for many of the domains that this standard covers. Although the performed research was focused only on the domains included in the ISO18864 draft standard, some descriptors included in the Trustworthiness, Maturity level and Semantic interoperability domains included in the Interoperability Asset Quality Framework could be considered as candidates to be included in this specification.

Interactions with the technical committees TC 215 in ISO and TC 251 CEN are foreseen in order to contribute to this standardization process. These recommendations are expected to provide a more exhaustive evaluation of CIMs and, at the same time, obtain better integration between multiple quality models.

4.8 Comparison with the ISO 13972 standard

4.8.1 Research objective

This research aimed to compare the requirements identified as part of the technical and human factors associated with the development process quality models and quality in use models with

the work carried out as part of the current draft standard ISO 13972 Detailed Clinical Models standard.

4.8.2 Methodology

The multiple quality metrics defined as part the current draft standard ISO 13972 Detailed Clinical Models standard were compared with the quality metrics and requirements identified as part of the previous research.

The analysis applied was focused on determining the level of alignment between multiple metrics and identifying new metrics that could be incorporated as part of the ISO13972 standard to improve the capabilities of evaluating the quality of CIMPs.

The multiple quality metrics defined as part the current draft standard ISO 13972 were compared with the quality metrics and requirements identified in:

- The analysis of the published literature and international survey of modelling initiatives associated summary of key findings (Table 29) and checklist (Table 30) about the CIMP
- Requirements and quality metrics for Clinical Information Modelling (Table 35)
- Interoperability Asset Quality Framework defined in section 4.6.3.5.7.

The analysis applied was focused on determining the level of alignment between multiple metrics and identify new metrics that could be incorporated as part of the ISO13972 standard to improve the capabilities of evaluating the quality of CIMs.

4.8.3 Results

The identified human factors for the development process quality models were compared with the requirements and methodology for DCM described as part of the ISO13972 draft standard. Metrics defined as part of the ISO13972 were aligned with the requirements identified in this research for establishing a development process quality model. This ISO specification evaluates if an organisation adopted some the most relevant steps identified as part of the CIMP. Defined metrics request the involvement of clinicians and domain experts as part of the requirement definition and validation. Multiple participants can be organised including author, editorial team and relevant domain experts. This specification requires the definition and implementation of governance policies that detail transparent processes for CIM submission and facilitate the identification of appropriate CIM based on keywords, versions, categories and metadata.

In addition, this specification requests the establishment of a Quality Management System for CIM development including a quality manual describing procedures for document control, records control, internal audit, control of non-conforming CIM artefacts and corrective and

preventive actions regarding such artefacts. Figure 56 shows how the multiple steps associated with the CIMP could be implemented as a continuous improvement cycle.

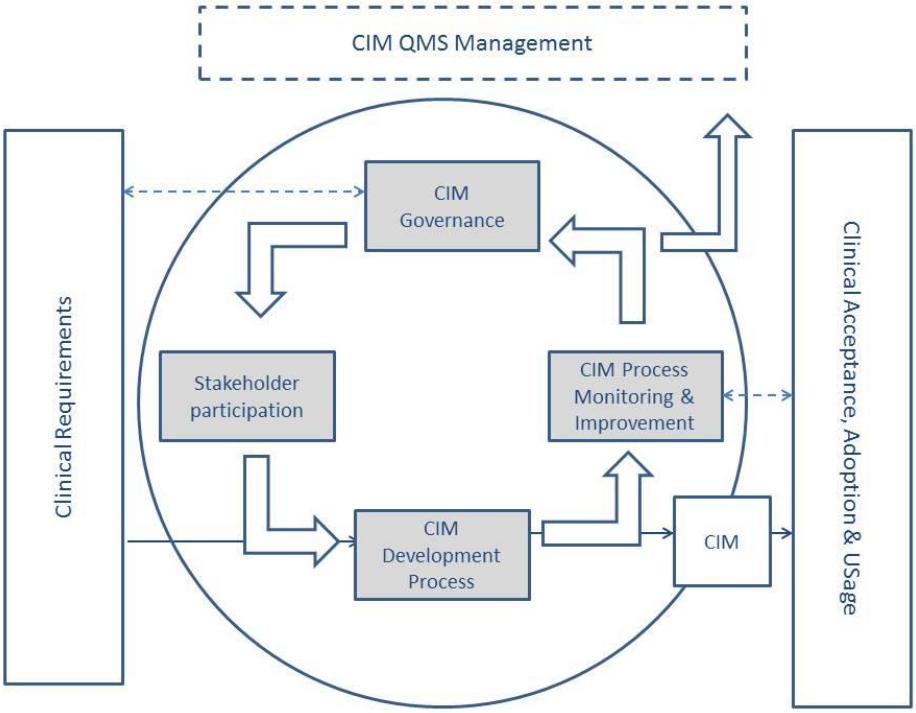


Figure 56. QMS for CIM Development and Implementation (source ISO13972 draft standard)

At the time of this thesis submission ISO13972 standard was in the process of being published without accepting additional modifications. Therefore, the analysed draft version of the standard will be similar to the approved version and our proposed recommendations can only be considered for a future revision of the standard. The detailed comparison between the multiple quality models included in the SIQF and the ISO 13972 draft standard are presented in Table 62. This comparison shows that most of the ISO 13972 requirements were identified in the proposed SIQF.

Given that the proposed Development Process Quality Model was based only on the CIMP, it was not expected to identify requirements related with the implementation of a Quality Management System. These will be required to be incorporated as well as those requirements associated with the outsourcing of task related with the modelling process and privacy of data of the participants.

Recommendations

The results obtained as part of this research suggest that additional metrics could be incorporated in ISO 13972 to avoid personal dependences as part of the team composition.

Metrics associated with the validation stage such as system prototype definition or ensuring that patient data could be collected according to the defined CIM could be considered.

Quality domains	Relationship with SIQF
5.2.1 Clinician / user requirements, involvement and verification for Detailed Clinical Models	
Designed and/or verified with multi-professional, domain experts and other pertinent input	▪ Check list for CIMP (CL10@table30) ▪ Requirements for CIMT (R20@table35) ▪ Interoperability Asset Quality framework (consultation process@table45)
Based on clinical and other relevant evidence as available in scientific literature and/or national and jurisdictional regulatory requirements and/or national or international guidelines	▪ Check list for CIMP (CL12@table30) ▪ Interoperability Asset Quality framework (evidence used@table45)
Differentiate between the structure of the data elements and the policy of how and what must be collected / used in a specified practice setting on implementation or computable level, allowing constraint to local settings.	▪ Requirements for CIMT (R3@table35) ▪ Interoperability Asset Quality framework (extensibility@table49)
5.3 Clinical Acceptance, Adoption and Use	
Verified by all identified stakeholders including author(s), clinicians, users, content reviewers, translators, terminologists and modellers.	▪ Check list for CIMP (CL8@table30) ▪ Requirements for CIMT (R16@table35)
Expressed such that their use and re-use for multiple purposes is facilitated.	▪ Check list for CIMP (CL13@table30) ▪ Interoperability Asset Quality framework (multiple domains@table46)
Endorsed by one or more relevant professional bodies in order to allow achieving proper status for its use in implementation.	▪ Check list for CIMP (CL3@table30) ▪ Interoperability Asset Quality framework (endorsement@table47)
Implementable in EHR, electronic messages and other health information technology systems	▪ Requirements for CIMT (R2@table35) Interoperability Asset Quality framework (implemented@table48)
NOT specially address one technical standard or implementation.	▪ Check list for CIMP (KF20@table29)
5.4 DCM QMS Processes for the systematic approach for quality of DCMs	
5.4.1.1 General Requirements	
SHALL have established, documented, implemented and currently maintain a Quality Management System for DCM development (QMS-DCM) in accordance with the normative requirements of ISO TS/13972.	▪ Specific from Quality Management system. It was not identified
In case of outsourced DCM development processes, the organization SHALL exercise sufficient control over such processes such that conformance to this Technical Specification ISO TS 13972 can be assured.	▪ Not specifically identified

Define its structure, such as membership, criteria and resources, including human (domain experts and secretariat) and infrastructure.	▪ Not specifically identified
Respect the patient privacy directives regarding the use and disclosure of sensitive information as patient information.	▪ Not specifically identified
Ensure the privacy of participants described in DCM work according to existing current regulations and measures.	▪ Not specifically identified
Ensure the security of participants described in DCM work and DCM materials according to existing current regulations and measures.	▪ Not specifically identified
5.4.1.2 General DCM Documentation Requirements	
QMS-DCM SHALL include documentation regarding its quality policy and quality objectives.	▪ Specific from Quality Management system. It was not identified
QMS-DCM SHALL maintain a DCM quality manual	▪ Specific from Quality Management system. It was not identified
QMS-DCM SHALL include procedures for document control, records control, internal audit, control of non-conforming DCM artefacts and corrective and preventive actions regarding such artefacts	▪ Specific from Quality Management system. It was not identified
QMS-DCM SHALL include effective planning, operation and control of its DCM development processes.	▪ Specific from Quality Management system. It was not identified
DCM Quality Manual SHALL include the scope of the QMS-DCM	▪ Specific from Quality Management system. It was not identified
Procedures of the QMS-DCM or references to them SHALL be documented.	▪ Specific from Quality Management system. It was not identified
interactions between the processes of the QMS-DCM and any gating processes requiring oversight, sign-off or other governance SHALL be included	▪ Specific from Quality Management system. It was not identified
Quality Manual SHALL include DCM Document Control Management	▪ Specific from Quality Management system. It was not identified
Quality Manual SHALL include Control of Records	▪ Specific from Quality Management system. It was not identified
5.5 DCM Governance	
5.5.2 Organizing Detailed Clinical Model governance	
SHOULD have appropriate mechanisms in place by which DCMs can be extended and maintained to fully support the requirements of the health care community	▪ Check list for CIMP (CL29@table29) ▪ Interoperability Asset Quality framework (maintenance@table52)
SHOULD ensure that appropriate effort has been made to identify relevant evidence, consult relevant stakeholders and examine existing systems and/or specifications in use.	▪ Check list for CIMP (CL7@table30) ▪ Interoperability Asset Quality framework (evidence@table45)
5.5.3 Submission criteria for Detailed Clinical Models	
Provide transparent processes for submission and inclusion for Detailed Clinical Models.	▪ Check list for CIMP (CL12@table30)
5.5.4 Search/access criteria for Detailed Clinical Models	
Facilitate clinicians, researchers, project leaders, technicians and other target groups / stakeholders in finding the appropriate Detailed Clinical Model via multimodal	▪ Requirements for CIMT (R13@table35) ▪ Interoperability Asset

approaches, such as keywords, versions, categories and metadata.	Register Functional Requirements (FR30searching@section 5.2)
5.5.5 Contributors and Key Competence	
SHOULD be led by an editorial team with domain specific expertise (e.g. immunology) relevant to the DCM in question (e.g. adverse reaction Detailed Clinical Model).	▪ Organizational levels of CIMP (coreteam@table13) ▪ Requirements for CIMT (R24@table35)
SHOULD be supported by a team of contributors with broader but balanced relevant clinical interests (e.g. general practice, internal medicine, respiratory medicine, nursing).	▪ Check list for CIMP (CL25@table30)
Provide a reviewing mechanism, which will allow the communications between the reviewers and the authors to be captured.	▪ Key findings of the CIMP (KF24@table29)
5.5.6 Clear Accountability	
Maintain overall responsibility for managing and if necessary delegating the processes/activities of DCM development including moderating inputs and resolving conflicts in opinion from contributors.	▪ Check list for CIMP (CL12@table30)
Provide the versioning control mechanism.	▪ Check list for CIMP (CL15@table30) ▪ Requirements for CIMT (R5@table35) ▪ Interoperability Asset Quality framework (11.1currentrelease@table72)
Support changing status of DCM versions.	▪ Check list for CIMP (CL15@table30) ▪ Requirements for CIMT (R5@table35) ▪ Interoperability Asset Quality framework (11.1currentrelease@table72)
5.5.7 Quality	
SHOULD be subjected to clinical risk assessment to ensure it is fit-for-purpose and meets clinical information safety requirements.	▪ Not specifically identified
5.5.7.2 Architectural/model flexibility and scalability	
Localizing a DCM for flexibility, scalability or other adaptation SHALL be achieved without compromising or contradicting its semantics. In other words, it SHALL not deviate from its intended meaning.	▪ Check list for CIMP (CL20@table30) ▪ Requirements for CIMT (R5@table35)
5.6 Stakeholder Participation	
All interests SHOULD be discussed and agreements reached using consensus methods without due influence or domination by a particular group of members.	▪ Check list for CIMP (CL12@table30)
Consent, dissent and any other comments SHOULD be recorded and made available in public record.	▪ Not specifically identified
Conflict resolution procedures SHALL be explicit and publicly available	▪ Check list for CIMP (CL12@table30)

5.6.1.2 Approval of Detailed Clinical Model development	
Detailed Clinical Model repository SHALL provide different certification levels to the DCMs to indicate the levels of review and approval this Detailed Clinical Model has received.	▪ Not specifically identified
Detailed Clinical Model repository SHALL provide a notification mechanism to notify/alert users, e.g. alert users with changes to the existing models, notify users with new models.	▪ Interoperability Asset Register Functional Requirements (FR39notification@section5.2)

Table 62. Comparison between the ISO 13972 draft standard and the quality models defined in this thesis

4.8.4 Discussion

The alignment of the defined CIMP with the ISO 13972 standard confirms that it will be possible to define a Quality Management System that is based on the identified process steps, requirements and recommendations. As a result it will be possible to contribute to the establishment of certification processes for organisations who develop CIMs. The establishment of these processes will ensure that organisations are able to implement a continuous improvement cycle in the management of semantic interoperability through the adoption recommended practices for developing CIMs and monitoring their use and acceptance by the end users.

Given that modelling tools were identified as important instruments that could help to improve the quality of CIMs, checking functional requirements of those tools applied in the CIMP could become another mechanism to identify quality of the resultant models.

4.9 Summary of the multiple researches performed

Next is presented the most relevant information collected as part of the multiple research studies included in this chapter.

Systematic literature review

The existing published literature published between 2000 and 2013 about EHR systems and semantic interoperability was analysed. This section presented the indicators about the CIMP collected from the 36 papers published in the literature that met inclusion criteria defined in the previously described systematic review. In addition, the inductive content analysis of the published literature allowed the identification of the initial set of steps that describe the CIMP.

The analysis of the published literature identified that most of the papers did not describe in detail the modelling process adopted or the methodologies applied for terminology binding. This analysis provided recommendations for sharing the results of the modelling process and improving CIMTs.

International study of experts on best practice

Results from the literature review were applied to develop a semi-structured questionnaire for interviewing experts from a representative sample of modelling initiatives about the processes adopted in their organisation. The interviews were transcribed and analysed based on the inductive content analysis methodology.

This section details the analysis of the interviews performed to 20 experts from 13 different countries experienced in CIMP. This research study provided further details about the steps of the CIMP including information about actors involved, modelling strategies and common barriers. They were applied to define a checklist to verify that each step of the CIMP is carried out according to the identified best practices.

The information collected from interview results was applied to discuss about the establishment of good modelling practices, scaling up the resource development process.

Requirements for Clinical Information Modelling Tools

Given that collected interview results highlighted the need for improved functionalities in CIMTs, research was carried out to identify the essential requirements that these tools should incorporate. A list of functional requirements was proposed based on the existing tools and the recommendations collected in the performed international survey of modelling practices (section 4.3). Functional requirements were classified based on a Delphi study that included two rounds of online surveys. The first round was answered by 57 experts to prioritise the requirements and the second round validated the classification of requirements according to the feedback provided by 38 experts. This section analysed the resultant classification of requirements for CIMTs and the reliability of results.

Evaluation of Clinical Information Modelling Tools

The resultant agreed 20 essential requirements were applied in section 4.5. for defining a framework for evaluating CIMTs. Nine of the eleven tools that were found applicable for clinical information modelling were evaluated against a set of metrics derived from the essential requirements. The evaluation of CIMTs proven that the essential requirements were able to be implemented and there were discussed the main areas of improvement of existing tools.

Definition and assessment of the Interoperability Asset Quality Framework

Through an iterative process for collecting multiple stakeholder needs based on workshops, online and face to face meetings, a set of metrics was defined to characterise interoperability assets from the end user point of view.

After presenting the multiple prototypes developed to collect expert feedback, this section detailed the descriptors and metrics included as part of the Interoperability Asset quality framework. The defined quality framework included a set of quality descriptors to evaluate interoperability resources based on end user point of view. These identified quality descriptors and methodology for graphical representation were externally assessed by 20 experts in this field through an online survey.

Answers provided by the 20 experts who participated in this research about their preferences to access multiple kinds of assets, quality descriptors and graphical representation showed a good level of acceptance. As a consequence, it was inferred that the proposed Interoperability Asset Quality Framework had the potential to support the management and discovery of interoperability assets. Last, possible factors were considered that might impact the adoption of the proposed framework

Comparison with ISO Quality standards

The multiple quality metrics defined as part of the ISO 18864 and ISO 13972 draft standards were compared with the results of this thesis. The performed comparison shows a good level of alignment and recommended new metrics to be incorporated as part of these standards when they are next revised.

Chapter 5. Discussion

5.1 Introduction

This chapter presents the analysis of the results reported about clinical information modelling processes. The information obtained through the multiple studies into the CIMP suggests that the published literature provides limited details about the adopted design processes and how CIMs are bound to terminologies. Moreover, these CIMs are not usually shared or accessible within the public domain and it has been identified that mapping CIMs to technical specifications is not a straightforward process and could result in different technical artefacts or standards derived from the same CIM that are not completely equivalent – and hence not supporting semantic interoperability. From the inductive analysis of the content extracted from literature and interviews it was possible to identify common processes that suggest the possibility of proposing one unified methodology for CIMP.

From interviews it was possible to determine barriers and recommendations for establishing good practices, and to perform an analysis of their concordance with the proposed standard quality metrics for DCM, and supporting knowledge management at large scale.

Furthermore, the information obtained suggests that improvements in CIM tooling will be required. The results from the Delphi study of the functional requirements for CIMTs were analysed according to the kind and number of participants in the study and the level of consensus. These results classified the functional requirements as essential or recommended, identifying the level of compliance of these functionalities by existing tools. These requirements led to defining an evaluation framework for CIMTs that was proven to be useful for tools based on any of the existing EHR interoperability standards and specifications

The definition of a quality in use model that is expected to evaluate multiple kinds of interoperability assets was externally assessed and implemented as part of the IA register. This register aims to become a point of reference where any stakeholder could find information about interoperability assets and their quality.

5.2 European Register of interoperability assets

The defined quality framework for interoperability assets was implemented as part the Interoperability Asset (IA) Register. The IA register was intended to become the recognised point of reference at a European level that will contain relevant material for analysis, design,

implementation, adoption or benefits realisation of interoperability within eHealth environments. The register was intended to enable someone searching for assets to meet a particular interoperability use case to discover relevant assets and learn enough about them to determine whether they should use those assets published in the public domain by EU Member States or license or purchase those assets and use them in their intended deployment situation. The register aimed to be able to classify and organise the collection of interoperability assets that includes requirements, specifications, standards, guidance on how standards may be used concurrently, implementation guides, educational resources, and other resources that support the design, implementation and successful adoption of eHealth services that can exchange data meaningfully.

5.2.1 Development process

The development of the IA register has benefitted from a resource, provided by the Research in Advanced Medical Informatics and Telematics Organisation a not for profit organisation based at Gent University, Belgium, to undertake an implementation of it. This development process was based on the functional requirements by the thesis author in collaboration with the thesis supervisor.

The information collected in the two workshops in Athens and Brussels previously described (Section 4.6.2) was useful for defining the initial set of register functional requirements. The collected information was combined with results from sections 4.2-4.5 to implement the first version of the IA register.

The IA register was developed according to an iterative development process focusing on obtaining feedback from interoperability asset developers and potential end users. The following mechanisms were carried out to validate the developed platform:

- The register was presented during the Lisbon eHealth week to representatives of the European Commission Directorate-General for Health and Consumers and ministries of health of the following countries and regions: Portugal, UK, Greece, France, Slovenia, Andalusia (Spain), Malta, Portugal, Cyprus, Greece, Luxembourg, Italy, Croatia, Switzerland, United Kingdom, Bulgaria, France and Germany. As part of this conference, the register was presented in a demonstration stand set in order to promote interactions with potential users and collect feedback and opinions.

- A webinar was conducted in order to train a group of users about how to upload and manage those assets produced by their projects and organisations.

- The register was tested by external users who uploaded and recorded multiple interoperability assets developed by their organisation.

Given that multiple quality models contained in the SIQF will require an adequate level of maturity in order to be implemented as part of the European Register of interoperability assets, this thesis includes an analysis on how this register will be coordinated with the results of the standardization process associated with the development of quality standards associated with interoperability assets.

5.2.2 Implemented system

The Interoperability Asset Register has been developed as an online register and discovery service for interoperability assets (Figure 57). The register is available online through the following URL:

http://interoperabilityassets.ramit.be/views/public/listAll.cfm?leftNavigation=listAssetAll

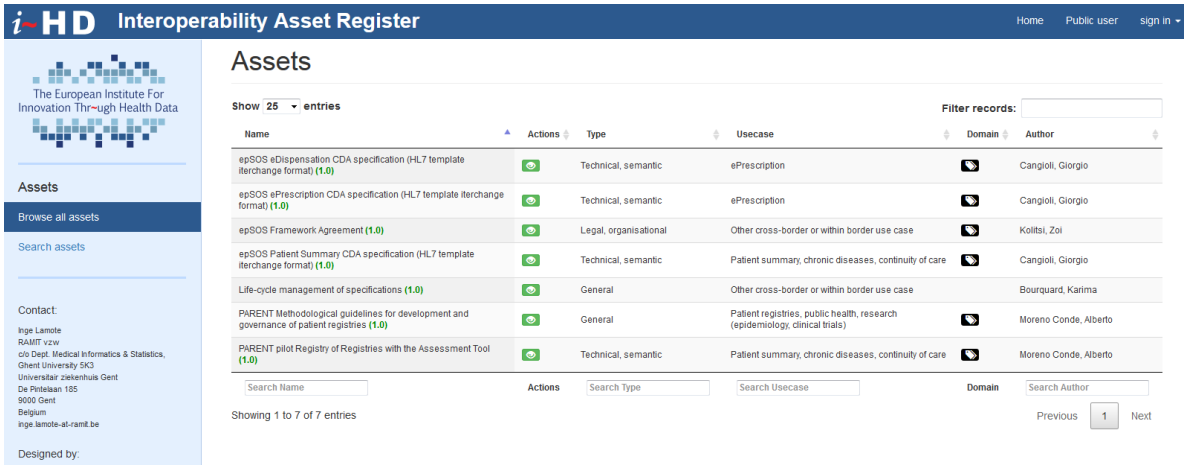


Figure 57. Screenshot of the IA register

This section details the functional requirements that IA register shall comply with according to the collected feedback from multiple workshops and iterative development process.

5.2.2.1 General requirements

FR1. This IA register shall provide a single point of reference to inform any stakeholder about assets without charge or license.

FR2. The register shall contain or reference any relevant resource that potential stakeholders who may need guidance, evidence, direction, specifications, standards, tools or software might require for designing or implementing IT solutions or policies based on eHealth interoperability.

FR3. The register shall be able to support end user discovery of relevant interoperability assets by combining search functionalities with classification and quality assessment functionalities.

FR4. The register shall provide an option for assets to be physically or logically incorporated within it, and permanently retained and made available to other register users, within reasonable limits on the technology requirements (including storage requirements) for each asset.

FR5. The register shall provide the means for interlinking multiple interoperability assets that would be required to fit together to satisfy a specific use case or supporting the evolution of the proposed technical solutions either incorporating new assets that provide additional evidence, complement or supersede an existing asset.

5.2.2.2 User management

FR6. The register shall include an administrative role for user and group management

FR7. The register shall allow users to become registered by providing the relevant information for their profile and managing their password

FR8. The register shall allow authoring users to invite new co-authors that could be included as part of the list of authors for an interoperability asset

FR9. The organisation responsible for the register should include a scientific advisory board that will ensure the appropriateness and accuracy of the collected asset metadata, as well as provide advice and arbitrate in case of doubts about how to satisfy the requirements.

5.2.2.3 Requirements for asset registration

FR10. The register shall enable any organization or user that produces or is responsible for an asset, to create a new register entry documenting the asset in a consistent and clear manner with an optional reference (URL link) to the asset itself.

FR11. The register shall allow individuals creating a register entry to self-declare descriptive and quality information about their asset.

FR12. The register shall allow identified individuals to create register entries or to be able to annotate or supplement existing entries.

FR13. The register shall allow users to register new assets providing the relevant information about purpose & usage

FR14. The register shall allow users to register new assets providing the relevant information about metrics defined as part of the quality in use model

5.2.2.4 Requirements for documenting scope, purpose and type of asset

Provision must be made within an asset register entry to provide the following descriptive information about the assets:

FR15. The physical nature of the asset and its functional purpose, drawn from a standardised vocabulary of terms, where possible adopting pre-existing standard terminologies.

FR16. The interoperability use cases to which may contribute in whole or part, where possible, drawn from established terms for describing use cases and, where possible referencing existing well-defined European interoperability use cases.

FR17. A description of the clinical specialities and/or care settings for which the asset is particularly targeted, if any particular ones apply.

FR18. A description of the kinds of end user who are expected to make use of the interoperability that is supported by this asset (for example, users of systems that have been made more interoperable through using the asset), or might be end beneficiaries of that interoperability for example, individuals and organisations that might make use of that interoperable information).

FR19. Provision for a longer free text description of the scope and purpose of the asset.

5.2.2.5 Quality assessment of an interoperability asset

FR20. The register shall include a form to collect those descriptors defined as part of the quality in use model

FR21. The register shall order the descriptors according to their associated level of compliance against the defined quality framework

FR22. The register shall show the results of the level of fulfilment of each interoperability asset against the quality in use model

5.2.2.6 Relationships between assets

FR23. The register shall be able to allow any registered user to group multiple assets in bundles detailing the kind of relationships between them

FR24. The register shall be able to display dependences between assets in order to support discovery of the specific set of assets that will meet a requirement or use case

5.2.2.7 Requirements for documenting the information about how to access an asset

The register entry for an asset shall support the provision of the following information about access to it:

FR25. The originating project or initiative that developed the asset.

FR26. The current organisation that is the custodian of the asset and optionally what responsibility for maintenance is provided.

FR27. The current release version and the date of this version

FR28. The contact details of the person or organisation to handle enquiries about the asset and to provide access to it if this is not directly supported from the register.

FR29. Information about the nature and possibly cost of obtaining a license for use, any other costs to be budgeted for and any other obligations on a potential user of the asset.

5.2.2.8 Requirements associated with searching functionality

FR30. The register shall provide an online searchable and indexed register of assets and provide information on how these assets may be accessed.

FR31. The register shall allow to search for and classify interoperability assets based on the multiple descriptors of purpose & usage

5.2.2.9 Collaboration

FR32. The register shall support collaboration between team members in order to agree the appropriate descriptors of the interoperability asset

FR33. The register shall ensure that the author of any part of a register entry can be determined by subsequent users.

FR34. The register shall provide the history of changes for each contained asset. Based on version-tracked mechanism it should be possible reverting the asset to a prior version if this is found necessary.

FR35. The register shall ensure that asset modifications are audited including a mechanism for inspection of that audit trail to be able to identify the person or organisation responsible in case of malfunction.

5.2.2.10 Governance

FR36. The organisation responsible for the register shall establish operating rules, governance rules and appoint a governance oversight body to ensure its trustworthy operation.

5.2.2.11 Register federation

FR37. The register shall be implemented as a single centralised information repository or as a federation of multiple information repositories. This functionality will allow external organisations the possibility of hosting their own repository of assets if they adhere to consistent operating and governance rules.

FR38. The register shall include a published interface and service specification to permit multiple instances of the register to federate, and to permit other kinds of asset register or repository to import and export register entries in an automated or semi-automated way.

5.2.2.12 Notification service

FR39. The register shall incorporate a notification service that allows users and user organisations to be notified of updates to the IA register for particular use cases or of particular types.

5.2.2.13 Collection of community adoption experience

FR40. The register entry for an asset shall enable any registered party to contribute additional descriptive information about the asset that either supports subsequent users to make best use of the asset or optionally warns about problems or limitations relating to its use that subsequent uses should be aware of before making an adoption decision.

FR41. The organisation responsible for the register shall publish a code of practice for registered users when revising or supplementing an asset register entry.

FR42. The organisation responsible for the register shall moderate the information provided by its registered users and publish a policy for handling inappropriate entries.

5.2.3 Expected impact of the Interoperability Asset Register

Currently there are a large number of organisations working on eHealth interoperability such as standard development organisations, healthcare providers, IT industry and eHealth researchers. The IA register has been designed as the first tool able to satisfy the requirements for becoming a single point of reference where any stakeholder could find information about interoperability assets. The IA register is open to include resources produced by any organization or initiative. As a result it is possible to increase competitiveness based on a transparent quality framework.

Any organization, including private companies and SMEs will be able to contribute to eHealth interoperability. IT vendors will benefit from easier access to the market by either adopting the most relevant specifications in their products or even suggesting improvements to existing specifications that their product has already incorporated to satisfy an advanced feature.

The register has the potential to reduce the complexity of decision making by indexing and classifying all the relevant resources that could fit within a specific use case in a single repository. The classification of the asset results from relevant projects in Europe and initiatives through a consistent quality assessment framework aims to benefit the eHealth community users by making it easier to discover those interoperability assets that could better fit their project and organisation needs. Based on the collaboration with EXPAND and SemanticHealthNet projects the IA register is aligned with the established priorities defined by the European Commission for cross border interoperability across Member States.

Associated with the IA register, a governance model was defined to support the management of the assets. This model was defined focusing on combining self-evaluation with basic external peer review in order to avoid delaying the incorporation of assets and avoid increasing the resources required for verifying them. Rather than providing a slow and exhaustive process for initial asset verification, it is expected that community of users will be able to provide feedback helping to detect any issue with the self-evaluations. The adoption of this crowdsourcing methodology as a distributed and transparent process for review is expected to provide sustainable management of the register. The importance of sustaining the Interoperability Asset Register is recognised, and the European Institute for Innovation through Health Data (i~HD), a not for profit association, has secured funds to maintain this and to further develop it. Established governance is expected to monitor how assets are developed, described and accessed in order to analyse how this framework could better satisfy user needs. As the number of assets in the register grows, and feedback from users of the register is accumulated, future versions of the register may assign more discriminating scores to the different values of each descriptor. As a consequence, the framework will be able to gradually evolve as long that more experience is obtained about the use of the quality metrics for interoperability assets

The definition of semantic relationships between interoperability assets is a mechanism that promotes the discovery of assets promoting the reusability. As a consequence, it could lead to a gradual harmonisation in the use of eHealth interoperability specifications that could accelerate the development of more mature eHealth interoperable specifications, through increased feedback and coordination. Moreover, the community of interoperability asset developers will receive guidance through the self-assessment about those areas that still need to be improved in their defined specifications or resources. Through the drop-down lists that contain multiple options for each quality descriptor ordered according to the level of fulfilment, interoperability asset developers will be aware about possible improvements to their adopted methodology for

interoperability asset definition. Users looking for interoperability resources will obtain clear and relevant information that is usually not provided by developers.

5.2.4 Reaching EHR vendors

As was described in section 1.2.3. and later reported as part of the barriers reported the performed interviews with experts about the CIMP (4.3.3), the proposed IA register is expected to counter the reluctance to adopt interoperable solutions by large IT providers if they don't have business incentives. In addition, this research identified that some large IT companies would be open towards adopting CIMs that have enough level of agreement. The Clinical Information Chief of one of the top EHR vendors claimed that "we don't have a lot of that (agreement) today, so I think that is a big thing. And what happens is that all the vendors end up solving that problem themselves but they all solve it slightly differently. It would really help the industry if that modelling was done better and that there was agreement to use it amongst the various bodies that produce it, I think the vendors would welcome that because we don't particularly like having to invent all these data structures over and over again. It's really hard work and if you don't get it right you have to go back and change everything. But since we don't have those shared models that everyone agrees upon we just go back and iterate with our own experts and with our customers who are giving us feedback and over time we'll get better and better at it and over time we'll get a pretty good model but it might take five years of iteration" (David McCallie 2013)

Given that, at a European level, there is not authority responsible for the transfers of eHealth information, the VALUeHEALTH project recommended to establish quality labeling and certification as a mechanism to guide the market towards increased harmonisation at regional, national and European level. This project reported how multiple strategies based on incentives, regulatory approaches, procurement or market pressure were able to influence large IT vendors towards more interoperable solutions in multiple countries (VALUeHEALTH D3.1 2016). The examples provided show how the funds required to make existing EHR solutions compatible with specifications defined at national levels are provided. Belgium and US provide economic incentives, UK provide them through procurement mechanisms but not all the solutions are just based on the direct allocation of public funds. In Ireland healthcare professional organisations were able to create enough market pressure to incentivise vendors towards adopting the requested specifications. As a result, it could be infered that obtaining enough level of agreement between the community of users could represent a useful incentive to influence the market.

At European level the European Commission is promoting the set of specifications included as part of the European eHealth Interoperability Framework as a mechanism to harmonise the demand of procurers and healthcare providers. This eEIF is supported by IHE and Continua Health Alliance (Continua Health Alliance 2016). These two organisations involve most of the major IT vendors and provide the certification mechanisms as part of their business revenue

plan. As a result they are pushing the market towards the adoption of the selected specifications.

The IA register could complement the existing eEIF initiative by indexing and providing quality assessment of the material associated with the requested specifications. The multiple educational documents, examples, value sets and implementation guides can be evaluated as part of the implemented SIQF.

Moreover the collaboration of the i~HD institute with multiple pharmaceutical companies as part of the EHR4CR champion program allows healthcare providers to share anonymised EHR data for study design and recruitment process. This collaboration promises healthcare providers to increase the number of clinical trials where they participate increasing their capability to receive research funding. On the other hand, the pharmaceutical industry expects to reduce the cost for conducting clinical trials. As a result this new emerging collaboration could become another finantial incentive towards the adoption of harmonised specifications in healthcare providers.

5.2.5 Limitations

It is recognised that this developed quality framework is primarily designed towards the evaluation of technical and semantic interoperability assets. This prioritisation was aligned with the results from the survey carried out in section 4.6.3.5. Nevertheless, it is expected that the descriptors associated with general purpose and organisational assets such as methodologies, clinical guidelines and legal documents will be refined in the future through usage experience and additional research about how to better characterise them in their relationship towards semantic interoperability.

Although there is need for a recognised point of reference at European level containing eHealth interoperability resources in our continent, it is recognised that this developed IA register has not guaranteed community adoption. Requirement identification and fulfilment needs to be complemented with developers and expert engagement. Several presentations, webinars and demonstrations were carried out. Up to now several projects, in addition to the EXPAND and SemanticHealthNet, intend to use the IA register to sustain and promote their assets including the Joint Action to support the eHealth Network (JAseHN), EHR4CR, TRANSFoRm, PARENT, SALUS, VALUeHEALTH. Moreover, collaboration was established with rare disease networks to consider how the register may support ERNs. Nevertheless, it is out the scope of this thesis to obtain the level of support that the IA register aims to obtain. i~HD will continue its promotion towards additional European eHealth organisations and projects in the near future.

5.3 Semantic interoperability Quality Framework

5.3.1 Relationship between multiple quality models

The presented results show that quality models are interrelated. The implemented IA register was focused only on the Quality in use model because the defined metrics were able to be widely accepted and understood by end users (Figure 58). Special effort was made for providing generic wording in order to allow the characterisation of the multiple types of interoperability assets and to facilitate the understanding by the general public.

Figure 58. Current implementation of quality in use model for interoperability assets

The presented results show three quality models that should be aligned in order to be able to provide a consistent evaluation of multiple semantic interoperability resources. According to the existing standardization processes carried out in CEN and ISO it is expected that the quality in use model could be complemented by the individual quality models. The individual quality models may become accepted by the eHealth community either because they were finally published as quality standards or they became the facto standard quality in use model.

Results from previous studies about CIM, CIMP and CIMT quality requirements were helpful to guide the definition of metrics and domains related with technical interoperabilty assets but they were not directly incorporated into the implemented quality in use model. According to the broader scope of the EXPAND project it was required to evaluate multiple kind of semantic and technical interoperability assets. Therefore, descriptors associated with the quality in use domain were written with generic wording that facilitated end user understanding.

The next section presents the relationships between the quality in use model with the complementary quality models defined as part of the SIQF and details the minor adjustments

that could be foreseen if these latter quality models have the appropriate level of maturity and adoption.

5.3.1.1 Relationship with CIMP quality metrics

Many of the identified requirements about the CIMP were incorporated into the development process, maturity level and maintainance domain. In addition, once the ISO13972 draft standard become published, it could be incorporated into the quality in use model. In this case, it could be incorporated as part of the development process domain that requests information about the use of a recognised quality management system. Table 63 details in green color how the value sets of the "quality processes used" descriptor can be modified.

Domain	Descriptor	Value set
Development process	Quality processes used:	1. External quality control process based in ISO9000, ISO13972 or other recognised methodologies 2. External quality control process 3. Internal quality control process 4. No verified quality control process 5. Not relevant

Table 63. Proposed modification of the value set to incorporate the QMS for CIMP defined in ISO 13972.

5.3.1.2 Relationship with CIMT quality metrics

The IA register includes the descriptors associated with tools as part of the support & skill domains but CIMT requirements identified in section 4.4 were not incorporated. Given that these requirements only apply to one of the multiple kind of the technical asset evaluated, it could be considered as a complementary evaluation framework. Moreover, it is perceived that increasing the complexity of this quality in use framework could impact on its end user acceptance. It will be necessary to wait for wider adoption of the CIMT essential requirements before these an be incorporated into this framework. In the case that the identified essential requirements for CIMT have enough level of acceptance they will be considered to be included as part of the skill & requirement domain. Table 64 details in green color how the value sets of the "extend of tool guidance" descriptor can be modified.

Domain	Descriptor	Value set
Support & Skills	Extent of tool guidance	1. There are available tools that satisfy the essential functional requirements for CIMT in order to support the definition, validation and certification of this class of assets 2. There are available tools able to support the definition, validation and certification of this class of assets 3. There are available tools able to support the definition and validation of this class of assets 4. There are available tools able to support the definition of this class of assets 5. There are not tools to support the use of this class of asset 6. Not relevant

Table 64. Proposed modification of the value set to incorporate essential functional requirements for CIMT

5.3.1.3 Relationship with CIM quality metrics

A subset of the metrics identified for clinical information models, either by studying the modelling process or the ISO 18864 standard, were directly incorporated into the semantic interoperability domain. In addition, once this standard becomes published a new descriptor called quality of the clinical information model could be incorporated into the semantic interoperability domain. Table 65 details the proposed content for the "quality of the clinical information model" descriptor.

Domain	Descriptor	Value set
Semantic Interoperability	Quality of the Clinical Information model	1. This asset satisfied the mandatory and optional metrics defined in the ISO18864 standard 2. This asset satisfied the mandatory metrics defined in the ISO18864 standard 3. This asset aims to satisfy the mandatory requirements defined in ISO18864 standard but evaluation is not finished yet. 4. This asset doesn't satisfy the mandatory requirements 5. Not relevant

Table 65. Proposed modification of the value set to incorporate essential functional requirements for CIMT

5.3.2 Implemented Quality framework foreseen evolution

The defined quality in use model is able to assess in detail the quality of the interoperability capabilities for technical and interoperability assets. As was previously explained in section 4.6.2, the selected methodology focused on prioritising the definition of descriptors on those assets that were identified with greater impact on eHealth interoperability. This was aligned with the perception of users according to the survey results (section 4.6.3.5.2) that identified these types of asset the most relevant for end users.

Nevertheless, generic, legal and organisational interoperability assets should benefit from better characterisation of their quality attributes. Therefore, the IA register is expected to evolve in the long term with the definition of individual quality metrics for each type of asset. The implemented quality in use model could be complemented with individual quality models refining descriptors and personalising them for each specific kind of interoperability asset. It would benefit from incorporating the research results from multiple quality models and further investigations for those assets that were not fully detailed. Results from researches associated with each individual kind of resource could lead to incorporate additional individual quality models. E.g. the approval of the product quality model standard for clinical information models could be just referenced in the value sets associated.

The SIQF will require time to get to the point that it can address this foreseen evolution that will include individual quality models for individual types of interoperability asset. According to the examples previously detailed, the SIQF could remain stable in the number of domains for the quality in use models with just including some additional descriptors or adding terms to the defined value sets. Figure 59 shows how multiple quality models could be interrelated. Each new quality model that could be incorporated to complement the defined quality in use model requires obtaining an appropriate level of consensus on the defined metrics and evaluation mechanisms and adoption either by eHealth community and/or standardization bodies.

Figure 59. Foreseen implementation of quality in use model for interoperability assets

5.4 General Discussion

5.4.1 Addressing the Research Hypothesis

This thesis is focused on a relativelly new area of research without any published quality standards. The exploratory research studies carried out were able to better characterise those relevant factors to evaluate the quality of the development processes and CIMs based on the published literature, as well as, interviews and workshops with multiple experts involved in the definition of CIMs or interested in applying them. This research was able to get inputs from a representative sample of experts on eHealth interoperability taking advantage of the connection with the SemanticHealthNet and EXPAND projects.

The defined quality metrics for the quality in use model and functional requirements for CIMTs were validated through online surveys with multiple experts in the field. Moreover the identified requirements for the Product Quality Model and the Development Process Quality Model were compared with the work carried out as part of the ISO and CEN standardisation bodies. This comparison confirmed that the research results were aligned with the ISO13972 and ISO 18864 draft standards and it highlighted a few areas were additional quality metrics could be incorporated into these standards.

This research has studied multiple areas related to the quality of semantic interoperability including multiple quality models and multiple kinds of interoperability resources. The defined Semantic Interoperability Quality Framework is composed of three models that could be interlinked and complement each other in order to provide the means for assessing how good a development process was adopted, the defined CIMs and end user expectations of the Interoperability Assets. The defined framework foresees a graduale evolution in the long term with minor adjustments.

The implemented IA register based on the quality in use model for interoperability assets could become a valuable instrument to obtain better understanding about what additional quality metrics for semantic interoperability resources should be incorporated. This register will allow direct interaction with end users, developers, regulators and vendors to obtain feedback about their individual needs for each specific kind of asset.

Based on the presented result this research was able to address the following set of hypothesis:

- **It is possible to define recommendations and quality metrics for clinical information modelling processes independently of the implemented EHR specification.**

  This research was able to analyse how clinical information modelling process was adopted through studying the published literature and interviewing a sample of initiatives working on the clinical information modelling field. The results were applied to describe how CIMP is recommended to be adopted (Sections 4.2 and 4.3). In addition, it was defined a checklist composed by a set of metrics to verify that the identified best practices as part of the CIMP (Section 4.3.3.22). This work was aligned with the work carried out as part of the ISO 13972 standard and identified possible contributions for its future revision (Section 4.8).

- **It is possible to define a set of requirements for scaling up the development process to promote sustainability of clinical information modelling processes**

  The performed research recommended the establishment of mechanisms for scaling up the clinical information modelling process as a mechanism for promoting the quality of

defined interoperability resources (Section 4.3.3.10). Several requirements were identified to promote collaboration between the involved stakeholders and monitoring related eHealth projects needs and results. In addition, it was recommended establishing a governance process associated to regulatory endorsement. A subset of the requirements for coordinating the development of clinical information models and interoperability assets were implemented as part of the IA register (Section 5.2).

- **It is possible to identify generic requirements for clinical information modelling tools, relating these to the existing tools and propose new requirements to guide the evolution of tools in the coming years.**

  A list of requirements for CIM tools were defined based on the study of published literature and interviewing a sample of initiatives working on the clinical information modelling field (Section 4.2 and 4.3). These requirements were prioritised based on the results of applying a Delphi study methodology with a representative sample of experts and were applied to define an evaluation framework for CIMTs (Section 4.4). The defined evaluation framework was tested and validated through the evaluation of most of the existing CIMTs (Section 4.5).

- **It is possible to specify quality metrics for clinical information models associated with user acceptance for healthcare professionals, decision makers and IT developers.**

  This research defined a set of quality metrics especially designed to measure the capability of interoperability resources to satisfy the end user interoperability needs (Section 4.6.3.5.7). The defined metrics were assessed through an online survey with a sample of potential end users obtaining an adequate level of acceptance (Section 4.6.3.5.6).

- **It is possible to implement the defined semantic interoperability quality framework as part of a European register for semantic interoperability resources. This register supports end users to identify relevant interoperability resources for their projects and organisations, as well as, providing guidance to developers of interoperability resources about the quality of their adopted methodologies and produced clinical information models, specifications and value sets.**

  The defined quality in use model was implemented as part of the IA register as an online tool able to contain, classify and quality assess multiple interoperability resources generated by those organisations working in the eHealth interoperability field (Section 5.2). This register has the objective of supporting and promoting the adoption of interoperability at European level. It aims to contain and provide access to the multiple

resources generated from the eHealth community such as educational material and resources in the form of generic, organisational and technical assets.

5.5 Summary of the discussion chapter

This chapter analysed how the overall SIQF studies were able to address the goals defined in their corresponding methodology and verified the fulfilment of the global hypotheses defined in this thesis.

European Register of interoperability assets

This section discussed the possible impact of the IA register for guiding interoperability asset developers and end users based on the functionalities that were implemented. Moreover, the level of support was described that this register obtained from existing European organisations and projects as an early achievement in its strategy for supporting the management of semantic interoperability resources. In addition, this section analysed the expected impact of the IA register and how to reach EHR vendors.

Semantic Interoperability Quality Framework

This section analysed how the multiple quality metrics defined for CIM, CIMT and CIMP are interrelated with the Interoperability Asset Quality Framework. Moreover, the foreseen evolution of the defined quality frameworks was explained.

General discussion

Finally, this section detailed how the multiple studies carried out in this research were able to address the hypotheses that were presented in the introduction chapter.

Chapter 6. Conclusion chapter

6.1 Introduction

Conclusions extracted from the performed research studies include recommendations for improving CIMP and for the development of a unified methodology. Further collaboration between the main organizations and professionals involved in this process is recommended as well as recommendations for tooling.

These recommendations were applied for identifying new functionalities for CIMTs that were included in the Delphi study about functional requirements in CIMTs described in section 4.3. Based on the obtained results, this research was able to obtain consensus for recommending, as essential functional requirements, a set of functionalities that are not yet widely adopted but should be adopted by CIMT in the coming years. The evaluation framework for CIMTs was tested and validated with the assessment of existing tools.

Multiple interactions with end users led to define and validate the first quality in use assessment model for interoperability assets. This quality assessment model is focused on providing the means to end users to identify interoperabilty assets able to be reused by their projects and organisations.

The implemented IA register has been designed according to the quality metrics defined as part of the quality in use model. This quality in use model acts as an umbrella that allows end user interaction with the multiple quality models defined for the SIQF and will be able to evolve according to the foreseen standardisation of especific quality standards related with semantic interoperability in CEN and ISO. The IA register established links with European organisations in order to be able to contribute towards the gradual harmonization of interoperable solutions in our continent.

6.2 General conclusions

This thesis focused on studying how could measure the quality associated with EHR semantic interoperability by understanding the processes, tools and resources associated with the definition, adoption and implementation of eHealth systems and solutions. The obtained results are expected to contribute towards the improvement of semantic interoperability capabilities in EHR systems by providing objective requirements and metrics that should be provided by CIMs and tools.

The adoption of methodologies that measure the quality of EHR interoperability resources are expected to contribute towards the evolution of technological solutions through the identification of those areas where semantic interoperability requirements are not fully satisfied. In addition, it will be increased the transparency about the relevant information useful to determine the suitability of reusing an interoperability asset that is usually not provided (e.g. the definition and validation processes adopted, viable business model, updating process, established mechanism response to incidents, etc.). As a result, members of the eHealth community will reduce the risk of failure when they adopt existing interoperability resources.

Multiple EHR specifications

This thesis focused on defining quality metrics for the semantic interoperability field without being dependent on any specific EHR specification. The large number of organisations working on the definition of EHR specifications resulted on a market fragmentation. The adopted approach independent from specific technologies allowed providing a consistent view of the processes and requirements associated with semantic interoperability and make the results useful for existing initiatives. Moreover, the defined quality metrics and semantic interoperability requirements were generic enough to remain applicable in the near future without expecting to become obsolete after the planed update process that existing standard had already scheduled.

Stakeholder Coordination

The multiple research studies performed identified the need for establishing a coordinated overall approach for semantic interoperability that ensures stakeholder participation as part of the governance process. The obtained results recommended scaling up the development process through the coordination of initiatives further than local and regional projects in order to ensure the definition of high quality interoperability resources. The large number of stakeholders involved requires common definition of concepts, supportive tools and educational resources specially designed for each target group. This thesis contributed towards the common understanding of the processes associated with clinical information modelling and requirements that tools associated with this processes should incorporate in the near future. The implemented IA register aims not only to support the implementation of EHR based on resources for IT developers. In addition it promotes the adoption of EHR interoperability containing resources specifically designed for decision makers, clinicians and other stakeholders.

Obtaining wider participation of clinicians as part of the CIMP remains as a challenge. Improved supportive tools and educational material could help to overcome barriers associated with the lack of understanding associated with this process but they need to be complemented with endorsement by relevant medical bodies. Currently, most of the professional medical bodies are not involved in task related with definition or validation of interoperability resources. A change in of paradigm will be required to involve these medical bodies as part of the CIMP, to ensure that

interoperability resources are able to satisfy the documentation needs, identified by the majority clinicians working in each specific domain. The existing experience on applying collaborative online tools for clinical information modelling associated with the establishment of clinical information modelling governance suggests that the structure of committees applied in medical bodies for obtaining consensus in clinical practice in the form of clinical guidelines could be useful for establishing a governance for CIMs.

European level

As was explained in section 1.2.4 European and international policies, the European Commission has defined an EIF that represents a first step towards the harmonisation of EHR communications in Europe. To reduce the uncertainty and complexity of choosing between multiple overlapping EHR specifications for eHealth interoperability projects, the EIF identified how a set of recommended standards can be applied to satisfy the needs for transferring patient data in some of the most relevant use cases for healthcare and telehealth. As a result, the EIF is expected to promote the adoption of Digital Single Market for eHealth in Europe. Nevertheless, technology, medical knowledge and patient needs are in continuous evolution requiring objective measures to determine what could be the best technological solution to address future clinical scenarios.

The defined SIQF might be applied as an instrument for evaluating new interoperability resources and specifications that will be generated in the coming years to evaluate their suitability for being incorporated as part of the EIF. Moreover, the IA registry will allow applying the identified requirements in real practice with direct interactions with representatives of healthcare providers, IT vendors and SDOs that are expected to enrich the proposed quality model by further refining the proposed metrics based on the adoption of multiple interoperability assets.

This register has the potential to contribute towards a changing the culture of traditional development of system through the coordination of the community of stakeholders interested in eHealth interoperability. Additional use cases for cross-border transference of healthcare information will be defined based on the international collaborations of multiple members of the eHealth community. Associated with this harmonisation of the adoption of EHR specifications in Europe it is expected that multiple IT developers will be able to reduce the costs associated with clinical information modelling based on the adoption or adaptation of interoperability resources developed by the multiple institutions working in the eHealth interoperability domain. This is especially relevant in the case of SMEs that will be able to reduce the barriers associated with access to eHealth market based on the adoption EHR interoperability standards adapted to their specific domain and endorsed by regulators or healthcare providers.

Healthcare impact

The expected improvements in EHR semantic interoperability will facilitate the continuity of care across healthcare settings and institutions increasing patient safety. Moreover, a reduction of the number of silos will enrich the capabilities for analysing clinical data promoting the evidence based medicine through clinical research and public health studies.

6.3 Conclusions from individual research studies

6.3.1 Analysis of literature

The use of CIMs has gained recognition as one of the essential aspects for the creation of standardised and interoperable EHR systems. Different standards and technical approaches exist (e.g. EN ISO 13606 and openEHR using archetypes, or HL7 v3 using templates), but the idea of separating the definition of the CIMs from the actual representation and persistence of the data values is shared among all of them. Moreover, the work of international modelling initiatives such as CIMI indicates an increased interest in creating reusable CIMs. Thus, it is important that the CIMP used to create those models follows clear and well defined steps.

This research characterized published experiences related to the creation of semantically interoperable EHR systems between 2000 and 2013, in order to obtain a better understanding about the steps followed by all of them during the creation of CIMs. It was found that most of the experiences share a similar approach, with many common steps during the creation of the CIMs. This suggests that it should be possible to create a common or unified methodology for clinical information modelling in the future. This conclusion is however limited due to the lack of detail describing the used CIMP in the selected papers. It is important to advocate further collaboration between the main organizations and professionals involved in CIM development, to reach a consensus in the definition of a unified best practice CIMP.

A commonly agreed CIMP will promote and emphasize the importance of analysing the information covered in a particular domain, the collaboration between different clinical and technical professionals and the search for consensus in the definition of CIMs. It will also minimize the diversity of ways in which a CIM can be designed and will make terminology bindings more consistent. All of this will be directly related to the improvement of the quality of CIMs.

6.3.2 International survey

This research has provided an overall description of the CIMP based on the experiences obtained with the definition and implementation of EHR systems in 13 countries. According to the collected answers, CIMP has been described as a process that includes multiple stages and multiple actors, which are coordinated to provide an inclusive collection of requirements and data items from multiple sites and domains. The research has identified a set of consistent barriers that previously were not reported in the literature such as personal dependences and emotional attachment, as well as recommended mechanisms to overcome them, making it possible to obtain an inclusive CIMP where participants have a clear understanding of their roles and duties.

Results show how a lack of understanding and multiple perceptions of the modelling process were identified as the most relevant barriers for clinical information modelling and several mechanisms were proposed to overcome it. As a result, it is recommended to increase efforts to define a common methodology for CIMP complemented with educational materials and programmes to overcome this problem. In addition, it is recommended that clinical information modelling tools provide new functionalities to better support CIMP with an easy collaboration between clinicians, modellers and IT professionals preserving the consistent definition of semantic structures for EHR systems.

Based on the experience from large scale infrastructures for clinical knowledge definition, the need is highlighted for monitoring and guiding projects that have a local scope. Collected results were analysed according to the previously performed literature review and compared with the proposed quality metrics for CIMs in order to validate our recommendations and clearly identify the new knowledge provided to this field.

6.3.3 Functional Requirements for Clinical Information Modelling Tools

This research helps to provide a better understanding about the basic and advanced functionalities that should be covered by CIMT, independently of the capabilities of existing tools. The results successfully identified a set of relevant and implementable requirements for CIMT. Based on a Delphi study methodology, requirements were classified and prioritized according to the opinion provided by a representative sample of experts in health informatics and clinical information modelling. It is expected that this list of requirements will guide developers on the implementation of new basic and advanced functionalities that have strong support from users. They could also guide regulators in order to identify requirements that could be demanded in tools adopted within their institution. Given that some functionalities were proposed based on the identification of barriers to the clinical information modelling process, some of these new functionalities will promote advances the adoption of good quality CIMP.

Over the following months, this work will continue with the definition of a self-assessment evaluation questionnaire and a test plan for CIMT that will be used to measure the functionalities already covered in existing tools.

6.3.4 Evaluation of Clinical Information Modelling Tools

This research defined the first evaluation framework for CIMTs. This framework was successfully tested and validated against a representative sample of existing tools. Based on the obtained results, it is expected that our defined framework will be applied by decision makers such as healthcare providers and IT developers for identifying CIMT performance against our previously published set of essential requirements. The defined conformance criteria have been demonstrated to be implementable and generic enough to be independent from specific EHR interoperability specifications.

The evaluation of existing CIMTs shows high level of adoption of those requirements related to the EHR specifications, data types, terminology binding and CIM metadata. Improvement is most needed in the support of the information modelling and software development processes. The most urgent improvements should be in those areas related to governance, clinician involvement and optimization of technical validation of testing processes.

Results show that CIMT have a lack of adoption of functional requirements for communicating of terminology servers and displaying semantic relationships between clinical concepts, especially for those metrics related with communication for management of terminologies and search and query terminologies. Therefore, it could be inferred that these tools should be improved in order to obtain an integrated management of terminologies and increase the usability and validation capabilities.

This research has demonstrated the applicability of this assessment framework for supporting decision makers in the selection of the most appropriate CIMT for their organization.

6.3.5 Interoperability Asset Quality Framework

This research was able to define and test the first quality in use assessment framework for interoperability assets. The defined framework is focused on providing the means to end users to identify interoperabilty assets able to be reused by their projects and organisations. Moreover, this framework is expected to guide those organisations and users who develop their own assets to comply with the recommended methodologies by providing them feedback about the quality obtained in the defined framework. The results obtained show adequate acceptance and support through an evaluation by 20 experts. The proposed quality framework was considered clear enough by participants, with small modifications that were then incorporated. Multiple domains of the framework were prioritised with a global good acceptance for 7 of the 8

domains proposed. The proposed graphical representation was declared useful for technical & semantic interoperability assets.

The overall evaluation of the proposed quality in use model had adequate support from participants and a minimal level of disagreement that is not perceived as a risk of failure for the proposed metrics. A broad sample of users declared that this proposal could be useful for discovering assets and would recommend it to their colleagues. Moreover, more than half of the users declared that this proposed framework could be useful for making decisions about recommended asset to adopt in their organisation or project. It is recognised that there is not yet the empirical evidence that this new methodology for quality assessment will be considered useful by the eHealth community. It is recommended to monitor how the final implemented interoperabiltiy asset register is adopted by potential asset users.

6.3.6 European Register of interoperability assets

The IA register has been defined according to the functional requirements for establishing the point of reference for searching interoperability assets produced by multiple organisations interested on eHealth interoperability. The register has been designed as an instrument that aims to support decision making about the technical specifications chosen for interoperable solution through the classification of semantic interoperability resources based on the quality in use model described in section 4.6.3.5.7. The consistent classification combined with establishment of semantic relationships of the interoperabilty resources produced by the most relevant European projects and eHealth interoperabilty initiatives is expected to contribute towards the gradual harmonization of interoperable solutions in our continent. Although it is still not proven the adoption of the eHealth community some of the most relevant EU projects expressed their interest in using the register and additional promotion will be carried out by the i~HD in the near future.

6.3.7 Comparison with ISO 18864 standard

According to the comparison performed in section 4.7 between the defined quality in use model and development process quality model with the ISO 18864 standard, it was detected clear alignment between them. It was identified that ISO 18864 standard covers only partially the identified requirements for CIMP and additional metrics, identified as part of this research, were suggested to be incorporated during the development process of this standard.

6.3.8 Comparison with ISO 13972 standard

The comparison of the identified process in section 4.3.3.5 and ISO13972 standard presented in section 4.8 shows it is possible to define an implement a Quality Management System for the CIMP and include metrics that ensure best practice in clinical information modelling avoiding the most relevant barriers associated with these processes.

6.4 Scientific contribution from this research

This research contributed to the scientific community with three published articles and another research manuscript is under peer review process. In addition, two oral communications were presented in health informatics conferences and a research project proposal related with the development of a clinical information modelling tool. Next are provided the details of the performed scientific dissemination based on this research. In addition, a R&D project coordinated by the author of this thesis has been recently funded. This project aims to develop a new tool focused on the adoption of best practices identified in this research about clinical information modelling process:

Published articles

- Moreno-Conde, A., T. Austin, J. Moreno-Conde, C. L. Parra-Calderón and D. Kalra (2016). "Evaluation of clinical information modeling tools." Journal of the American Medical Informatics Association: ocw018.
- Moreno-Conde, A., F. Jodar-Sanchez and D. Kalra (2015). "Requirements for clinical information modelling tools." Int J Med Inform 84(7): 524-536.
- Moreno-Conde, A., D. Moner, W. D. d. Cruz, M. R. Santos, J. A. Maldonado, M. Robles and D. Kalra (2015). "Clinical information modeling processes for semantic interoperability of electronic health records: systematic review and inductive analysis." Journal of the American Medical Informatics Association 22(4): 925-934.

Conference communication

- Alberto Moreno-Conde, Thienpont G, Lamote I, Coorevits P, Parra C. and Kalra D. European Interoperability Assets Register and quality framework implementation. Medical Informatics Europe Conference. 28 August – 2 September 2016
- Moreno Conde A. Estado en el desarrollo de las normas: Registro de Recursos de Interoperabilidad y normas de calidad. VI Reunión del Foro de Interoperabilidad en Salud Valladolid 2016

Manuscript under peer review process

- Moreno-Conde A, Corevits P, Parra-Calderón C, et al. International survey of development practice for EHR clinical information models. 2015

R&D project

- HEMIC: Tool for Clinical Information Modelling. Andalusian Ministry of Health R&D Call

6.5 Future Work

This research has defined and implemented a SIQF that will be applied for multiple interoperability resources but, as well, it is required new challenges still require to be addressed to continue working towards increasing the quality of these resources.

- Study how to better characterise generic, legal and organisational assets.
- Collaborate with the ISO TC 215 in the definition of the final version of the ISO 18864 standard Quality Metrics of Detailed Clinical Models
- Collaborate with CEN TC 251 in the next review round of the ISO 13972 standard Detailed Clinical Models, characteristics and processes, International Standardization Organization.(ISO/DTS 13972 2014, ISO/DTS 13972 2015).
- Based on the thesis results a R&D project coordinated by the author has been recently funded with the aim of developing and validating a software tool for standardising information contained within EHR systems. This tool will be oriented towards supporting the participation of healthcare professionals in the CIMP and establishing of mechanisms for information governance.
- In collaboration with the i-HD institute it is expected to promote the adoption of the Quality framework for interoperability resources through the IA register and monitoring the uptake of the defined quality framework in order to identify how to better support the user needs. Through the author's participation as part of the editorial board of the i-HD institute it would be possible to determine which were the interoperability assets with greater level of acceptance and the end user perceived usefulness of the multiple descriptors included in the proposed Interoperability Asset Quality Framework. Additional collaboration is expected with existing health informatics initiatives in order to allow the federation of multiple repositories. i-HD plans multiple interactions with existing European projects to collect a representative sample of interoperability assets that would be attractive for the eHealth community.

6.6 Summary of the conclusion chapter

This chapter started explaining the general conclusions of this thesis with regard to the multiple EHR specifications, stakeholder coordination, European perspective and healthcare impact. They were complemented with the conclusions derived from each individual research studies carried out to define the SIQF. In addition, it was presented the future areas of research that could be derived from this work.

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Chapter 8. Appendix

Appendix A: Analysis of the published literature

This document provides the complementary material related with the analysis of the published literature research study in order to detail the searches and process performed as part of the systematic review. This Appendix includes the defined template for collecting descriptors from the reviewed papers (section A.1) and the set of papers identified in the search phase and qualitative synthesis phase of the review process *Section A.2 and A.3*.

A.1. Template for collecting data items and indicators from selected papers

Paper number:	
After reading, is the paper still suitable to be included in our study?	
Which is the domain covered by the clinical information models (CIM)?	
Which kind of CIM do the authors use? Archetypes, templates, XML Schema, relational database schema, ontologies…	
Is a standard reference model used? 13606, openEHR, HL7 CDA, HL7 RIM, CCR…	
Are terminologies used?	
Have health professionals been asked or have participated during the development of the CIMs?	
Do the authors use a methodology for the development of CIMs?	
If yes, is the methodology described in detail?	
Do the authors use specific tooling for the development of CIMs?	
Do the authors reuse existing CIMs?	
Are the resulting CIMs shared publicly?	
Are the resulting CIMs used/implemented in a real system or environment?	
Is there any validation step as part of the CIMP?	
Other comments:	

Table 66. Template for collecting indicators from papers selected as part of the literature review

A.2. List of paper obtained after the search phase

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NOTE: Papers from number 33 to 36 were manually added after the search.

Appendix B. International Survey of Modelling Initiatives

B.1. Introduction

This appendix provides complementary information related with the research study about the international survey of clinical information modelling initiatives.

Section B.2 details the questionnaire applied for conducting the interviews. This questionnaire was sent before the interview to those candidates to be included in the study in order to allow them prepare the interview.

Section B.3 details a summary of the tags and categories extracted from interviews that are related with each questions.

Section B.4 outlines the correlation of areas covered in the interview with the identified phases of the clinical information modelling process.

B.2. Semi-Structured Interview Questionnaire

Presentation

I want to thank you for taking the time to meet with me today. My name is Alberto Moreno and I would like to talk about your experiences in the definition of functional requirements on Electronic Health Record systems, including the clinical models and data sets used within them. This information will be applied for research purposes as part of my thesis about clinical information modelling at University College London.

The interview should take less than an hour. Please be sure to speak up and clear because this session will be recorded to ensure that we don't miss any of your comments.

This material will be kept confidential and your interview responses will only be shared with research team members. Also, we will ensure that any information we include in our report does not identify you as the respondent. Remember, you don't have to talk about anything you don't want to and you may end the interview at any time.

Are there any questions about what I have just explained?

Interviewee Personal Details

a) For how long where you involved in the definition of functional requirements for EHR systems? (This includes developing data sets and clinical models that are used within or between EHR systems)

b) Please could you summarise the EHR systems or clinical modelling design projects you have been involved in, their scale, and what you played in those projects.

Questionnaire

1. How was the organisation of the people involved in the definition of EHR functional requirements? Please describe number of people involved and their roles and prioritization mechanisms.
2. How well did the final system or systems fulfil the requirements/models you were involved in developing? What was the perception of end users and other people involved in the functional requirements definition?
3. What where the main barriers to finally agreeing the requirements and definitions (e.g. common areas of disagreement, lack of understanding and detail)?
4. Please describe the modelling process from collecting sources of information, pilot and validation or prototype. How do you think a clinical modelling (design) process could be improved? What mechanisms could be established to ensure quality of the designed clinical models and data?
5. How can we model the clinical information to best prevent medical errors? Please provide examples of strategies for minimising incompleteness, fuzzy and wrong data that you adopted, or can now think of.
6. How do you recommend using free text entries? What are the kinds of clinical information for which you feel this should be preferred over structured data?
7. What functionalities of Graphical User Interface are relevant for presenting the quality or safety of the information, and should be shared across different systems? (e.g. change colour if data out of range)
8. How does the system that you use now become updated to reflect changes in medical knowledge or user requirements? How do you think that we could support a better knowledge evolution on a large scale (e.g. at country level)?
9. What mechanisms do you have implemented for the management of terminologies? Please also detail the terminologies applied in your system and the approximate percentage of coded entries. Are there any particular challenges that you faced when working out which terms are relevant to your developed clinical models and data sets?
10. How can we define the information to be used in a specific domain and shared within the same specialty in other locations?

11. What strategies do you know for maximising the reuse of information across multiple domains (for example to share information meaningfully between professional groups, specialities, care settings or even countries)? Which of them do you prefer?
12. What will be the areas that you would recommend to prioritize in order to be defined by international experts? (e.g. Patient summary, prescription, international scales) Why?
13. Which other actors (non-clinical) should be involved in the process of developing clinical models? Epidemiologist, public health experts, patient associations, professional bodies, system vendors, health authorities?
14. How can we establish mechanisms for summarising the information (e.g. chronic patients over time) to support monitoring trends, tracking a care pathway and highlighting checks that are due?
15. How does your organization ensure that their system is aligned with latest clinical evidence? How do think that this process could be improved?
16. Is there any decision support functionalities implemented in your systems? How well are they integrated with the EHR?
17. How do you define clinical workflows and paths to be supported by the system? What strategy do you recommend for avoiding including excessive restrictions on the clinical workflow, to allow for individual patient needs?

Is there anything more you would like to add?

B.3. Tags classifications in inductive content analysis

This section details the main categories identified and the detailed set of tags and categories generated in the Nvivo software as part of the inductive content analysis.

A. Organization of the people involved in requirements definition can be classified in the following groups	
- Leading clinical information modelling team - Core team of domain experts	- Validation team - Technical team - Prioritising committee
B. Recommendations to Fulfil the requirements by the definitive systems	
- Apply continuous improvement cycles & iterations	- Apply methods for evaluation success based on questionnaires and screen feedback buttons
C. Barriers to reach consensus on the definition of the EHR functional requirements	
- Changes in requirement definitions - Different perspectives for clinical information modelling in multiple participants - Commercial, economic and administrative issues are commonly found and should be identified - Organizational issues includes personal dependences and missing relevant stakeholder groups	- Scope definition issues - Lack of proper tooling because modelling tools are not well understood by clinicians - Lack of understanding of modelling and system requirements by non-technical users - Lack of clinical consensus before requirement definition
D. Steps of the Clinical Information Modelling Process	
- The process is recommended to apply agile deployment plus continuous improvement cycles in combination with feedback & iterations - Prioritisation & Scope definition - Collecting sources of information	- Collecting requirements from health and IT professionals - Defining Prototype - Defining implementable clinical information models - Validation stage with domain experts not involved in definition - Implementation stage - Governance and maintenance
E. Recommendations for improving the Clinical Information Modelling Process	
- Improve tools to facilitate clinician participation - Define formal clinical information modelling process - Provide additional resources to cope with iterative cycles	- Professional body participation - Improve semantic definitions and applications of standards
F. Recommended mechanisms to ensure quality of the clinical information models	
- Improve tools with syntactical and semantic validation capabilities - Increase the clinician's perception of usefulness of information	- Quality principles for each step of clinical information modelling methodology - Check EHR functional requirements and related standards
G. Recommendations for preventing Medical Errors	
- Analyse how data is collected - Ensure that usability & Graphical User Interface has been well designed	- Education for participants on requirement definition processes - Strong work on requirement definition
H. Recommendations using Free Text and structured data	
- Balance between free text and structured data	- Consider to incorporate supportive NLP functionalities in EHR systems

I. Terminologies	
- Terminology servers and tools for terminology management were commonly applied - Experts requested additional guidance when terminologies have overlapping scope	- Clinician and terminology experts involvement is recommended - Determine sensible length of value list - Mapping to international terminologies
J. Recommendation for sharing information with other locations and domains	
- Common reference able to be specialized for local context - Convince clinicians for generic wording - It is expected a gradual harmonization	- Involve clinicians from other locations - Focus on increase quality of care rather than reuse clinical information models
K. Recommendations for Knowledge evolution at larger scale	
- clinical engagement and acceptance are the most important factors - Collaborative tools are beneficial - Clinicians education about knowledge definition 1.	- Organizational structures for cooperating between national projects and maintaining and updating models - Monitor local eHealth projects - Required economical resources

Table 67. Main categories identified as part of the inductive content analysis

B.4. Correlation of areas covered in the interview with the identified phases of the clinical information modelling process

ID	Subject headings of the interview questionnaire	Priorisation & Scope	Collecting sources	Collecting requirements	Defining Prototype screens	Defining clinical information models	Validation	Implementation	Governance & maintenance
	Main areas								
A	Organization of people involved in requirements definition								
	This area covers the organisation of health managers, teams of domain experts and IT professionals coordinated by the leading team.	X	X	X	X	X	X	X	X
B	Fulfilling of the requirements by the definitive systems								
	Requirements as an iterative process that can improve their definition according to the feedback from the different stages of the CIMP. In addition, the implemented system will be able to collect additional requirements through the governance and maintenance step			X					X
C	Barriers to reach consensus on the definition of the EHR functional requirements								
	Barriers to reach consensus on the definition of the EHR functional requirements were mainly detected for defining steps, collecting requirements, defining CIMs and setting governance stage	X		X		X			X
D	Current clinical information modelling process								
	CIMP was defined from the reported modelling steps identified in the analysed initiatives	X	X	X	X	X	X	X	X
E	Improving the clinical information modelling process								
	Suggested improvements addressed the full CIMP with special focus on requirements definition, definition of CIMs and governance			X		X			X
F	Mechanisms to ensure quality of clinical information models								
	Proposed mechanisms addressed all stages of the CIMP with special focus on requirements definition, definition of CIMs and governance			X		X	X		
G	Preventing medical errors								

	Recommendations addressed setting governance to analyse how data is collected and strong work on requirement definition and usability			X	X				X
H	Using free text and structured data								
	The collected answers were focused on how to define the structure of information as a source for the requirements that will be included in prototype screens and clinical information models			X	X	X			
I	Knowledge evolution at a larger scale								
	This area is focused in how to harmonise governance between multiple projects within the same region and reuse previous project results to guide requirements and clinical information model definition			X		X			X
J	Terminologies								
	Terminologies are identified as sources to define clinical information models that could be applied as requirements in the definition of prototype screens and clinical information models		X	X	X	X			
K	Sharing information with other locations and domains								
	Sharing information between centres and domains set requirements that will affect the definition of clinical information models			X		X			
	Complementary areas								
L	Graphical User Interface functionalities able to be shared between systems								
	This area explored the possibility of including additional requirements for clinical information model specifications that might impact on requirement definition, CIM definition and implementation stage			X		X		X	
M	Updating EHR systems								
	The updating process of EHR systems is aligned with the definition of governance for collecting feedback for new requirements			X					X
N	Non-clinical actors								
	This area is focused on team composition according to those users that			X	X	X	X		X

	make secondary use of the EHR data								
O	Areas for prioritization								
	This area is focused on determining priorities for modelling relevant clinical information at large scale in order to be reused as sources of information in the modelling process	X	X						
P	Summarizing information over time								
	Requirements related with the long term management of information also affect how CIMs are defined			X		X			
Q	Alignment with latest clinical evidence								
	Alignment with latest clinical evidence impact on requirement definition and governance			X					X
R	Clinical Decision support								
	This area covered the impact on requirement definition and implementation stages for those systems that include decision support functionalities			X				X	
S	Clinical workflows								
	This area covered the impact on requirement definition and implementation stages for those systems that include functionalities based on modelling clinical processes			X				X	

Table 68. Correlation between interview questions with the clinical information modelling process

Appendix C: CIMT Requirements

C.1. Introduction

This appendix provides complementary information related with the research for defining requirements for Clinical Information Modelling Tools.

Section C.2. provides links to the questionnaires applied in first and second round of the Delphi study about CIMT requirements

Section C.3. provides the results for each of the questions contained in the first and second survey.

C.2. Questionnaires

- ✓ **First Round questionnaire:**

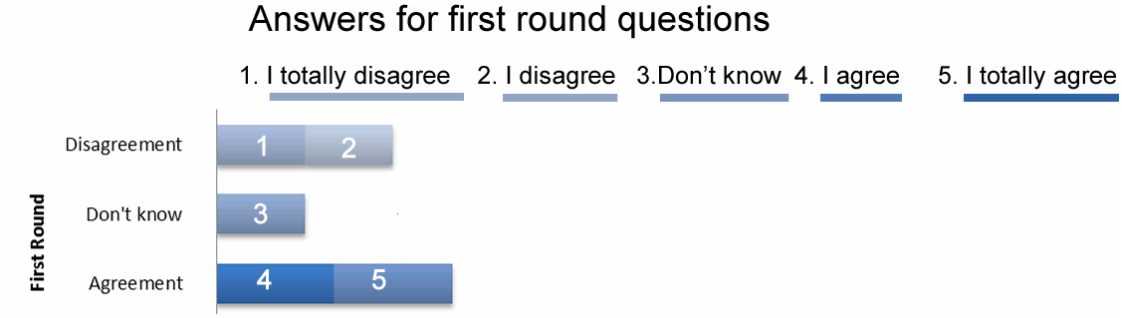
  https://docs.google.com/forms/d/1mr7PXUC9T3JOlq47QHRunOlBAnmmFDYupydBDPOmB4c/viewform

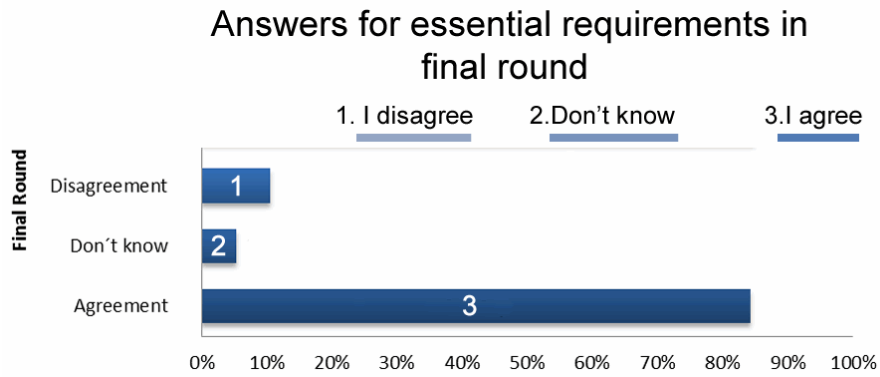
- ✓ **Second round questionnaire:**

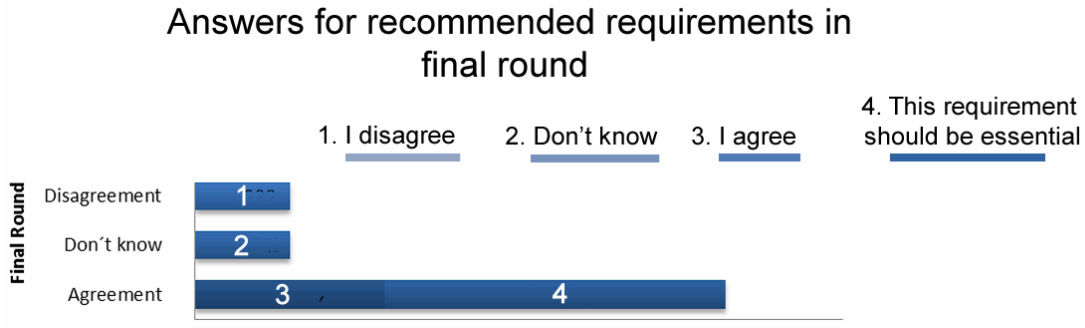
  http://www.digitalicahealth.com/survey/index.php/955744/lang-en

C3. Statistics results

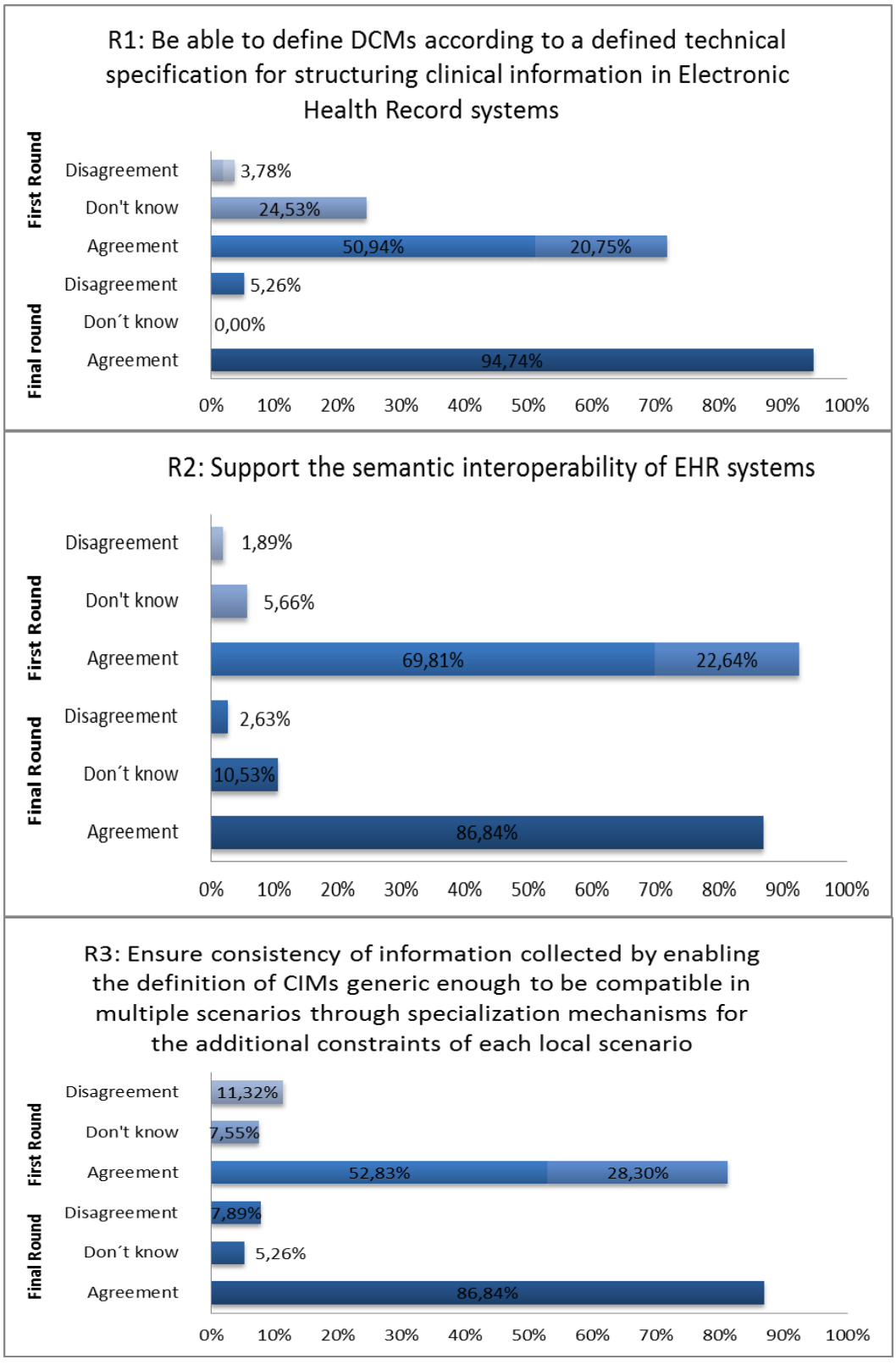
Next it is explained how the results are displayed for each kind of question according to the Delphi study performed about CIMT.

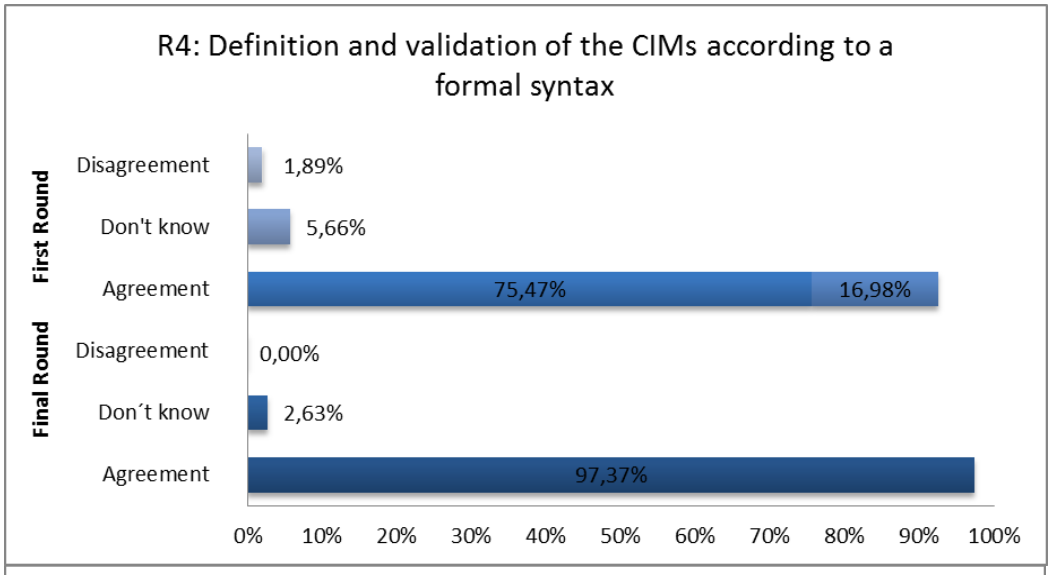

Answers for first round questions
1. I totally disagree
2. I disagree
3.Don't know
4. I agree
5. I totally agree
First Round
Disagreement
Don't know
Agreement
1
2
3
4
5

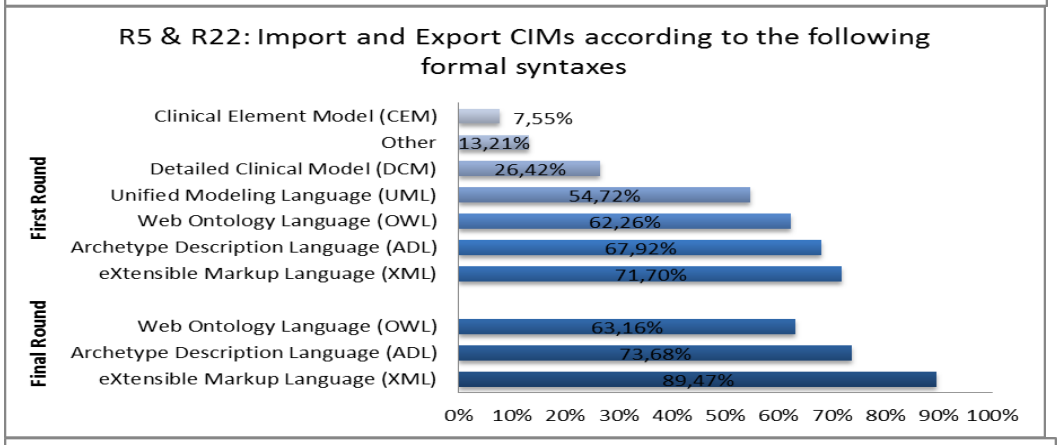

Answers for essential requirements in final round
1. I disagree
2.Don't know
3.I agree
Final Round
Disagreement
Don´t know
Agreement
1
2
3
0%
10%
20%
30%
40%
50%
60%
70%
80%
90%
100%

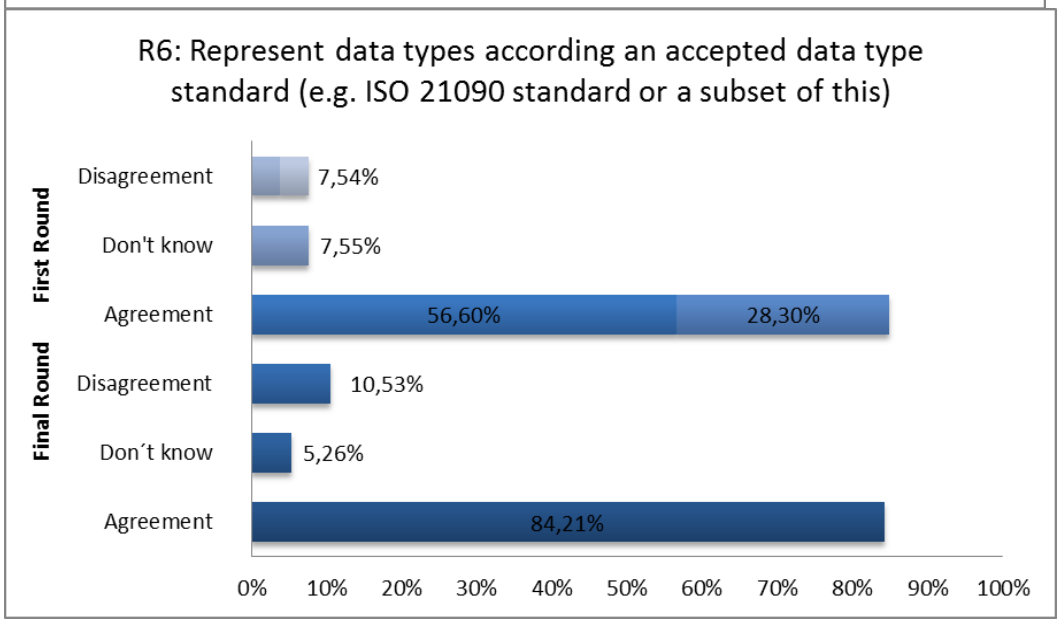

Answers for recommended requirements in final round
1. I disagree
2. Don't know
3. I agree
4. This requirement should be essential
Final Round
Disagreement
Don´t know
Agreement
1
2
3
4

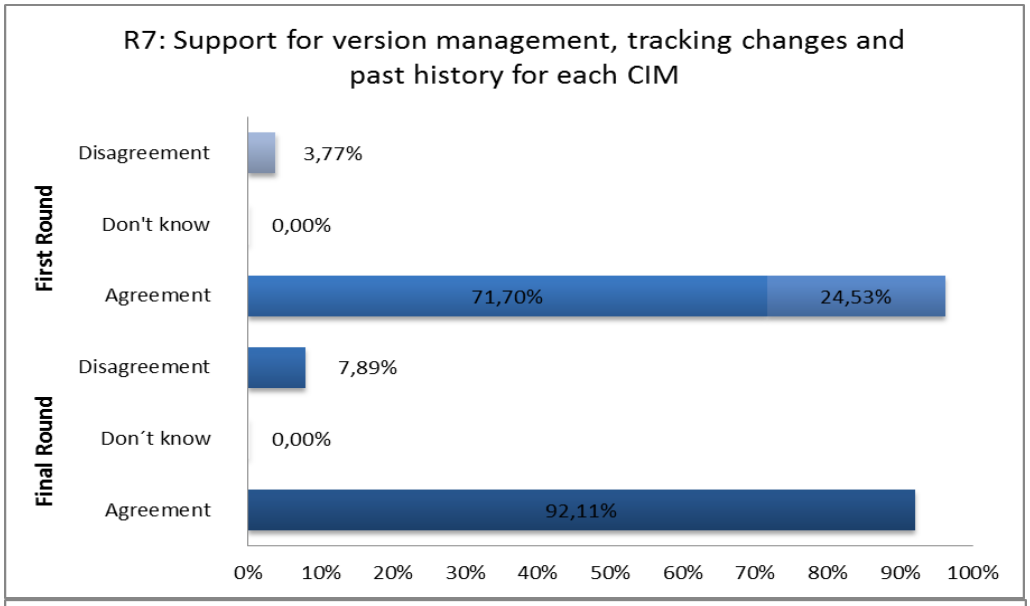
C.3.1 Essential requirements results

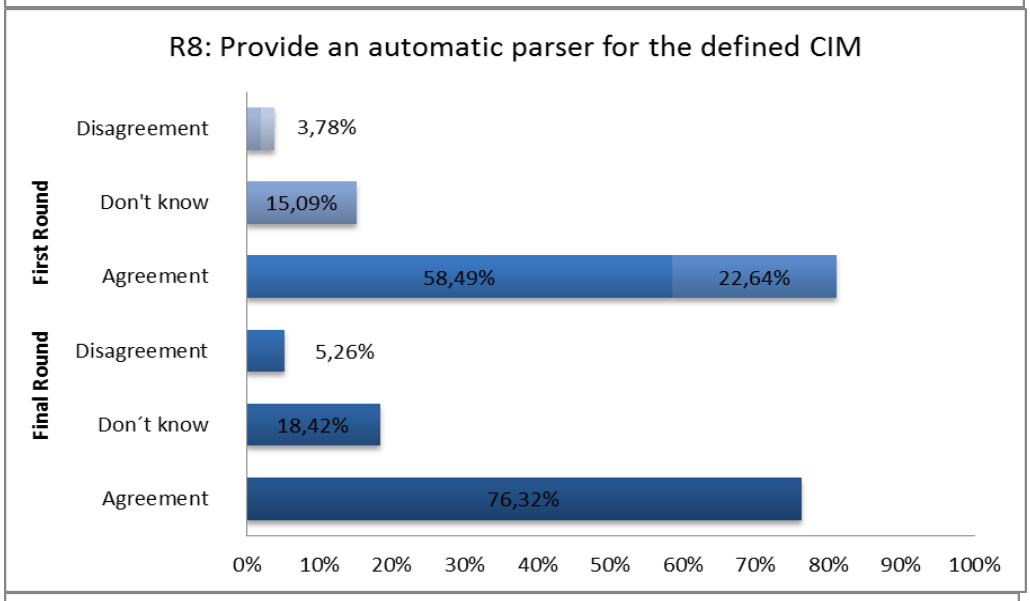


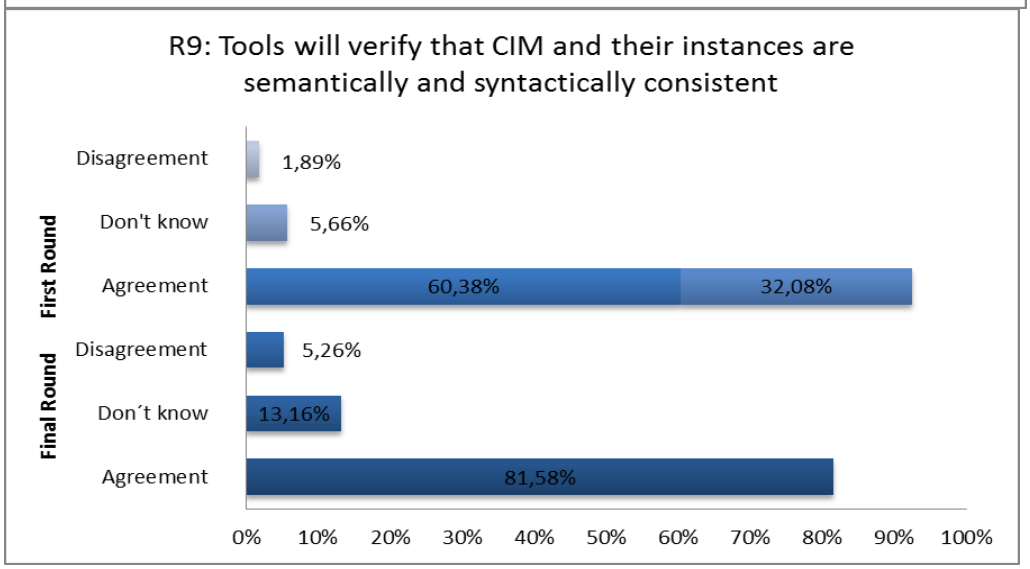

R4: Definition and validation of the CIMs according to a formal syntax
First Round
Final Round
Disagreement
Don't know
Agreement
Disagreement
Don´t know
Agreement
1,89%
5,66%
75,47%
16,98%
0,00%
2,63%
97,37%
0%
10%
20%
30%
40%
50%
60%
70%
80%
90%
100%

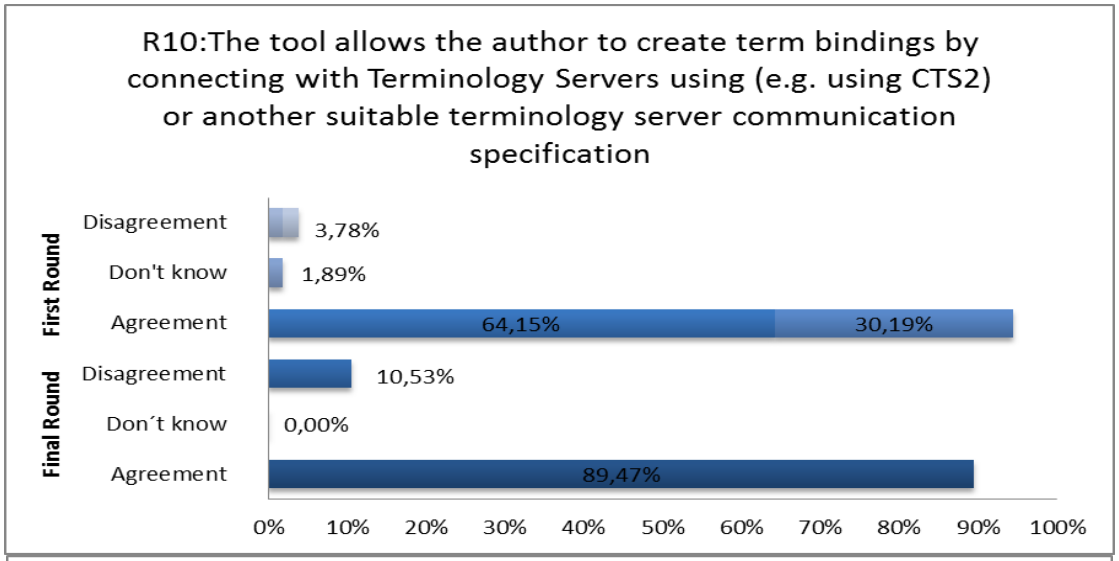

R5 & R22: Import and Export CIMs according to the following formal syntaxes
First Round
Final Round
Clinical Element Model (CEM)
Other
Detailed Clinical Model (DCM)
Unified Modeling Language (UML)
Web Ontology Language (OWL)
Archetype Description Language (ADL)
eXtensible Markup Language (XML)
Web Ontology Language (OWL)
Archetype Description Language (ADL)
eXtensible Markup Language (XML)
7,55%
13,21%
26,42%
54,72%
62,26%
67,92%
71,70%
63,16%
73,68%
89,47%
0%
10%
20%
30%
40%
50%
60%
70%
80%
90%
100%

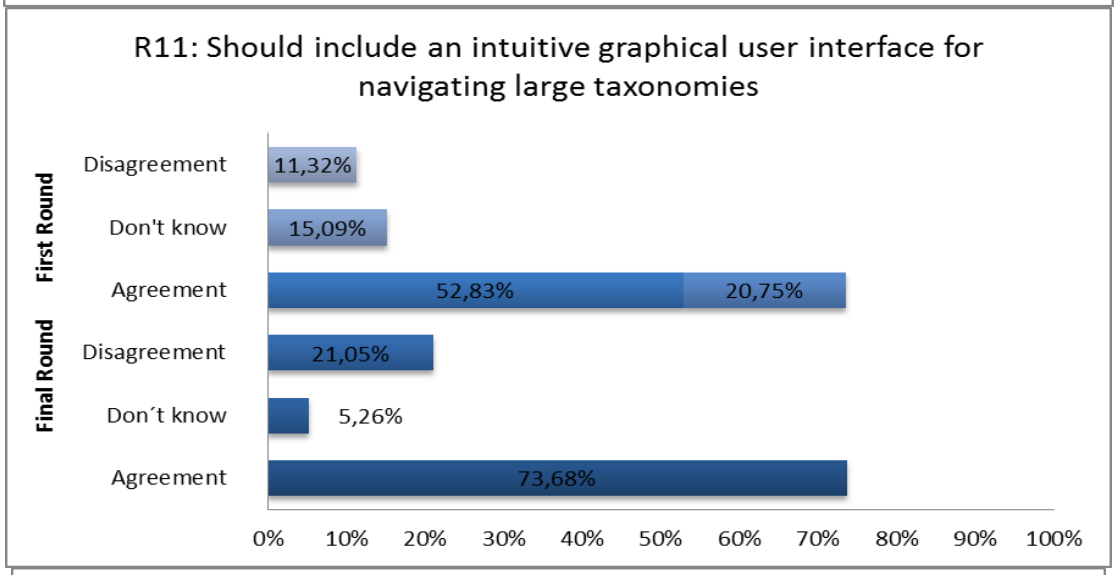

R6: Represent data types according an accepted data type standard (e.g. ISO 21090 standard or a subset of this)
First Round
Final Round
Disagreement
Don't know
Agreement
Disagreement
Don´t know
Agreement
7,54%
7,55%
56,60%
28,30%
10,53%
5,26%
84,21%
0%
10%
20%
30%
40%
50%
60%
70%
80%
90%
100%

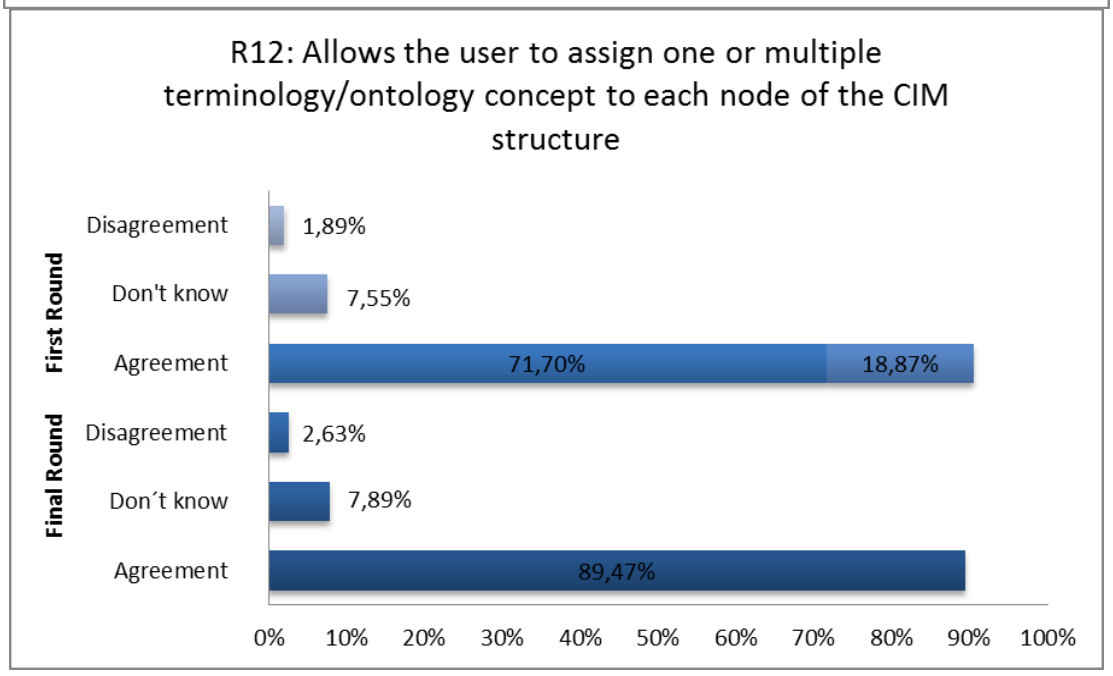

R7: Support for version management, tracking changes and past history for each CIM
First Round
Disagreement
3,77%
Don't know
0,00%
Agreement
71,70%
24,53%
Final Round
Disagreement
7,89%
Don´t know
0,00%
Agreement
92,11%
0%
10%
20%
30%
40%
50%
60%
70%
80%
90%
100%

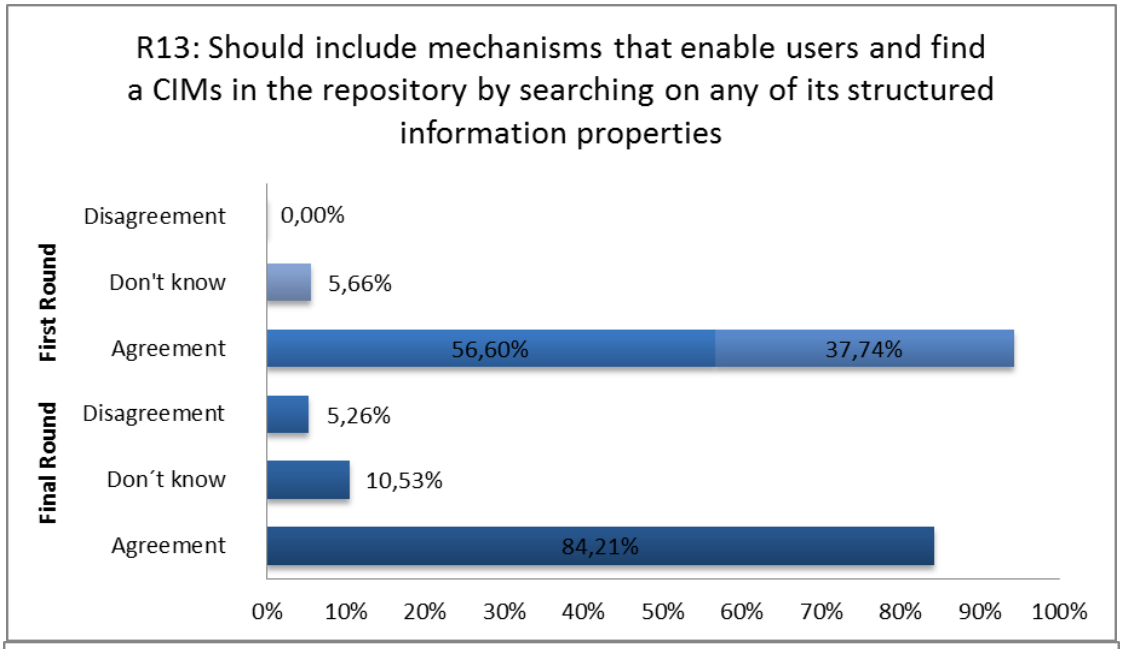

R8: Provide an automatic parser for the defined CIM
First Round
Disagreement
3,78%
Don't know
15,09%
Agreement
58,49%
22,64%
Final Round
Disagreement
5,26%
Don´t know
18,42%
Agreement
76,32%
0%
10%
20%
30%
40%
50%
60%
70%
80%
90%
100%

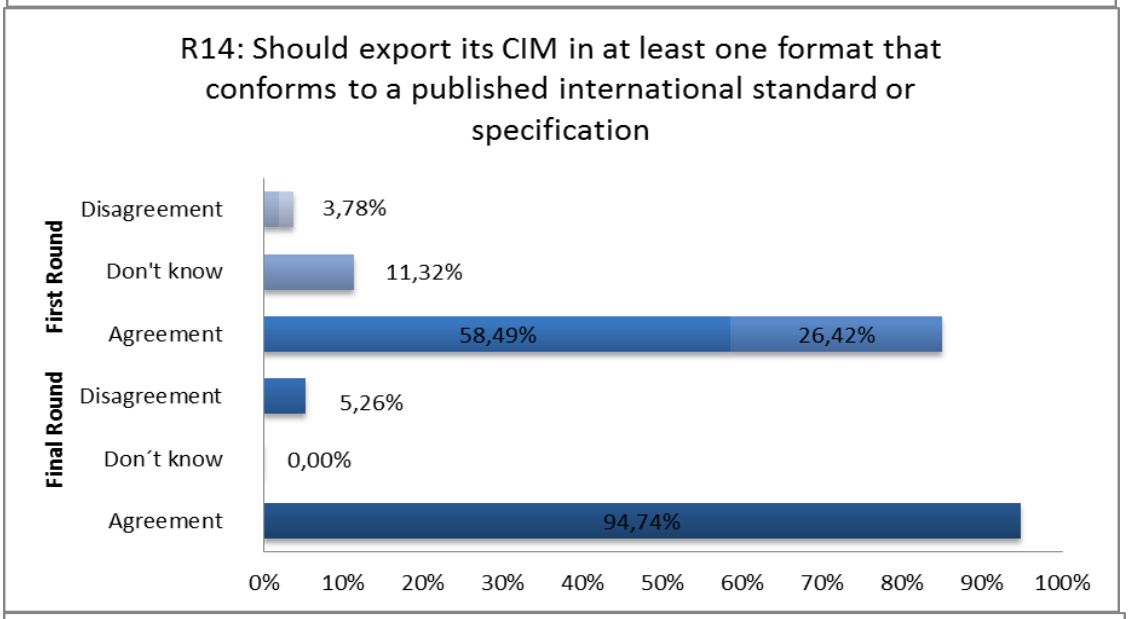

R9: Tools will verify that CIM and their instances are semantically and syntactically consistent
First Round
Disagreement
1,89%
Don't know
5,66%
Agreement
60,38%
32,08%
Final Round
Disagreement
5,26%
Don´t know
13,16%
Agreement
81,58%
0%
10%
20%
30%
40%
50%
60%
70%
80%
90%
100%

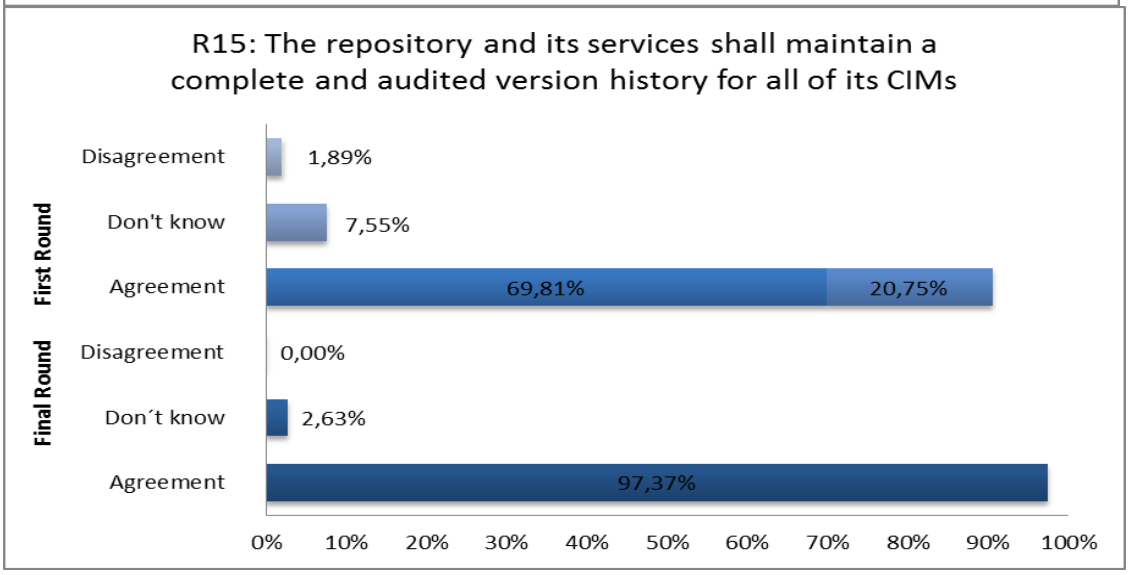

R10:The tool allows the author to create term bindings by connecting with Terminology Servers using (e.g. using CTS2) or another suitable terminology server communication specification
First Round
Disagreement
3,78%
Don't know
1,89%
Agreement
64,15%
30,19%
Final Round
Disagreement
10,53%
Don´t know
0,00%
Agreement
89,47%
0%
10%
20%
30%
40%
50%
60%
70%
80%
90%
100%

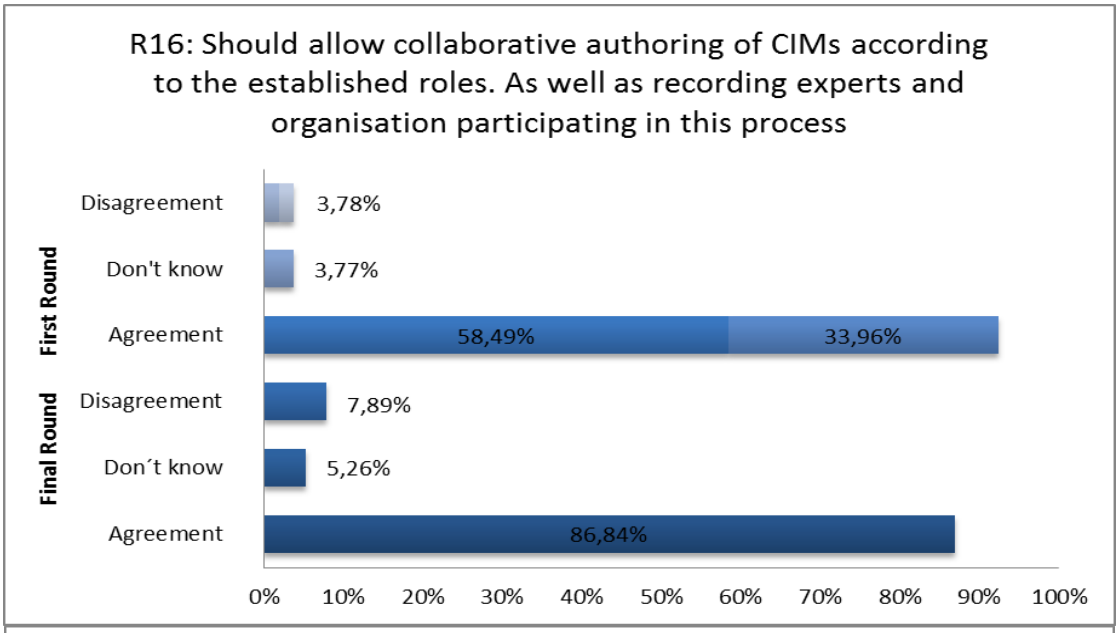

R11: Should include an intuitive graphical user interface for navigating large taxonomies
First Round
Disagreement
11,32%
Don't know
15,09%
Agreement
52,83%
20,75%
Final Round
Disagreement
21,05%
Don´t know
5,26%
Agreement
73,68%
0%
10%
20%
30%
40%
50%
60%
70%
80%
90%
100%

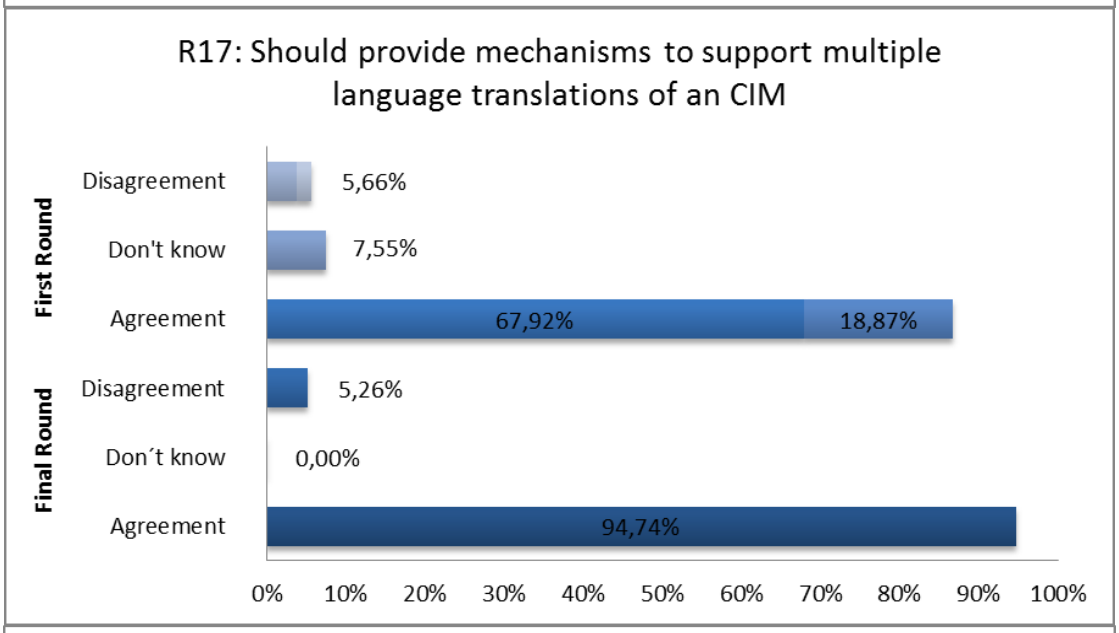

R12: Allows the user to assign one or multiple terminology/ontology concept to each node of the CIM structure
First Round
Disagreement
1,89%
Don't know
7,55%
Agreement
71,70%
18,87%
Final Round
Disagreement
2,63%
Don´t know
7,89%
Agreement
89,47%
0%
10%
20%
30%
40%
50%
60%
70%
80%
90%
100%

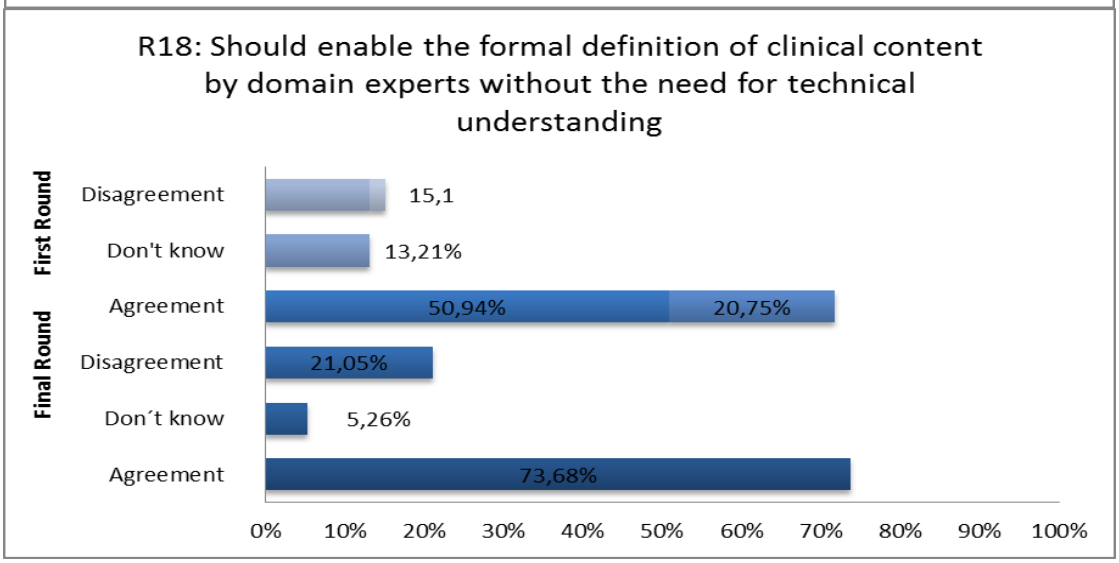

R13: Should include mechanisms that enable users and find a CIMs in the repository by searching on any of its structured information properties
First Round
Disagreement
0,00%
Don't know
5,66%
Agreement
56,60%
37,74%
Final Round
Disagreement
5,26%
Don´t know
10,53%
Agreement
84,21%
0%
10%
20%
30%
40%
50%
60%
70%
80%
90%
100%

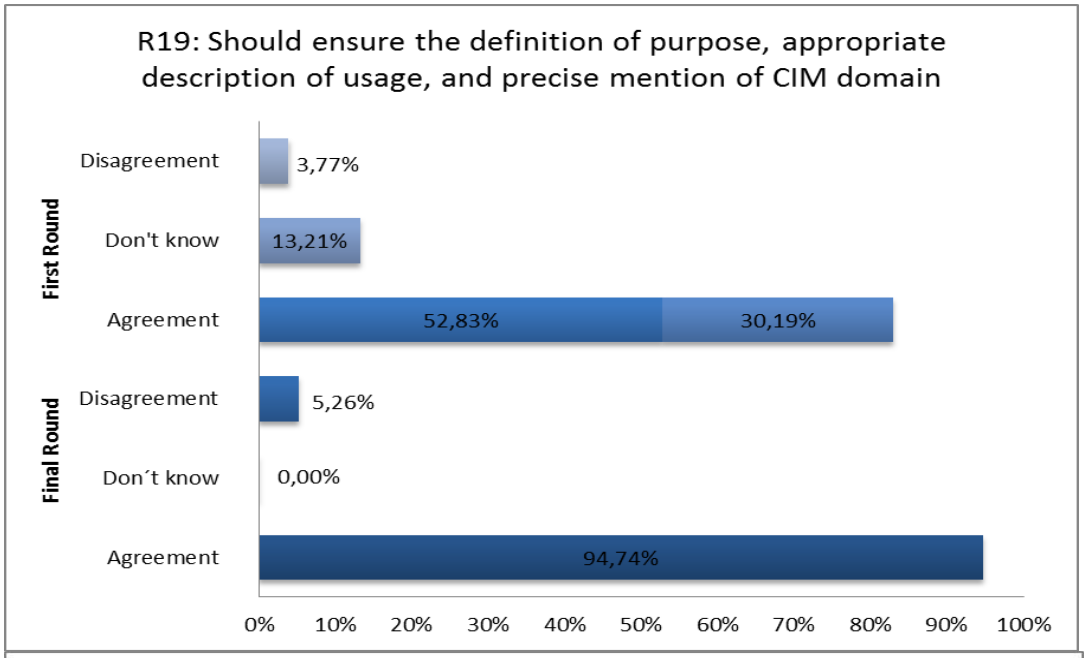

R14: Should export its CIM in at least one format that conforms to a published international standard or specification
First Round
Disagreement
3,78%
Don't know
11,32%
Agreement
58,49%
26,42%
Final Round
Disagreement
5,26%
Don´t know
0,00%
Agreement
94,74%
0%
10%
20%
30%
40%
50%
60%
70%
80%
90%
100%

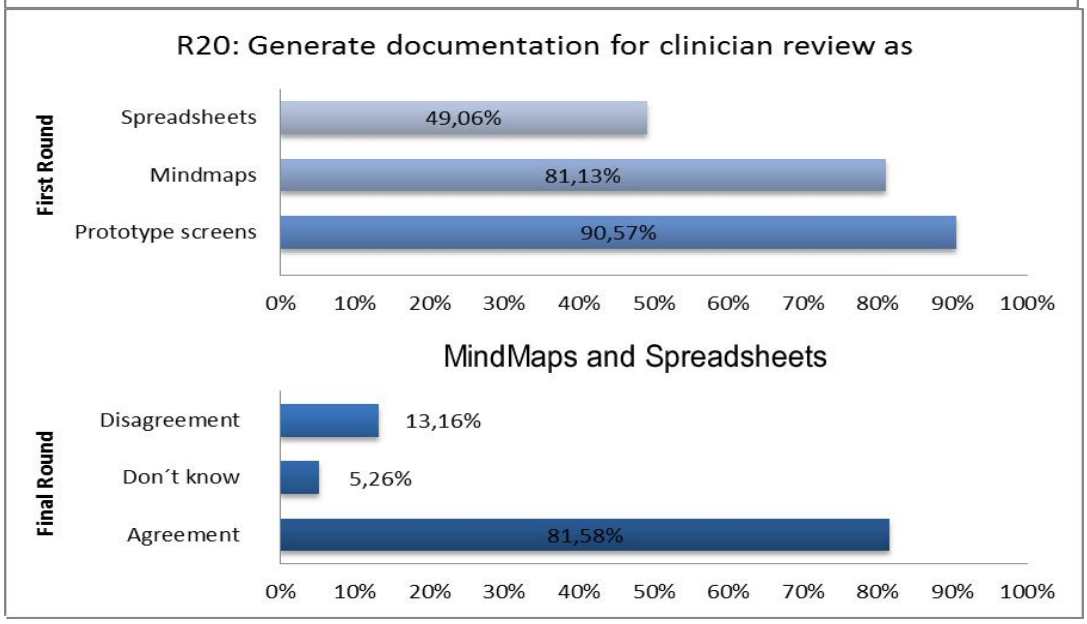

R15: The repository and its services shall maintain a complete and audited version history for all of its CIMs
First Round
Disagreement
1,89%
Don't know
7,55%
Agreement
69,81%
20,75%
Final Round
Disagreement
0,00%
Don´t know
2,63%
Agreement
97,37%
0%
10%
20%
30%
40%
50%
60%
70%
80%
90%
100%

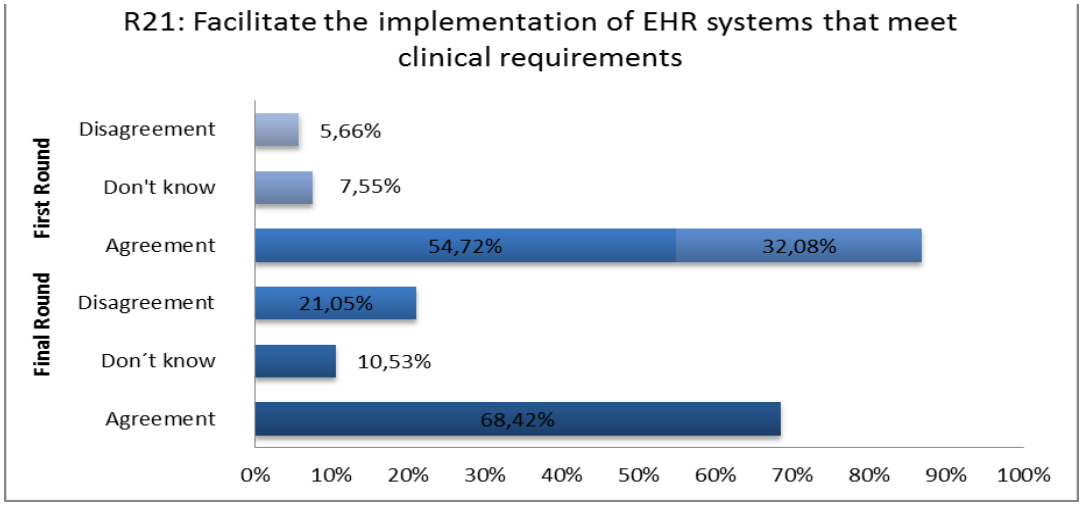

R16: Should allow collaborative authoring of CIMs according to the established roles. As well as recording experts and organisation participating in this process
First Round
Disagreement
3,78%
Don't know
3,77%
Agreement
58,49%
33,96%
Final Round
Disagreement
7,89%
Don´t know
5,26%
Agreement
86,84%
0%
10%
20%
30%
40%
50%
60%
70%
80%
90%
100%


R17: Should provide mechanisms to support multiple language translations of an CIM
First Round
Disagreement
5,66%
Don't know
7,55%
Agreement
67,92%
18,87%
Final Round
Disagreement
5,26%
Don´t know
0,00%
Agreement
94,74%
0%
10%
20%
30%
40%
50%
60%
70%
80%
90%
100%

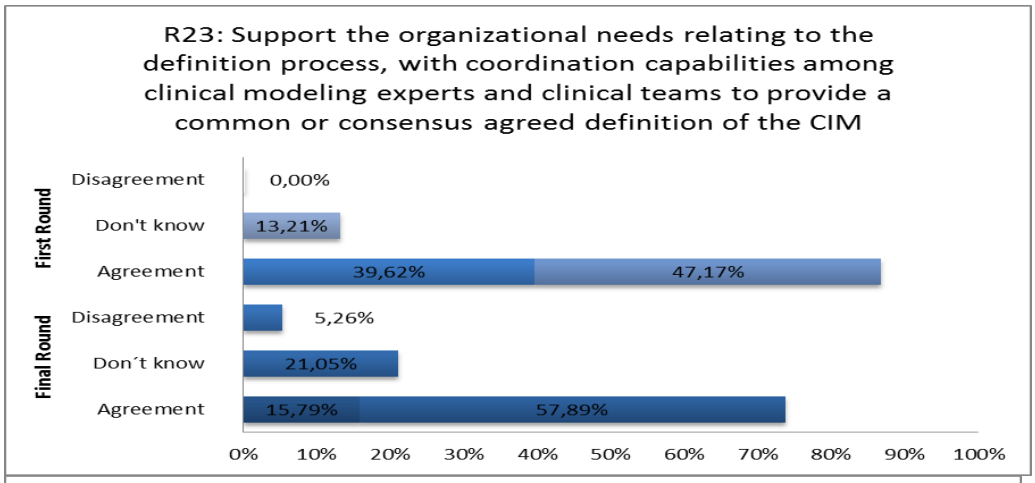

R18: Should enable the formal definition of clinical content by domain experts without the need for technical understanding
First Round
Disagreement
15,1
Don't know
13,21%
Agreement
50,94%
20,75%
Final Round
Disagreement
21,05%
Don´t know
5,26%
Agreement
73,68%
0%
10%
20%
30%
40%
50%
60%
70%
80%
90%
100%

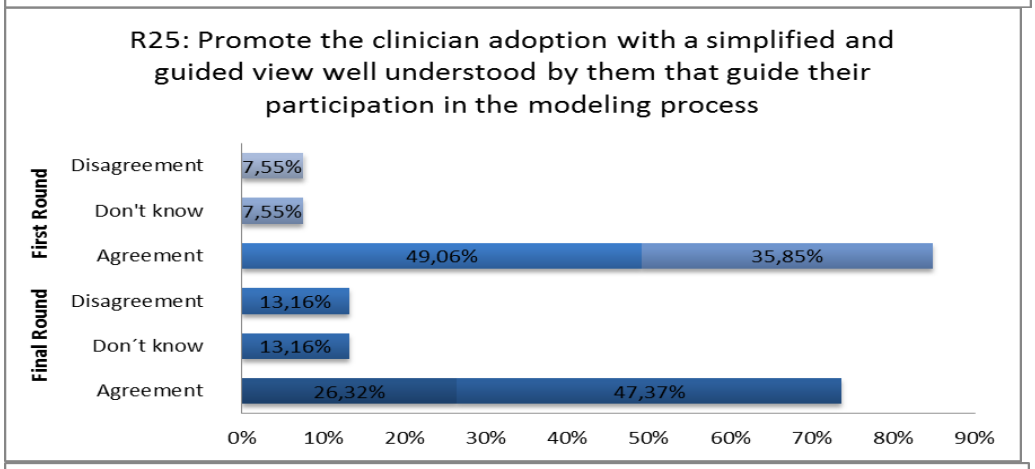

R19: Should ensure the definition of purpose, appropriate description of usage, and precise mention of CIM domain
First Round
Disagreement
3,77%
Don't know
13,21%
Agreement
52,83%
30,19%
Final Round
Disagreement
5,26%
Don´t know
0,00%
Agreement
94,74%
0%
10%
20%
30%
40%
50%
60%
70%
80%
90%
100%

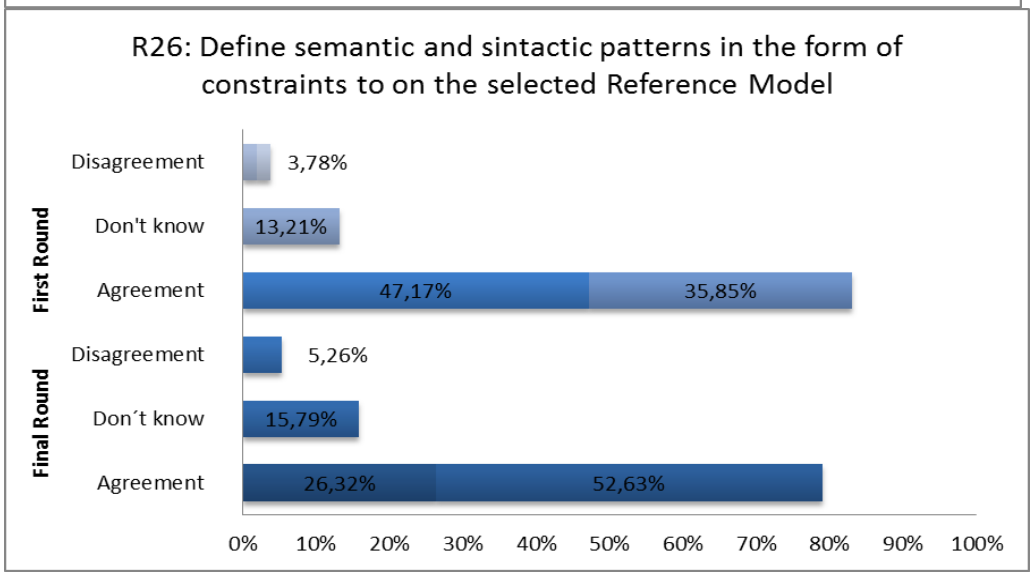

R20: Generate documentation for clinician review as
First Round
Spreadsheets
49,06%
Mindmaps
81,13%
Prototype screens
90,57%
0%
10%
20%
30%
40%
50%
60%
70%
80%
90%
100%
MindMaps and Spreadsheets
Final Round
Disagreement
13,16%
Don´t know
5,26%
Agreement
81,58%
0%
10%
20%
30%
40%
50%
60%
70%
80%
90%
100%

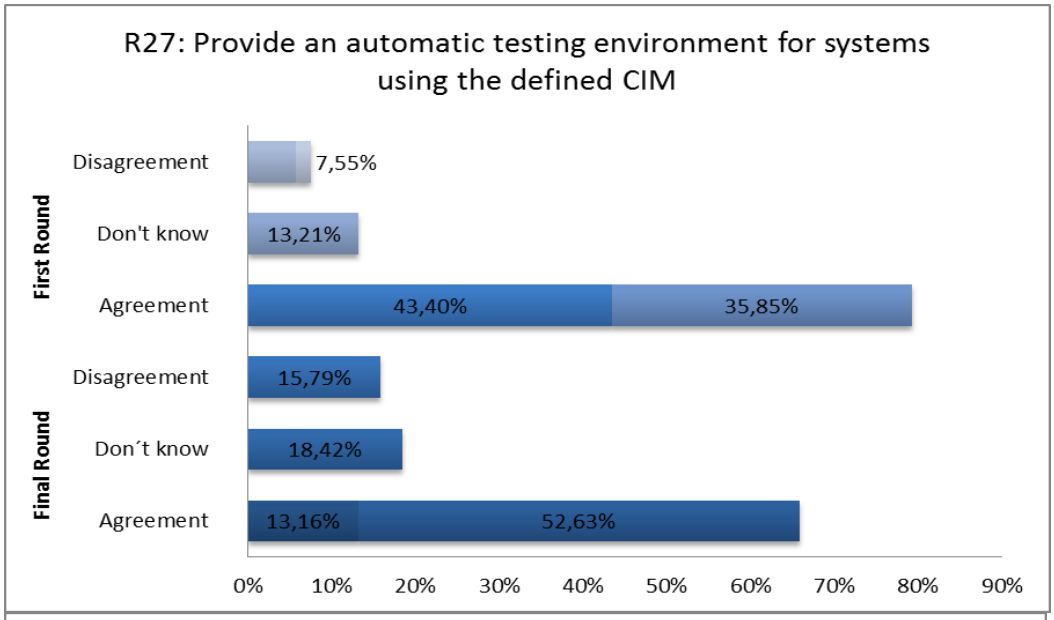

R21: Facilitate the implementation of EHR systems that meet clinical requirements
First Round
Disagreement
5,66%
Don't know
7,55%
Agreement
54,72%
32,08%
Final Round
Disagreement
21,05%
Don´t know
10,53%
Agreement
68,42%
0%
10%
20%
30%
40%
50%
60%
70%
80%
90%
100%

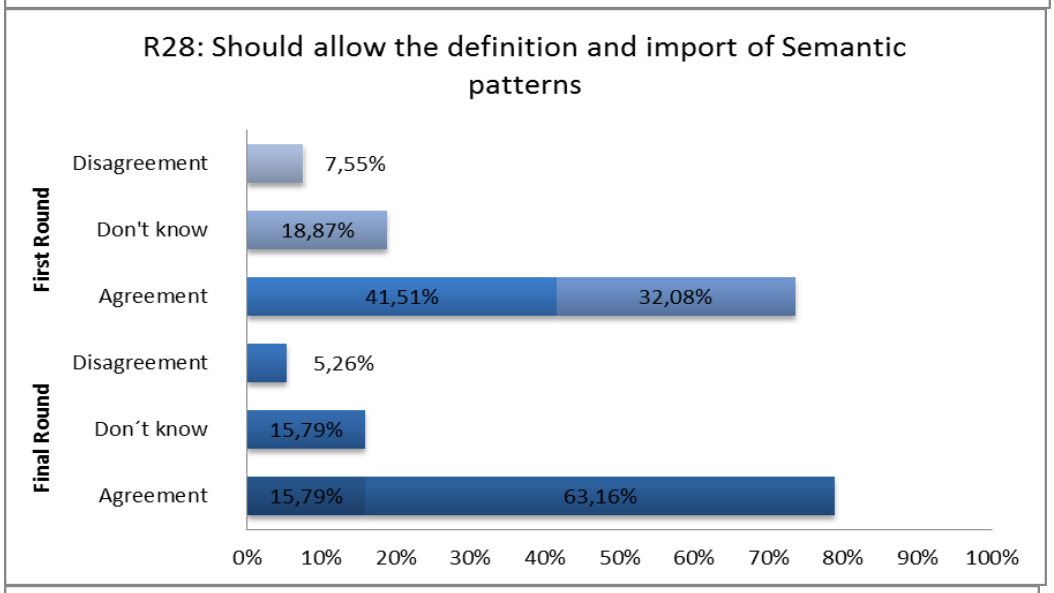
C.3.2. Recommended requirements

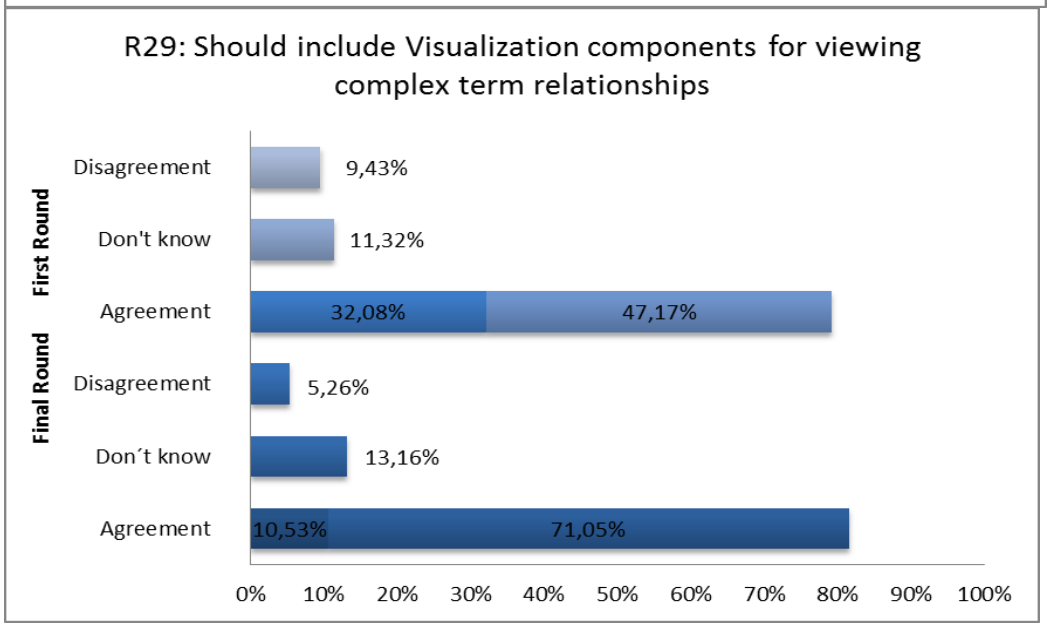


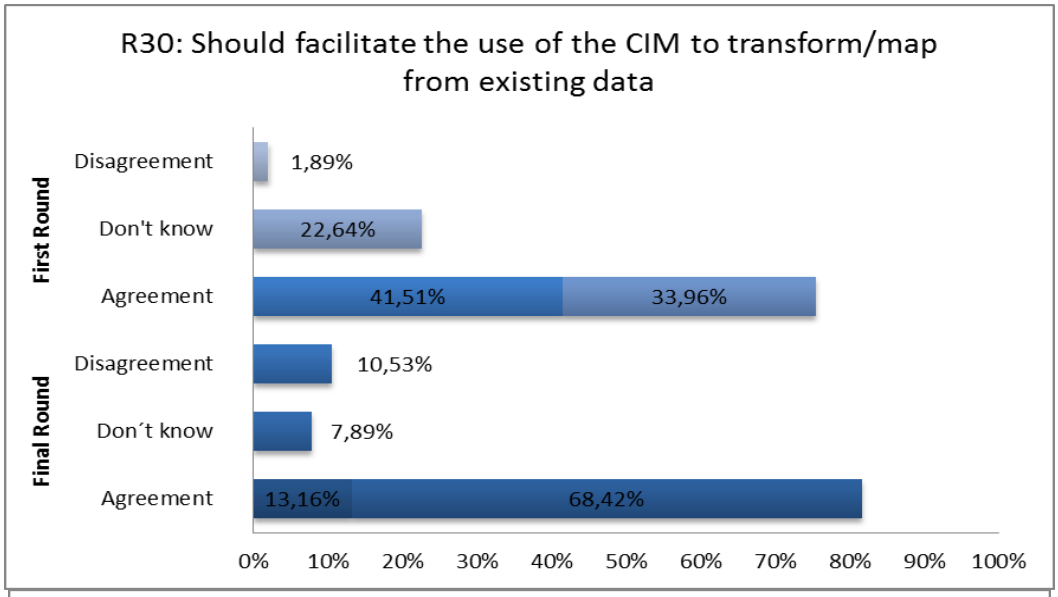


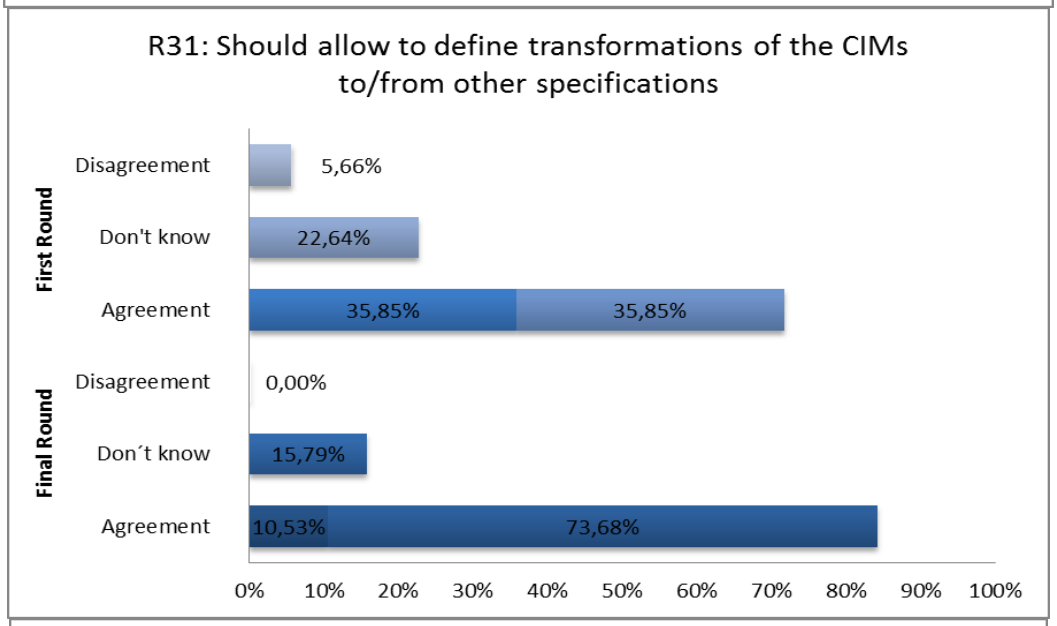


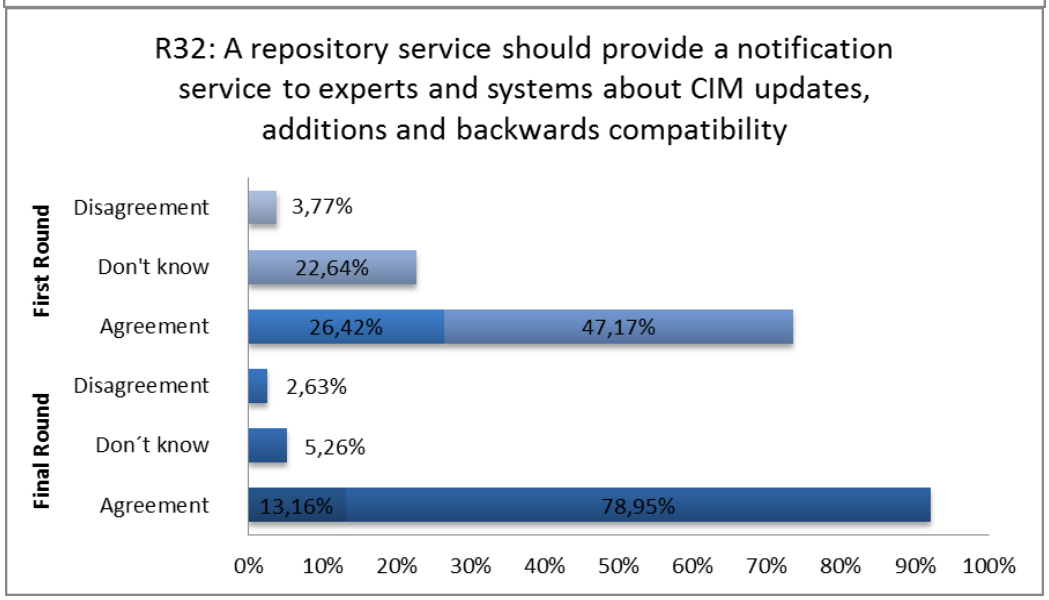

R27: Provide an automatic testing environment for systems using the defined CIM
First Round
Disagreement
Don't know
Agreement
Final Round
Disagreement
Don´t know
Agreement
7,55%
13,21%
43,40%
35,85%
15,79%
18,42%
13,16%
52,63%
0%
10%
20%
30%
40%
50%
60%
70%
80%
90%

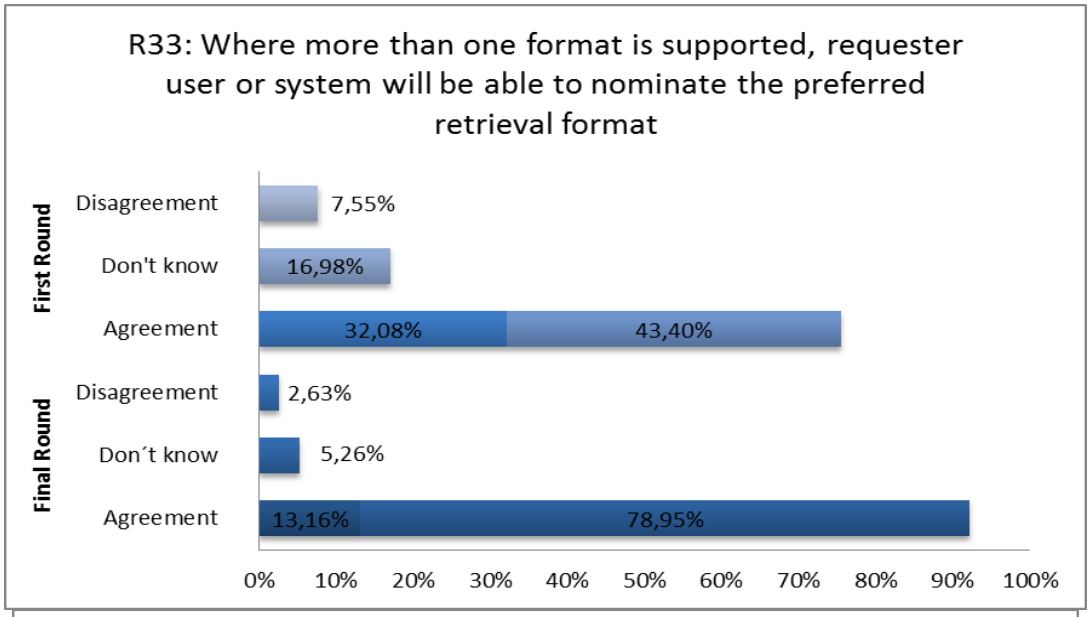

R28: Should allow the definition and import of Semantic patterns
First Round
Disagreement
Don't know
Agreement
Final Round
Disagreement
Don´t know
Agreement
7,55%
18,87%
41,51%
32,08%
5,26%
15,79%
15,79%
63,16%
0%
10%
20%
30%
40%
50%
60%
70%
80%
90%
100%

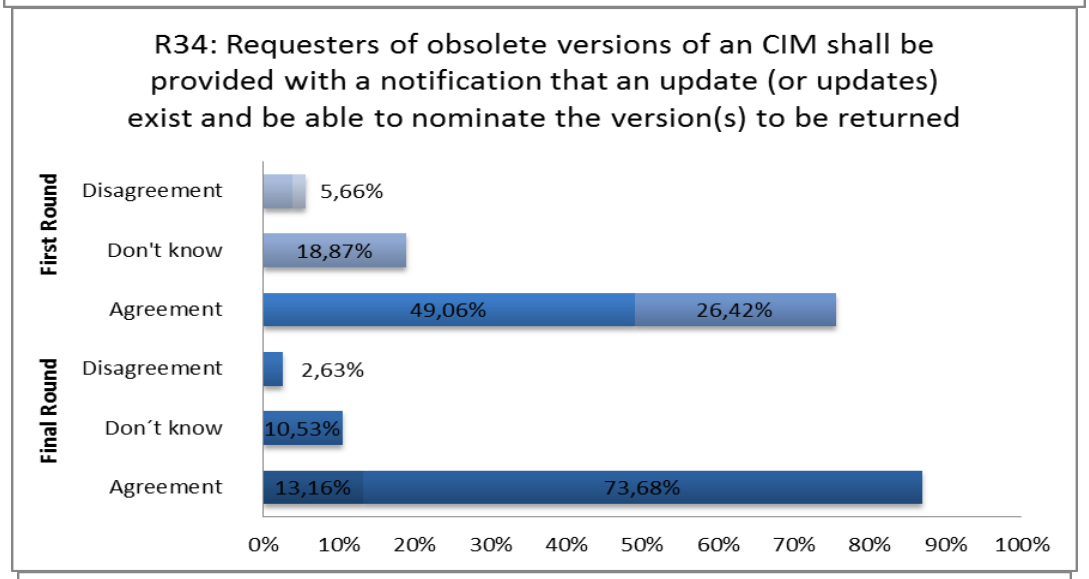

R29: Should include Visualization components for viewing complex term relationships
First Round
Disagreement
Don't know
Agreement
Final Round
Disagreement
Don´t know
Agreement
9,43%
11,32%
32,08%
47,17%
5,26%
13,16%
10,53%
71,05%
0%
10%
20%
30%
40%
50%
60%
70%
80%
90%
100%

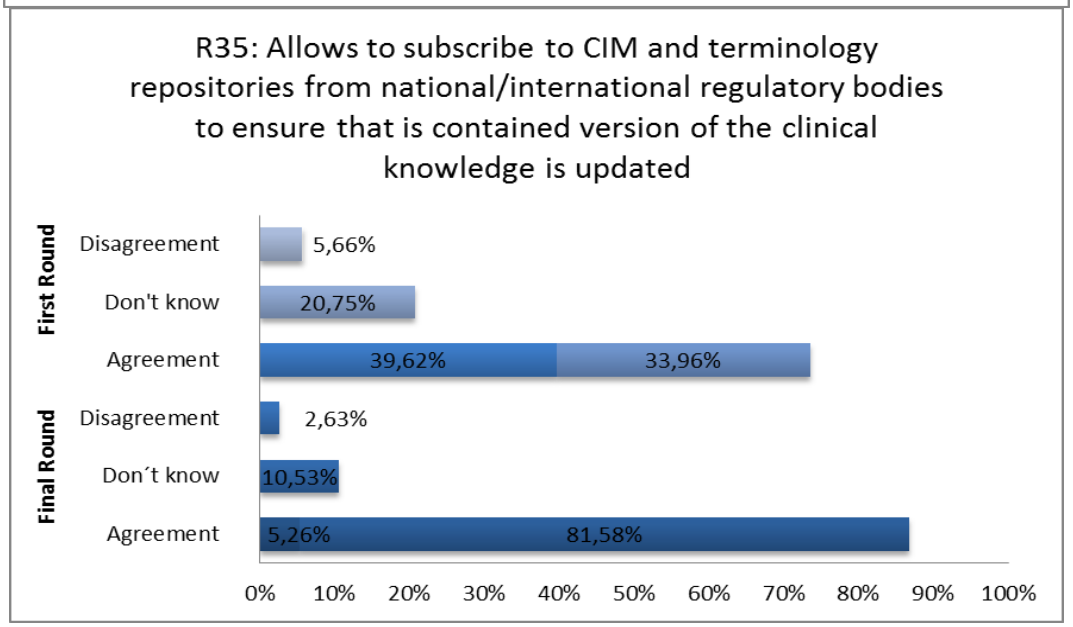

R30: Should facilitate the use of the CIM to transform/map from existing data
First Round
Disagreement
1,89%
Don't know
22,64%
Agreement
41,51%
33,96%
Final Round
Disagreement
10,53%
Don´t know
7,89%
Agreement
13,16%
68,42%
0%
10%
20%
30%
40%
50%
60%
70%
80%
90%
100%

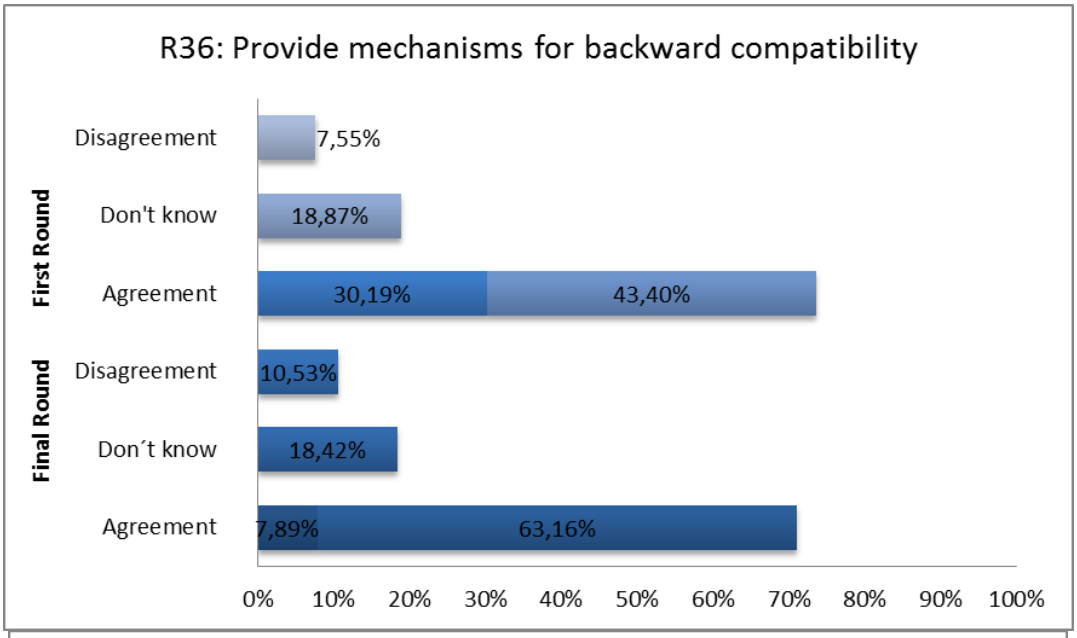

R31: Should allow to define transformations of the CIMs to/from other specifications
First Round
Disagreement
5,66%
Don't know
22,64%
Agreement
35,85%
35,85%
Final Round
Disagreement
0,00%
Don´t know
15,79%
Agreement
10,53%
73,68%
0%
10%
20%
30%
40%
50%
60%
70%
80%
90%
100%

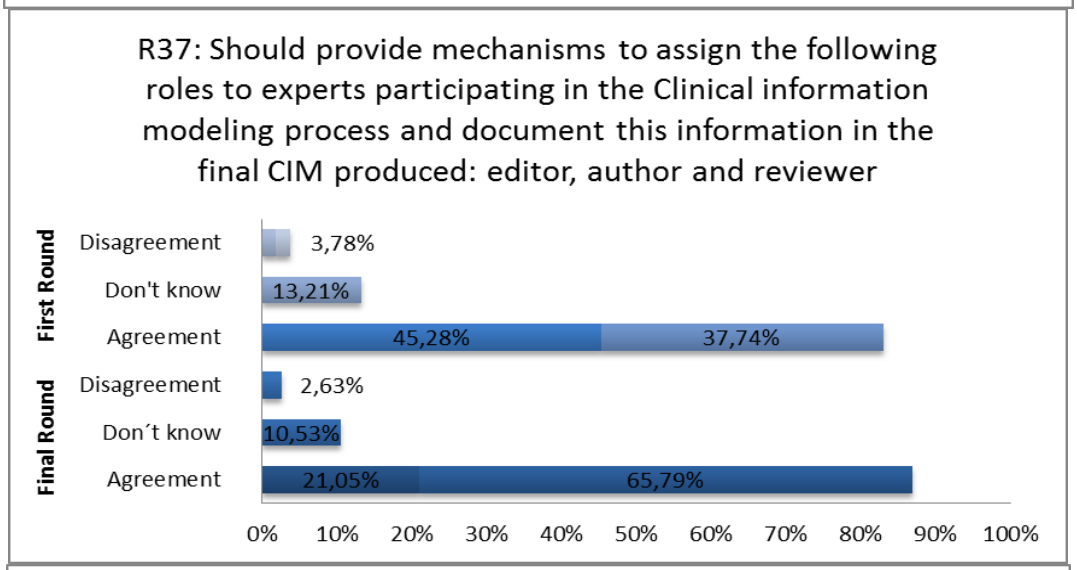

R32: A repository service should provide a notification service to experts and systems about CIM updates, additions and backwards compatibility
First Round
Disagreement
3,77%
Don't know
22,64%
Agreement
26,42%
47,17%
Final Round
Disagreement
2,63%
Don´t know
5,26%
Agreement
13,16%
78,95%
0%
10%
20%
30%
40%
50%
60%
70%
80%
90%
100%

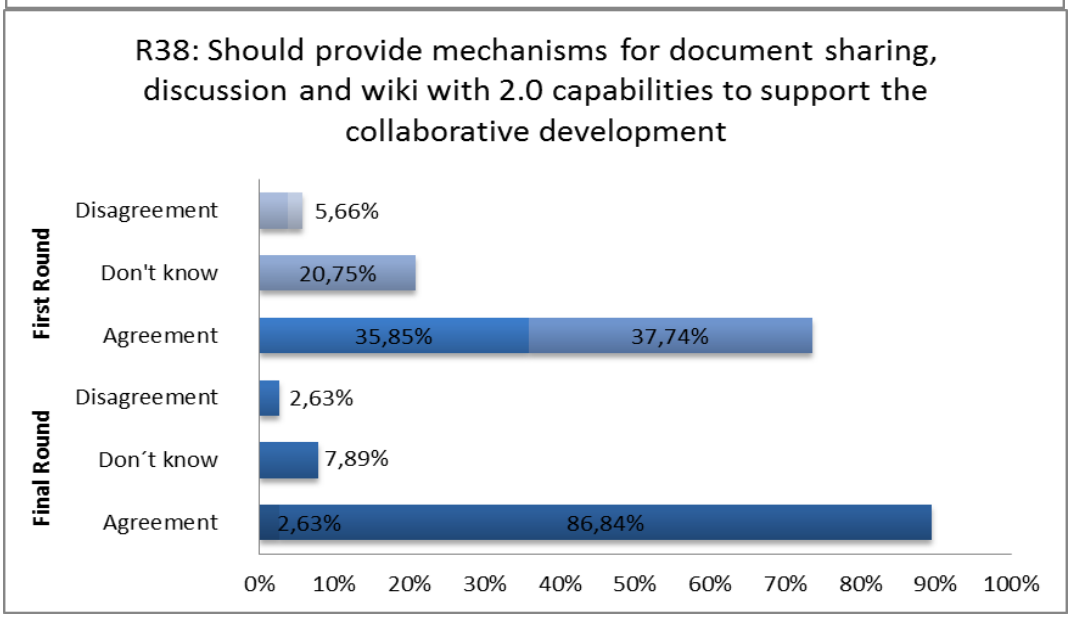

R33: Where more than one format is supported, requester user or system will be able to nominate the preferred retrieval format
First Round
Disagreement
Don't know
Agreement
Final Round
Disagreement
Don´t know
Agreement
7,55%
16,98%
32,08%
43,40%
2,63%
5,26%
13,16%
78,95%
0%
10%
20%
30%
40%
50%
60%
70%
80%
90%
100%

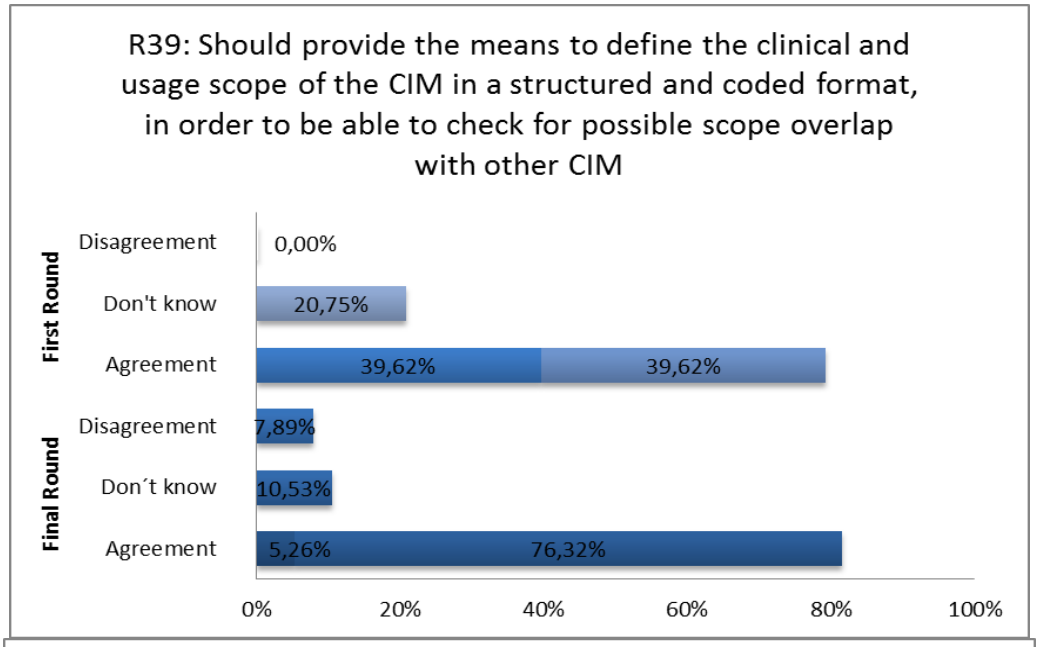

R34: Requesters of obsolete versions of an CIM shall be provided with a notification that an update (or updates) exist and be able to nominate the version(s) to be returned
First Round
Disagreement
Don't know
Agreement
Final Round
Disagreement
Don´t know
Agreement
5,66%
18,87%
49,06%
26,42%
2,63%
10,53%
13,16%
73,68%
0%
10%
20%
30%
40%
50%
60%
70%
80%
90%
100%

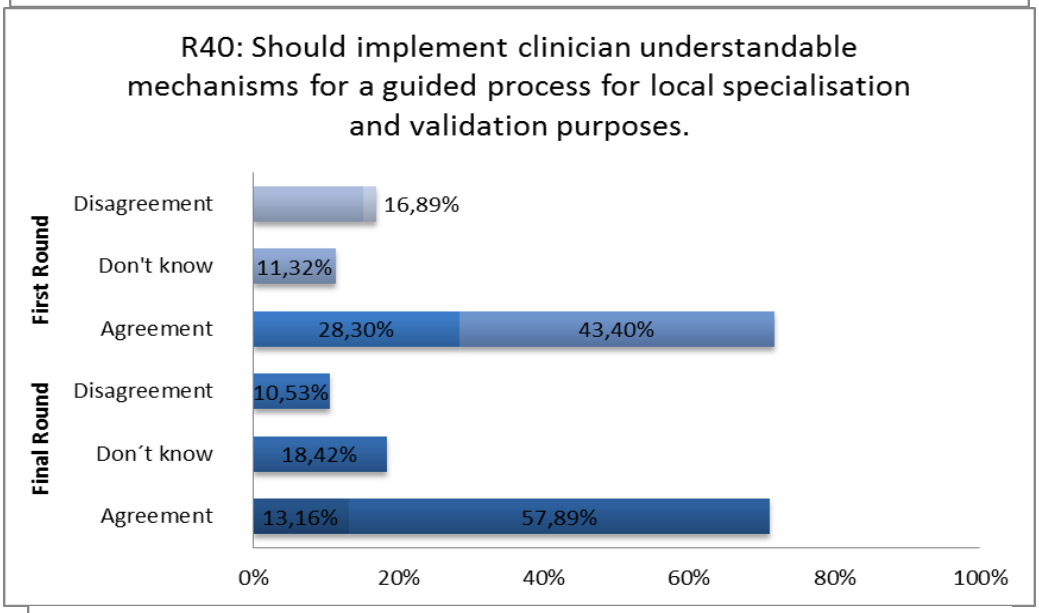

R35: Allows to subscribe to CIM and terminology repositories from national/international regulatory bodies to ensure that is contained version of the clinical knowledge is updated
First Round
Disagreement
Don't know
Agreement
Final Round
Disagreement
Don´t know
Agreement
5,66%
20,75%
39,62%
33,96%
2,63%
10,53%
5,26%
81,58%
0%
10%
20%
30%
40%
50%
60%
70%
80%
90%
100%

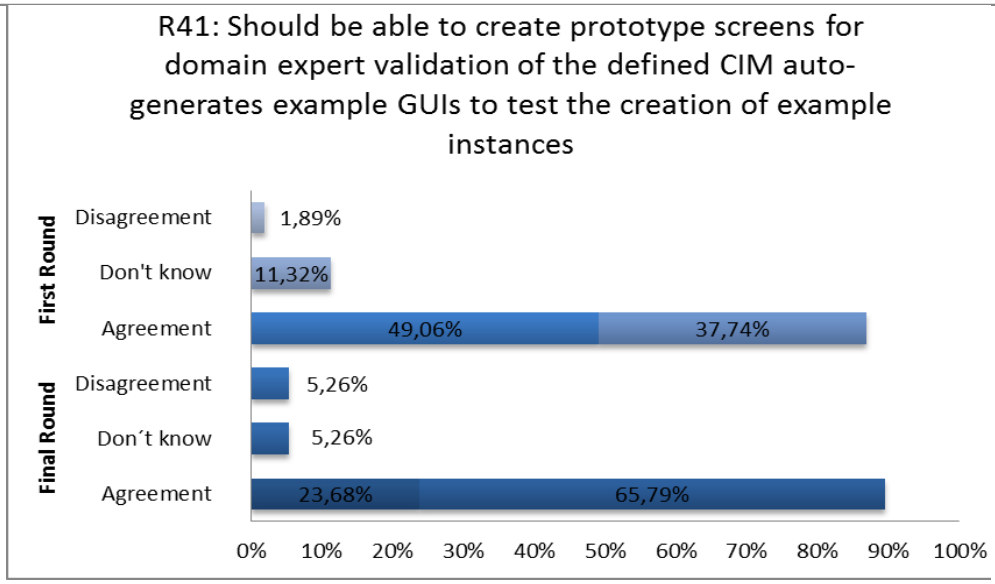

R36: Provide mechanisms for backward compatibility
First Round
Disagreement
Don't know
Agreement
Final Round
Disagreement
Don´t know
Agreement
7,55%
18,87%
30,19%
43,40%
10,53%
18,42%
7,89%
63,16%
0%
10%
20%
30%
40%
50%
60%
70%
80%
90%
100%

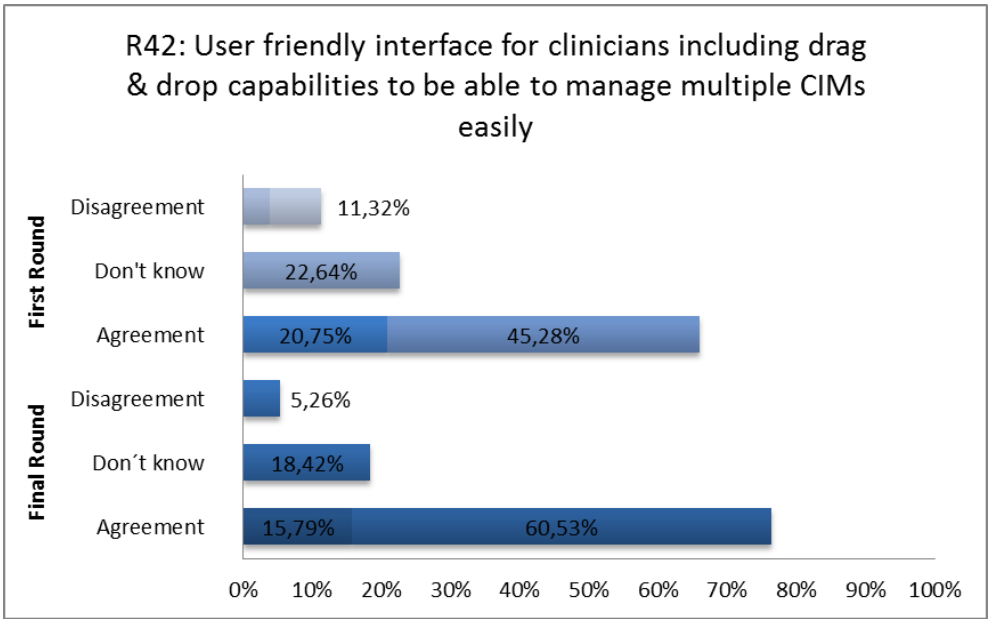

R37: Should provide mechanisms to assign the following roles to experts participating in the Clinical information modeling process and document this information in the final CIM produced: editor, author and reviewer
First Round
Disagreement
Don't know
Agreement
Final Round
Disagreement
Don´t know
Agreement
3,78%
13,21%
45,28%
37,74%
2,63%
10,53%
21,05%
65,79%
0%
10%
20%
30%
40%
50%
60%
70%
80%
90%
100%

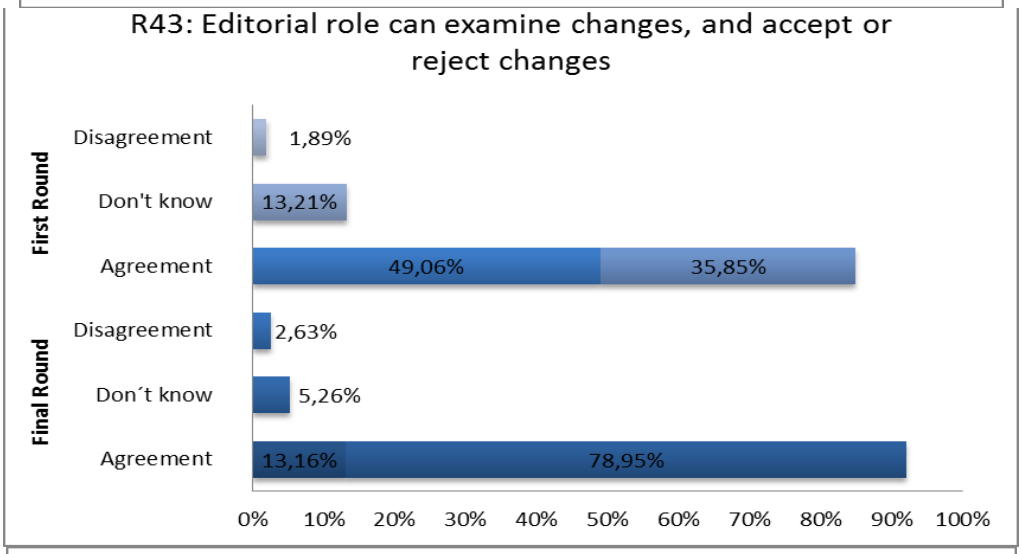

R38: Should provide mechanisms for document sharing, discussion and wiki with 2.0 capabilities to support the collaborative development
First Round
Disagreement
Don't know
Agreement
Final Round
Disagreement
Don´t know
Agreement
5,66%
20,75%
35,85%
37,74%
2,63%
7,89%
2,63%
86,84%
0%
10%
20%
30%
40%
50%
60%
70%
80%
90%
100%

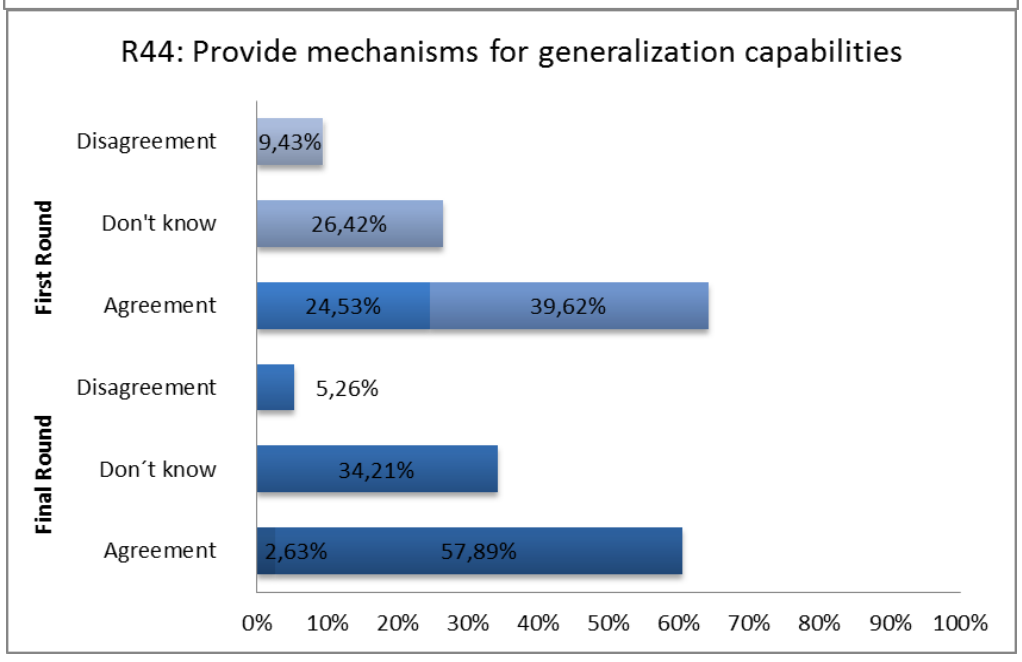

R39: Should provide the means to define the clinical and usage scope of the CIM in a structured and coded format, in order to be able to check for possible scope overlap with other CIM
First Round
Disagreement
0,00%
Don't know
20,75%
Agreement
39,62%
39,62%
Final Round
Disagreement
7,89%
Don´t know
10,53%
Agreement
5,26%
76,32%
0%
20%
40%
60%
80%
100%


R40: Should implement clinician understandable mechanisms for a guided process for local specialisation and validation purposes.
First Round
Disagreement
16,89%
Don't know
11,32%
Agreement
28,30%
43,40%
Final Round
Disagreement
10,53%
Don´t know
18,42%
Agreement
13,16%
57,89%
0%
20%
40%
60%
80%
100%


R41: Should be able to create prototype screens for domain expert validation of the defined CIM auto-generates example GUIs to test the creation of example instances
First Round
Disagreement
1,89%
Don't know
11,32%
Agreement
49,06%
37,74%
Final Round
Disagreement
5,26%
Don´t know
5,26%
Agreement
23,68%
65,79%
0%
10%
20%
30%
40%
50%
60%
70%
80%
90%
100%


R42: User friendly interface for clinicians including drag & drop capabilities to be able to manage multiple CIMs easily
First Round
Disagreement
11,32%
Don't know
22,64%
Agreement
20,75%
45,28%
Final Round
Disagreement
5,26%
Don´t know
18,42%
Agreement
15,79%
60,53%
0% 10% 20% 30% 40% 50% 60% 70% 80% 90% 100%


R43: Editorial role can examine changes, and accept or reject changes
First Round
Disagreement
1,89%
Don't know
13,21%
Agreement
49,06%
35,85%
Final Round
Disagreement
2,63%
Don´t know
5,26%
Agreement
13,16%
78,95%
0% 10% 20% 30% 40% 50% 60% 70% 80% 90% 100%


R44: Provide mechanisms for generalization capabilities
First Round
Disagreement
9,43%
Don't know
26,42%
Agreement
24,53%
39,62%
Final Round
Disagreement
5,26%
Don´t know
34,21%
Agreement
2,63%
57,89%
0% 10% 20% 30% 40% 50% 60% 70% 80% 90% 100%

Appendix D: Evaluation of CIMTs

D.1. Introduction

This appendix provides complementary information about the research study for Clinical Information Modelling Tool evaluation.

- Section D.2. details the questionnaire applied as part of this research
- Section D.3. details the list of tools identified for clinical information modelling and their suitability to be included as part of the CIMT evaluation study.
- Section D.4. provides the detailed results of evaluating each of the Clinical Information Modelling tools identified.

D.2. Questionnaire for evaluating Clinical Information Modelling Tools

In this research we use the expression clinical information model (CIM) as a generic term that subsumes any technical specification defining how clinical information is organized inside an EHR system or for EHR communication. A CIM defines both the information structure and the description of the semantics of clinical concepts. CIMs are a fundamental semantic artefact to facilitate registering, storing and displaying clinical data, exchanging that data between different information systems, querying the EHR and performing analytics and decision support based on existing clinical data. In order to support semantic interoperability, the structure of CIMs can be bound to medical terminologies to provide a univocal definition of the model. Some of the most relevant specifications include: HL7 FHIR, HL7 Clinical Document Architecture, HL7 Version 3, EN ISO 13606 or openEHR archetypes, Detailed Clinical Models.

Evaluation of (include the name of the tool)				
I	Description	Yes	No	Don't know
Define clinical information models according to a defined technical specification				
1	Users can easily determine which CIM specification and which version of that specification is supported by the tool			
2	If the tool supports more than one CIM specification, users can select which one to use when designing a new model			
3	If the tool supports more than one CIM specification, it is clear to a user which specification a CIM conforms to when opening (viewing or			

	editing) an existing model			
4	The tool developer has demonstrated a process of verifying that the CIMs produced or modified using the tool do conform to each CIM specification that is supported (e.g. through import of models into other conformant tools, or by demonstrated parsing tests against the published specification)			
Support the semantic interoperability of EHR systems				
5	Each node of a CIM could be mapped to a term within a published international terminology (automatically, or by end users manually or a combination of these)			
6	Each value list created or reviewed by a user can be drawn from or mapped to terms from a published international terminology			
7	An author constructing a terminology value list can use the tool to identify one or more suitable terms from a published international terminology and incorporate such terms and any relevant child concepts			
8	If the tool supports the use of more than one published international terminology, a user may map each node name to more than one terminology (including multiple language translations of each term, if relevant)			
9	If the tool supports the use of more than one published international terminology, a user may map each term in a value list to more than one terminology (including multiple language translations of each term, if relevant)			
Ensure consistency of information collected by enabling the definition of clinical information models generic enough to be compatible in multiple scenarios through specialization mechanisms for the additional constraints of each local scenario				
10	Does your tool allow to select an existing CIM and define further constrains making possible to specialise its definition for local scenario ensuring compatibility with the generic definition?			
11	If your tool has been used to create a CIM that is a specialisation (or localisation) of another, does the specialised CIM include a reference to the more general one it has specialised?			
12	Does your tool allow to identify all those specialised versions of CIM defined for local scenario from a CIM defined for generic scenario			
Definition and validation of the clinical information models according to a formal syntax				
13	Is your tool able to define a CIM according to a formal syntax that conforms to an open (published) specification?			
14	Is your tool able to validate that a defined or imported CIM is			

	conformant to the selected specification?			
15	Is your tool able to show any validation errors a specific CIM has according to the selected specification?			
Import and Export clinical information models according to the following formal syntaxes: XML and ADL				
16	Does your tool allow importing/exporting CIM in XML format, according to a publicly accessible XML schema?			
17	Does your tool allow importing/exporting CIM in ADL format, to a specified version?			
Represent data types according an accepted data type standard (e.g. ISO 21090 standard or a subset of this)				
18	Can your tool represent data types according to a specified data type standard?			
19	Is your tool able to define and manage the following datatypes: 1. Boolean 2. Integer 3. Double date 4. date-time 5. URI 6. Multimedia 7. Concept Descriptor 8. Physical Quantity 9. String with Language			
Support for version management, tracking changes and past history for each CIM				
20	Does your tool allow the creation of new versions of a previously defined CIM?			
21	Does your tool allow displaying previous versions of a CIM, detailing the changes made in the current version?			
Provide an automatic parser for the defined clinical information model *An automatic parser can be used by developers to facilitate processing the information transferred according to the CIM in the implemented EHR system*				
22	With a valid Clinical Information Model, does your modelling tool emit an XML Schema (or similar, please state) against which instances of it may be validated?			
23	Does your modelling tool emit library code by which valid instances in XML Schema (or other, as above) may be parsed into a common			

	object-oriented programming environment (if so, please state which)?			
Tools will verify that CIM and their instances are semantically and syntactically consistent *The semantic consistency checking will consist of verifying that CIMs are consistent with regards to its semantic underlying terminology / ontology model.*				
24	A mechanism exists through use of the tool for a CIM author or reviewer to determine the semantic relationships between node names within a CIM by reference to their concept relationships within a published international terminology			
25	A mechanism exists through use of the tool for a CIM author or reviewer to determine the semantic relationships between a node name and its value list if this is a terminology value set			
The tool supports the author to create term bindings by connecting with Terminology Servers using (e.g. using CTS2) or another suitable terminology server communication specification				
26	Does your tool support connecting with remote (online) Terminology servers that conform to published standards and specification (e.g. CTS2)			
27	Does your tool support connecting with Terminology servers based on specifications to provide functionalities for terminology service administration. Some functionalities could include the ability to load terminologies, export terminologies, activate terminologies, and retire terminologies.			
28	Does your tool support connecting with Terminology servers based on specifications to provide functionalities for search & query concepts within terminology server based on some search criteria. This includes restrictions to specific associations or other attributes of the terminology, including navigation of associations for result sets.			
Should include an intuitive graphical user interface for navigating large taxonomies				
29	Does your tool allow searching in large taxonomies that will be bound to CIM nodes			
30	Does your tool allow user to define value sets that will be bounded to CIM nodes			
Allows the user to assign one or multiple terminology/ontology concept to each node of the clinical information model structure				

End user will define list of candidate terminology/ontology terms (value sets)				
31	Does your tool allow mapping nodes to one or multiple terminology concepts?			
32	Does your tool allow mapping nodes to one or multiple ontology concepts?			
33	Terminology bindings will be defined according to the chosen specification?			
Should include an intuitive graphical user interface for navigating large taxonomies				
34	Does your tool allow searching CIMs based on CIM name?			
35	Does your tool allow searching CIMs based concept codes and attributes associated with CIM nodes?			
36	Does your tool allow searching CIMs based on domain?			
37	Does your tool allow searching CIMs based on value sets and terms bound to nodes?			
Export CIM in at least one format that conforms to a published international standard or specification				
38	Does your tool allow to export/import according to a specified international standard for CIM representation?			
The repository and its services shall maintain a complete and audited version history for all of its clinical information models				
39	Does your tool contain or link to a repository of all previous versions of any particular CIM?			
40	Does your tool contain or reference, or can it generate a track of changes between all previous versions of a particular CIM?			
Allow collaborative authoring of CIM according to the established roles. As well as recording experts and organisation participating in this process *The tool will facilitate the coordination of the multiple experts participating in the CIM definition process*				
41	Does your tool allow creating profiles for modelling experts such as author, editor or reviewer and their organizations?			
42	Is your tool able to support the registration of multiple users so that the actions of different users on the same CIM can be attributed to each			

	user?			
Should provide mechanisms to support multiple language translations of a clinical information model				
43	Does your tool allow a user to enter language translations of terms and concepts used within a CIM definition?			
Should enable the formal definition of clinical content by domain experts without the need for technical understanding *A specialized view should display the information adapted to clinicians. "non-technical understanding" means having no previous knowledge about CIM specifications but still there could still be a need for support by a health informatician during the CIMP*				
44	Does your tool include a simplified view for clinical experts to define or review clinical concepts that should be included as CIM nodes?			
45	Does your tool include a simplified view for clinical experts to define or review clinical concepts that can be bound, or are bound, to CIM nodes?			
Should ensure the definition of purpose, appropriate description of usage, and precise mention of clinical information model domain				
46	Does your tool support defining for which purpose a CIM is recommended to be applied?			
47	Does your tool support defining for which usage a CIM is recommended to be applied?			
48	Does your tool support defining for which clinical domain or clinical user a CIM is recommended to be applied?			
Generate documentation for clinician review as MindMaps and Prototype Screens				
49	Does your tool provide a representation of CIM nodes and value sets in form of a MindMap?			
50	Does your tool provide a representation of CIM nodes and value sets in form of a Prototype screen form?			

Table 69. Questionnaire for evaluating clinical information modelling tools

D.3. List tools identified for clinical information modeling.

Domain	Tool name	Suitable	Status
HL7	ART DÉCOR	Yes	Evaluated
	Data Information System Solutions - CDAR2.Net	No	--
	eTransX	No	--
	Eversolve Medi7	No	--
	LINK Medical Computing, Inc. Toolkits for Building/Parsing HL7 Messages	No	--
	Orion Systems Symphonia	No	--
	PilotFish eiConsole for Healthcare Integration	No	--
	TL7	No	--
	Open Mapping Software	Yes	No feedback
	Trifolia from Lantana Group	Yes	Evaluated
	MDHT	Yes	Evaluated
	DCM content, model,	Yes	Evaluated
	CDA Generator	No	--
OpenEHR	Archetype Editor	Yes	Evaluated
	Template Editor	Yes	Evaluated
	Clinical Knowledge Manager	Yes	Evaluated
	LiU Archetype Editor	Yes	No feedback
ISO13606	LinkEHR tool	Yes	Evaluated
	OntoCR tool	Yes	Evaluated
Other	UCL pattern tool	Yes	Evaluated
CEM	Clinical Element Model Browser	Yes	Evaluated

Table 70. List tools identified for clinical information modeling.

D.4. Detailed results of Clinical Information Modelling tool evaluations

ID	Description	MDHT	CEM Browser	ART-DECOR	Trifolia	DCM modeller	OpenEHR AE	OpenEHR TE	OpenEHR CKM	OntoCR	LinkEHR	UCL pattern
1	Users can easily determine which CIM specification and which version of that specification is supported by the tool	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
2	If the tool supports more than one CIM specification, users can select which one to use when designing a new model	-	-	Y	Y	Y	-	-	-	Y	Y	Y
3	If the tool supports more than one CIM specification, it is clear to a user which specification a CIM conforms to when opening (viewing or editing) an existing model	-	-	Y	Y	Y	-	-	-	Y	Y	Y
4	The tool developer has demonstrated a process of verifying that the CIMs produced or modified using the tool do conform to each CIM specification that is supported (e.g. through import of models into other conformant tools, or by demonstrated parsing tests against the published specification)	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
5	Each node of a CIM could be mapped to a term within a published international terminology (automatically, or by end users manually or a combination of these)	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
6	Each value list created or reviewed by a user can be drawn from or mapped to terms from a published international terminology	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
7	An author constructing a terminology value list can use the tool to identify one or more suitable terms from a published international terminology and incorporate such terms and any relevant child concepts	Y	N	Y	Y	Y	N	N	N	Y	Y	N
8	If the tool supports the use of more than one published international terminology, a user may map each node name to more than one terminology (including multiple language translations of each term, if relevant)	Y	N	Y	Y	Y	Y	Y	Y	Y	Y	Y
9	If the tool supports the use of more than one published international terminology, a user may map each term in a value list to more than one terminology (including multiple language translations of each term, if relevant)	Y	N	Y	Y	Y	Y	Y	Y	Y	Y	Y
10	Does your tool allow to select an existing CIM and define further constrains making possible to specialise its definition for local scenario ensuring compatibility with the generic definition?	Y	N	N	Y	Y	Y	Y	N	Y	Y	Y

11	If your tool has been used to create a CIM that is a specialisation (or localisation) of another, does the specialised CIM include a reference to the more general one it has specialised?	Y	N	Y	Y	Y	Y	Y	Y	Y	Y	Y
12	Does your tool allow to identify all those specialised versions of CIM defined for local scenario from a CIM defined for generic scenario	Y	N	Y	N	Y	N	Y	Y	Y	Y	N
13	Is your tool able to define a CIM according to a formal syntax that conforms to an open (published) specification?	Y	Y	Y	Y	Y	Y	Y	N	Y	Y	Y
14	Is your tool able to validate that a defined or imported CIM is conformant to the selected specification?	Y	Y	Y	Y	Y	N	Y	Y	Y	Y	Y
15	Is your tool able to show any validation errors a specific CIM has according to the selected specification?	Y	N	Y	N	Y	N	N	Y	N	Y	N
16	Does your tool allow importing/exporting CIM in XML format, according to a publicly accessible XML schema?	N	Y	Y	Y	Y	Y	Y	Y	Y	Y	N
17	Does your tool allow importing/exporting CIM in ADL format, to a specified version?	N	N	N	N	Y	Y	Y	Y	Y	Y	N
18	Can your tool represent data types according to a specified data type standard?	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
19	Is your tool able to define and manage the following datatypes: Boolean, Integer, Double, date, date-time, URI, Multimedia, Concept Descriptor, Physical Quantity, String with Language	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
20	Does your tool allow the creation of new versions of a previously defined CIM?	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
21	Does your tool allow displaying previous versions of a CIM, detailing the changes made in the current version?	Y	N	Y	N	Y	N	Y	Y	N	N	Y
22	With a valid Clinical Information Model, does your modelling tool emit an XML Schema (or similar, please state) against which instances of it may be validated?	Y	N	N	Y	N	Y	N	N	N	Y	Y
23	Does your modelling tool emit library code by which valid instances in XML Schema (or other, as above) may be parsed into a common object-oriented programming environment (if so, please state which)?	Y	Y	N	N	N	N	N	N	N	Y	Y
24	A mechanism exists through use of the tool for a CIM author or reviewer to determine the semantic relationships between node names within a CIM by reference to their concept relationships within a published international terminology	Y	N	Y	N	Y	N	N	N	Y	N	N
25	A mechanism exists through use of the tool for a CIM author or reviewer to determine the semantic relationships between a node name and its value list if this is a terminology value set	Y	N	Y	N	Y	N	N	N	Y	N	N
26	Does your tool support connecting with remote (online) Terminology servers that conform to published standards and specification (e.g. CTS2)	Y	Y	Y	N	Y	N	N	Y	N	Y	N

27	Does your tool support connecting with Terminology servers based on specifications to provide functionalities for terminology service administration. Some functionalities could include the ability to load terminologies, export terminologies, activate terminologies, and retire terminologies.	Y	N	N	Y	N	N	N	N	N	N	N
28	Does your tool support connecting with Terminology servers based on specifications to provide functionalities for search & query concepts within terminology server based on some search criteria. This includes restrictions to specific associations or other attributes of the terminology, including navigation of associations for result sets.	Y	N	N	N	N	N	N	N	N	Y	N
29	Does your tool allow searching in large taxonomies that will be bound to CIM nodes	Y	N	Y	N	N	N	Y	Y	Y	Y	N
30	Does your tool allow user to define value sets that will be bounded to CIM nodes	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
31	Does your tool allow mapping nodes to one or multiple terminology concepts?	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
32	Does your tool allow mapping nodes to one or multiple ontology concepts?	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	N
33	Terminology bindings will be defined according to the chosen specification?	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
34	Does your tool allow searching CIMs based on CIM name?	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
35	Does your tool allow searching CIMs based concept codes and attributes associated with CIM nodes?	Y	Y	N	Y	Y	N	N	N	Y	Y	N
36	Does your tool allow searching CIMs based on domain?	Y	N	N	N	Y	N	N	Y	N	Y	N
37	Does your tool allow searching CIMs based on value sets and terms bound to nodes?	Y	Y	N	N	Y	N	N	N	N	Y	N
38	Does your tool allow to export/import according to a specified international standard for CIM representation?	Y	Y	N	N	Y	Y	Y	Y	Y	Y	N
39	Does your tool contain or link to a repository of all previous versions of any particular CIM?	N	N	Y	Y	Y	Y	Y	Y	N	N	Y
40	Does your tool contain or reference, or can it generate a track of changes between all previous versions of a particular CIM?	Y	N	Y	Y	Y	N	N	Y	N	N	Y
41	Does your tool allow creating profiles for modelling experts such as author, editor or reviewer and their organizations?	N	N	Y	Y	Y	Y	N	Y	N	N	N
42	Is your tool able to support the registration of multiple users so that the actions of different users on the same CIM can be attributed to each user?	Y	N	Y	Y	Y	Y	N	Y	Y	N	Y
43	Does your tool allow a user to enter language translations of terms and concepts used within a CIM definition?	Y	N	Y	Y	Y	Y	Y	Y	Y	Y	Y

44	Does your tool include a simplified view for clinical experts to define or review clinical concepts that should be included as CIM nodes?	N	N	Y	N	Y	Y	Y	Y	Y	Y	N
45	Does your tool include a simplified view for clinical experts to define or review clinical concepts that can be bound, or are bound, to CIM nodes?	N	N	Y	N	Y	Y	Y	N	Y	Y	N
46	Does your tool support defining for which purpose a CIM is recommended to be applied?	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
47	Does your tool support defining for which usage a CIM is recommended to be applied?	N	N	Y	Y	Y	Y	Y	Y	Y	Y	Y
48	Does your tool support defining for which clinical domain or clinical user a CIM is recommended to be applied?	N	N	Y	Y	Y	Y	Y	Y	Y	Y	Y
49	Does your tool provide a representation of CIM nodes and value sets in form of a MindMap?	N	N	Y	N	Y	Y	N	Y	Y	Y	N
50	Does your tool provide a representation of CIM nodes and value sets in form of a Prototype screen form?	N	N	Y	N	Y	Y	Y	N	Y	Y	Y

Table 71. Detailed presentation of the evaluation of requirements for Clinical Information Modelling tools. Y=Requirement is satisfied; N=Requirement is not satisfied; P=Requirement partially satisfied

Appendix E: Interoperability Asset Quality Framework

E.1. Introduction

In order to provide examples of asset evaluation, details are given below of how different assets can be assessed according to the defined descriptors.

- Section E.2. lists the modifications carried out based on the comments obtained in the online survey for assessing the proposed Quality Framework for Interoperability Assets
- Section E.3 details the descriptors and value sets of the Quality Framework for Interoperability Assets
- Section E.4 to E.8 provide examples of interoperability assets evaluated according to the defined framework. The current evaluation was performed according to the documentation available from those assets. Although there were in collaboration with experts familiar with their related projects not all the the evaluations were verified by relevant experts involved in the project. The presented examples are expected to illustrate the use of the asset descriptions.

E2. Modifications of the registry after evaluation

The online survey carried out to assess the proposed Quality Framework for Interoperability Assets collected a few minor comments that led to the following adjustments in the wording of some of the metrics proposed. Next are detailed the list of modiications performed:

- **Modification 1: Development process domain.** The term quality control process was replaced by quality assessment process in descriptor. The modified text is shown in green color.
- **Modification 2: Maturity level domain.** It was deleted the term associated with space technologies from the TRL9 definition
- **Modification 3: Semantic interoperability domain:** It was added a possible answer for those cases when there is not any node mapped with terminologies.
- **Modification 4: Cost & Effort domain.** It was replaced the unit for measuring implementation effort from the number of entries that are required to be processed in

one system by the number of terms that are required to be mapped at implementation stage.

ID	Domain	Modification
1	Development process	d) Quality processes used: 1. External quality management process based in ISO9000 or other recognised methodologies 2. External quality assesment process 3. Internal quality assesment process 4. No verified quality assessment process 5. Not relevant
2	Maturity level	a) Technical completeness 1. TRL 9. Actual system proven in operational environment (competitive manufacturing in the case of key enabling technologies~~; or in space~~)
3	Semantic interoperability	b) Clinical information model Terminology Binding 1. All of the nodes defined in the clinical information models have been mapped to international terminologies 2. Some of the nodes defined in the clinical information models have been mapped to international terminologies 3. All of the nodes defined in the clinical information models have been mapped to local terminologies 4. None of the nodes have been mapped to international or local terminologies 5. Not relevant
4	Cost & Effort	c) Effort for required implementation 1. The implementation of the selected asset requires mapping of less than 25 terminology concepts 2. The implementation of the selected asset requires mapping of less than 50 terminology concepts 3. The implementation of the selected asset requires mapping of less than 100 terminology concepts 4. The implementation of the selected asset requires mapping of less than 250 terminology concepts 5. The implementation of the selected asset requires mapping 250 terminology concepts or more 6. Not relevant

Table 72. Adjustments in the proposed Quality Framework for Interoperability Assets based on the survey results

E.3. Definition of descriptors and value sets

1.2. Type of asset	
a. General	1. Use case 2. Methodology 3. Requirements specification 4. Design guidelines
b. Legal, organisational	1. Policy 2. Operational guidelines 3. License or contract, specimen contract 4. Procurement template 5. Educational or training resource 6. Safety or risk assessment 7. Governance or audit framework 8. Benchmarking data
c. Technical, semantic	1. Standards, Specifications 2. Information model 3. Knowledge model 4. Data set specification 5. Terminology resource 6. Mappings 7. Architecture specification 8. Message or interface model 9. Component engineering specification 10. Specification guidelines 11. Interoperability profile 12. Implementation guidelines 13. Engineering artefact (software) 14. Source code 15. Software service (e.g. hosted) 16. Conformance specification 17. Conformance guidelines 18. Test plan 19. Test data set 20. Test guidelines 21. Benchmarking data 22. Deployment guidelines
1.3. Use cases supported	
• Patient summary, chronic diseases, continuity of care • ePrescription • Patient registries, public health, research (epidemiology, clinical trials) • Rare diseases, European Reference Networks • Medical imaging information sharing • Hospital diagnostic imaging workflow • Laboratory information sharing	

- Hospital laboratory workflow
- Tele-monitoring of chronic diseases (hospital / home), telemedicine services
- Integrated neonatal care
- Well-being management information shared within EHRs
- Other cross-border or within border use case

1.4. Scope/purpose

- Scope/purpose

1.5. Domain coverage

- Cardiology/Vascular Diseases
- Community care
- Dental and Oral Health
- Dermatology
- Devices
- Endocrinology
- Emergency: medical
- Emergency: trauma, surgery
- Family Medicine
- Gastroenterology
- Genetic Disease
- Hematology
- Hepatology (Liver, Pancreatic, Gall Bladder)
- Immunology
- Infections and Infectious Diseases
- Internal Medicine
- Medical imaging
- Mobility and frailty
- Musculoskeletal
- Nephrology
- Neurology
- Nutrition and Weight Loss
- Obstetrics/Gynecology (Women's Health)
- Oncology
- Ophthalmology
- Orthopedics/Orthopedic Surgery
- Otolaryngology (Ear, Nose, Throat)
- Pathology
- Pediatrics/Neonatology
- Pharmacology/Toxicology
- Physiotherapy and rehabilitation
- Podiatry
- Prevention and Wellness
- Psychiatry/Psychology
- Pulmonary/Respiratory Diseases
- Rheumatology
- Sleep

- Urology
- Vaccines
- Other (please specify)

1.6. Targeted user groups

- IT developers
- IT business analysts
- Terminologists and linguists
- Managers and decision makers
- Clinicians
- Health informatics experts
- Lawyers
- Policy-makers
- Other (Please specify)

1.7 Type of license

- Copyright protected
- Attribution (CC-BY)
- Attribution Share Alike (CC-BY-SA)
- Attribution No Derivatives (CC-BY-ND)
- Attribution Non-Commercial (CC-BY-NC)
- Attribution Non-Commercial Share Alike (CC-BY-NC-SA)
- Attribution Non-Commercial No Derivatives (CC-BY-NC-ND)
- Open source license (Please detail)
- Public domain

1.8 Language

(list of languages is not included to reduce the length of the document)

1.9 Certification

- Certification

1.10. Revision cycle

- Expected revision

2. Development process

2.1. Evidence used

1. Guideline (complies with or aligns with one or more specified evidence based clinical guidelines or equivalent good practice publications)
2. Literature review and meta-analysis (design or content has been informed by published evidence, in the literature)
3. Regional/National practice (design or content reflects the consensus of existing practice within a health region or country)
4. Local practice (design or content reflects the consensus of opinions or practices within a participating community such as a single care setting, a research consortium, an advisory board or a focus group).
5. No evidence

2.2. Consultation process

1. An open access consultation process was used, resulting in >50 respondents spanning multiple relevant stakeholder groups
2. A wide multi-organisation and multi-stakeholder consultation process was adopted at some point in the development life-cycle (resulting in

>20 respondents)
3. At least one representative from most stakeholder groups who might be users or impacted by the asset's use were consulted on requirements or to peer review the design or completed asset
4. <5 independent domain experts were consulted on requirements or to peer review the design or completed asset
5. Only those experts directly engaged in the asset development were consulted

2.3. Conformance to standards

1. Fully conforms to the following standards: ….
2. Has drawn on and complies to some extent to the following standards: ….
3. Conform to, or aligns, with the following other assets: …
4. Has not adhered to any standards
5. Not relevant

2.4. Quality processes used:

1. External quality control process based in ISO9000 or other recognised methodologies
2. External quality control process
3. Internal quality control process
4. No verified quality control process
5. Not relevant

3. Maturity level

3.1. Technical completeness

- TRL 9. Actual system proven in operational environment (competitive manufacturing in the case of key enabling technologies; or in space)
- TRL 8. System complete and qualified
- TRL 7. System prototype demonstration in operational environment
- TRL 6. Technology demonstrated in relevant environment (industrially relevant environment in the case of key enabling technologies)
- TRL 5. Technology validated in relevant environment (industrially relevant environment in the case of key enabling technologies)
- TRL 4. Technology validated in lab
- TRL 3. Experimental proof of concept
- TRL 2. Technology concept formulated
- TRL 1. Basic principles observed
- Not relevant

3.2. Domain completeness

1. Full coverage for multiple domains
2. Full coverage of the stated domain
3. Partial (incomplete) coverage of the stated domain
4. Not relevant

3.3. Adoption scale

1. Multiple countries for cross border care
2. National healthcare provider
3. Regional healthcare provider
4. Local healthcare provider

5. Not deployed yet

3.3. Market adoption

1. Adopted by most commercial solutions (more than 75%)
2. Wide adoption in commercial solutions (more than 30%)
3. Adopted by multiple commercial solutions
4. Adopted by a small number of commercial solutions
5. Not adopted yet by commercial solutions

4. Trustworthiness

4.1. Endorsements

1. Governmental policy or strategy or law
2. National Healthcare provider
3. European scientific or international scientific society
4. National Scientific society
5. National or European Patient Association
6. Regional Healthcare provider
7. Regional Scientific society
8. Small/Medium healthcare provider
9. Non-profit organization
10. Company customer or research project testimonials
11. Not relevant

4.2. Reliability of access

1. The asset is held and made available by an organisation that has committed to making it available indefinitely.
2. The asset is held and made available by an organisation that has committed to making it available for at least the next three years.
3. The asset is held and made available by an organisation that has committed to making it available for at least the next year.
4. The asset is being held by a temporary body, and plans are in place for it to be transferred to a long-term source.
5. The asset is being held by a temporary body, and there are no plans as yet in place for it to be transferred to a long-term source.

4.3. Communities of use

1. This asset has both user and developer communities, available online, to provide support in how to use the asset and to receive new requirements that might be incorporated into future versions of it.
2. An online community exists, and may be contacted, to provide advice and to share experiences and how best to use the asset.
3. Apart from other asset users, it is possible to find and seek advice from experts who have substantial knowledge about how the asset may best be used, and any localisation issues that may be required (not necessarily free of charge).
4. It is possible to find and contact other asset users, who may be able to share their experience and offer advice, on an informal basis.
5. The original development group, or the present asset holder, is available to provide support and guidance to downstream users of the asset (not necessarily free of charge).
6. Not relevant

5. Technical support & skills

5.1. Extent of documentation and training
1. Technical documentation and certified training program based on the technical specification with a large volume of examples for adapt the proposed implementation in multiple scenarios 2. Technical documentation and training program based on the technical specification with a large volume of examples for adapt the proposed implementation in multiple scenarios 3. Technical documentation based on the technical specification with a large volume of examples for adapt the proposed implementation in multiple scenarios 4. Technical documentation only, based on the technical specification 5. Not relevant
5.2. Extent of tool guidance
1. There are available tools able to support the definition, validation and certification of this class of assets 2. There are available tools able to support the definition and validation of this class of assets 3. There are available tools able to support the definition of this class of assets 4. There are not tools to support the use of this class of asset 5. Not relevant
5.3. Third party Support
1. There is available third party support 24/7 2. There is available third party support on office hours 3. There is not third party support for the implementation 4. Not relevant
5.4. Skills required
1. There are not previous skills required 2. General background in the asset field 3. Specialised background associated with the asset field 4. Specialised background that have some previous knowledge about those related assets and specifications/regulations 5. Professionals with specialised training program and expertise in those related assets and specifications/regulations 6. Not relevant
6. Sustainability
6.1. Viable business model
1. The asset has an established adoption model, evidenced by its uptake and business success. 2. The organisation holding or productising the asset has a formal business plan for its sustainability and maintenance. 3. A business model has been developed to define the market for this asset, including a financial model for purchasers and providers, for products or services that incorporate this asset. 4. An outline business model has been developed for this asset, giving some confidence of its viability. 5. Multi-stakeholder value propositions have been developed for this asset, indicating why it should be successfully adopted.

6. Some basic work has been undertaken to indicate why this asset provides a useful business purpose.
7. No formal work has yet been done to establish the business case for the wide-scale adoption of this asset.
8. Not relevant

6.2. Extensibility

1. Designed to be extended by others including feedback from open consultation into review cycles and yearly maintenance
2. Designed to be extended by others including feedback from open consultation into review cycles
3. Designed to be extended by others without including feedback from open consultation into review cycles with maintenance
4. Relevant example of implementation of the selected domain that could be reused or adapt in other implementations
5. Not relevant

7. Semantic Interoperability

7.1. Clinical information model specification

1. Based on standard specification
2. Based on open specification
3. Based on proprietary solution
4. Not relevant

7.2. Clinical information model Terminology Binding

1. All of the nodes defined in the clinical information models have been mapped to international terminologies
2. Some of the nodes defined in the clinical information models have been mapped to international terminologies
3. All of the nodes defined in the clinical information models have been mapped to local terminologies
4. Not relevant

7.3. Value sets

1. All the terms were mapped to international terminologies
2. Some the terms were mapped to international terminologies
3. The terms were mapped to local terminologies
4. There is not terms mapped to terminologies
5. Not relevant

8. Cost & effort

8.1. Validation Cost

1. The validation and certification program is based on third party organization
2. Certification and validation is partially supported by third party organization and there are validation tools and example of models (e.g. schematrons) available to support validate the local implementation
3. There are validation tools but there is not example of models (e.g. schematrons) available to support validate the local implementation
4. There is not validation tools
5. Not relevant

8.2. Asset Cost

1. The selected asset is free of charge for any purpose
2. Free for non commercial use
3. Costs are covered by a framework contract (e.g. governmental)
4. It is needed to pay in order to use the selected asset
5. Not relevant

8.3. Effort for required implementation

1. The selected implementation requires that system process less than 5 Clinical Entries
2. The selected implementation requires that system process less than 15 Clinical Entries
3. The selected implementation requires that system process less than 30 Clinical Entries
4. The selected implementation requires that system process less than 50 Clinical Entries
5. The selected implementation requires that system process more than 50 Clinical Entries
6. Not relevant

8.4. Maintainance effort

1. Minimal maintenance effort is required foreseen to adopt this asset
2. It is recommended that adopters assign resources to implement new releases regularly that could be automatised to be incorporated in their system
3. It is recommended that adopters assign resources to implement new releases regularly that might impact on their system
4. .Not relevant

9. Maintainance

9.1 Problem resolution by the asset custodian

1. Change management process based on priorisation according to team leader and open consultation for evaluating complexity, gravity and feasibility of change
2. Change management process based on priorisation according to team leader for evaluating complexity, gravity and feasibility of change
3. Not implemented process for change management
4. Not relevant

9.2 Updating process

1. The update process has a regular updating process with new releases every 6 months or less
2. The update process has a regular updating process with new releases every year or less
3. The update process has not planed regular updates but new releases are foreseen in the future
4. There is not update process defined
5. Not relevant

9.3 Response to incidents by asset custodian

1. Critical incidents and problems have a maximum allowed time to be addressed
2. There are enough resources to address incidents and problems in a

reasonable time 3. There are not resources to address incidents and problems in short period of time 4. Not relevant
10.1. Alignment and usability with other assets
• Implementation of another asset • Sub-component of another asset • Incorporates another asset • Extends another asset • Supports adoption of another asset • Provides evidence for another asset • Supersedes another asset
10.2. Misalignment and usability with other assets
• Partially overlaps with the following asset • Fully overlaps with the following asset
11.1. Access information
• Originating project or initiative • Current custodian/curator • Current release version • Version and date of Asset descriptors and quality metrics • Dependences • Enquiry and access channels • Register information provider

Table 73. Full list of the defined descriptors for the Interoperability Asset Quality Framework

E.4. epSOS patient summary

Asset name	epSOS patient Summary
Asset type	Technical / information model
Use cases supported	Patient summary, chronic diseases, continuity of care
Scope/purpose	Supporting cross border access to patient information for emergency purposes
Domain coverage	Trauma (Emergency, Injury, Surgery)
Targeted user groups	IT developers

Quality metrics for Technical assets				
200	**Development process**	0.6575	Selection	Free text for additional information
201	**Evidence used**	0.5	3. Regional/National practice (design or content reflects the consensus of existing practice within a health region or co	
202	**Consultation process**	0.8	2. A wide multi-organisation and multi-stakeholder consultation process was adopted at some point in the developmer	
203	**Conformance to standards**	1	1. Fully conforms to the following standards:	HL7 CDA
204	**Quality processes used**	0.33	3. Internal quality control process	
300	**Maturity level**	1	Selection	Free text for additional information
301	**Technical completeness**	1	1. Validated: Final version tested and deployed (production version, has been formally evaluated and/or already usec	
302	**Domain completeness**	1	1. Full coverage for multiple domains	
303	**Adoption scale**	1	1. Deployed and used in multiple countries	
400	**Trustworthiness**	0.5	Selection	Free text for additional information
401	**Endorsements**	0.9	2. National Healthcare provider	
402	**Reliability of access**	0.4	4. The asset is being held by a temporary body, and plans are in place for it to be transferred to a long-term source.	
403	**Communities of use**	0.2	5. The original development group, or the present asset holder, is available to provide support and guidance to downs	
500	**Support & skills**	0.5375	Selection	Free text for additional information
501	**Extent of documentation and training**	0.75	2. Technical documentation and training program based on the technical specification with a large volume of example	
502	**Extent of tool guidance**	1	1. There are available tools able to support the definition, validation and certification of the selected CIM	
503	**Commercial Support**	0	3. There is not commercial support for the implementation	
504	**Skills required**	0.4	4. IT professionals with specialised training program in the selected specification and experienced in previous SOA/	
600	**Sustainability**	0.53571	Selection	Free text for additional information
601	**Viable business model**	0.57143	4. An outline business model has been developed for this asset, giving some confidence of its viability.	
603	**Extensibility**	0.5	3. Designed to be extended by others without including feedback from open consultation into review cycles with mai	
700	**Semantic interoperability**	1	Selection	Free text for additional information
701	**Clinical information models**	1	1. Based on standard specification and all their nodes v	mapped to international terminologies
702	**Value sets**	1	1. All the terms were mapped to international terminologies	
800	**Cost & Effort**	0.725	Selection	Free text for additional information
801	**Validation Cost**	1	1. The validation and certification program is based on third party organization	
802	**Asset Cost**	1	1. The selected asset is free of charge for any purpose	
803	**Effort for required implementation**	0.4	4. The selected implementation requires that system process less than 50 Clinical Entries	
903	**Maintainance effort**	0.5	2. It is recommended that adopters assign resources to implement new releases regularly that could be automatised to	
900	**Maintainance**	0.44333	Selection	Free text for additional information
901	**Change Management & Problem resolution**	0.5	2. Change management process based on priorisation according to team leader for evaluating complexity, gravity and	
902	**Updating process**	0.33	3. The update process has not planed regular updates but new releases are foreseen in the future	
903	**response to incidents & problems**	0.5	2. There are enough resources to address incidents and problems in a reasonable time	

Figure 60. Detailed evaluation of the epSOS patient summary

- **Development process** Fairly good. It could be improved with external quality assurance and open consultation. Moreover it is based on common practice but not supported by guideline (we expect that in future guidelines will promote the use of information models)
- **Maturity** Maximum level based on the implementation on multiple countries, full coverage of the multiple domains addressed
- **Trustworthiness:** It has the support of national healthcare providers but it is not sure who will support this asset in the future and there is not a community of support
- **Support & skills:** There are certified training programs, technical documentation and examples but this documentation is directed for experts in the selected specification and there is not commercial IT support for the selected specification
- **Semantic interoperability:** maximum level
- **Cost & effort:** This specification is free and certification can be done by third party but it requires to implement a large volume of clinical concepts and it is recommended to include cost for maintenance

- **Maintenance:** change management is directed without collecting open consultation from end users for prioritisation, uncertainties about the future release process and there is not a maximum time to address incidents and problems with the specification

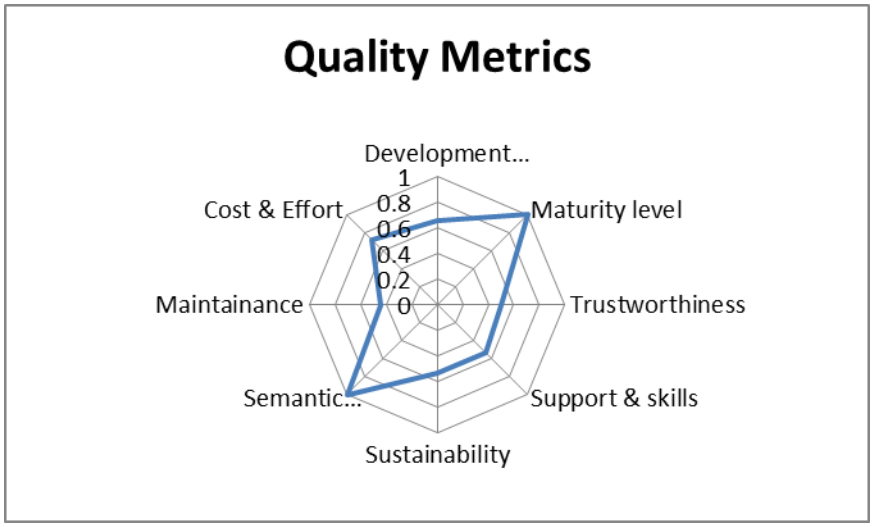


Figure 61. Graphical representation of epSOS patient Summary quality evaluation

E.5. SemanticHealthNet heart failure patient summary

Asset name	SHN Heart Failure patient summary
Asset type	Technical / Information model
Use cases supported	Patient summary, chronic diseases, continuity of care
Scope/purpose	Supporting continuity of care for heart failure patients
Domain coverage	Cardiology/Vascular Diseases
Targeted user groups	IT developers

Quality metrics for Technical assets				
200	**Development process**	0.7825	Selection	Free text for additional information
201	**Evidence used**	1	1. Guideline (complies with or aligns with one or more specified evidence based clinical guidelines or equivalent good	
202	**Consultation process**	0.8	2. A wide multi-organisation and multi-stakeholder consultation process was adopted at some point in the developmen	
203	**Conformance to standards**	1	1. Fully conforms to the following standards:	HL7 CDA, ISO13606, openEHR
204	**Quality processes used**	0.33	3. Internal quality control process	
300	**Maturity level**	0.58333	Selection	Free text for additional information
301	**Technical completeness**	0.75	2. Published: Final version ready to deploy (production version, suitable for use in real world settings, but not formall	
302	**Domain completeness**	1	2. Full coverage of the stated domain	
303	**Adoption scale**	0	8. Not deployed yet	
400	**Trustworthiness**	0.36667	Selection	Free text for additional information
401	**Endorsements**	0.1	10. Company customer or research project testimonials	
402	**Reliability of access**	0.8	2. The asset is held and made available by an organisation that has committed to making it available for at least the ne	
403	**Communities of use**	0.2	5. The original development group, or the present asset holder, is available to provide support and guidance to downs	
500	**Support & skills**	#N/A	Selection	Free text for additional information
501	**Extent of documentation and training**	#N/A	4. Technical documentation based on the technical specification	
502	**Extent of tool guidance**	0.5	2. There are available tools able to support the definition and validation of the selected CIM	
503	**Commercial Support**	0	3. There is not commercial support for the implementation	
504	**Skills required**	0.4	4. IT professionals with specialised training program in the selected specification and experienced in previous SOA/	
600	**Sustainability**	0.67857	Selection	Free text for additional information
601	**Viable business model**	0.85714	2. The organisation holding or productising the asset has a formal business plan for its sustainability and maintenanc	
603	**Extensibility**	0.5	3. Designed to be extended by others without including feedback from open consultation into review cycles with mai	
700	**Semantic interoperability**	1	Selection	Free text for additional information
701	**Clinical information models**	1	1. Based on standard specification and all their nodes were mapped to international terminologies	
702	**Value sets**	1	1. All the terms were mapped to international terminologies	
800	**Cost & Effort**	0.8175	Selection	Free text for additional information
801	**Validation Cost**	0.67	2. Certification and validation is partially supported by third party organization and there are validation tools and ex	
802	**Asset Cost**	1	1. The selected asset is free of charge for any purpose	
803	**Effort for required implementation**	0.6	3. The selected implementation requires that system process less than 30 Clinical Entries	
903	**Maintainance effort**	1	1. It is not required to include maintainance effort to adopt this asset	
900	**Maintainance**	0.33333	Selection	Free text for additional information
901	**Change Management & Problem resolution**	1	1. Change management process based on priorisation according to team leader and open consultation for evaluating c	
902	**Updating process**	0	4. There is not update process defined	
903	**response to incidents & problems**	0	3. There are not resources to address incidents and problems in short period of time	

Figure 62. Detailed evaluation of the SemanticHealthNet heart failure patient summary

- **Development process** Fairly good. It could be improved with external quality assurance and open consultation. It is based on the review of the Heart Failure guideline (we expect that in future guidelines will promote the use of information models)
- **Maturity** Medium since it is ready to be implemented but it was not implemented, full coverage of the multiple domains addressed
- **Trustworthiness:** Medium. It is based on research project but it is not sure who will support this asset in the future and there is not a community of support
- **Support & skills:** There are certified training programs, technical documentation without many examples but this documentation is directed for experts in the selected specification and there is not commercial IT support for the selected specification
- **Semantic interoperability:** maximum level
- **Cost & effort:** High. This specification is free and certification can be done by third party but it requires to implement a large volume of clinical concepts and it is recommended to include cost for maintenance

- **Maintenance: Low level of maintenance.** Change management is directed without collecting open consultation from end users for prioritisation, there are not planed the future release process and there is not resources for assigned to address incidents and problems with the specification

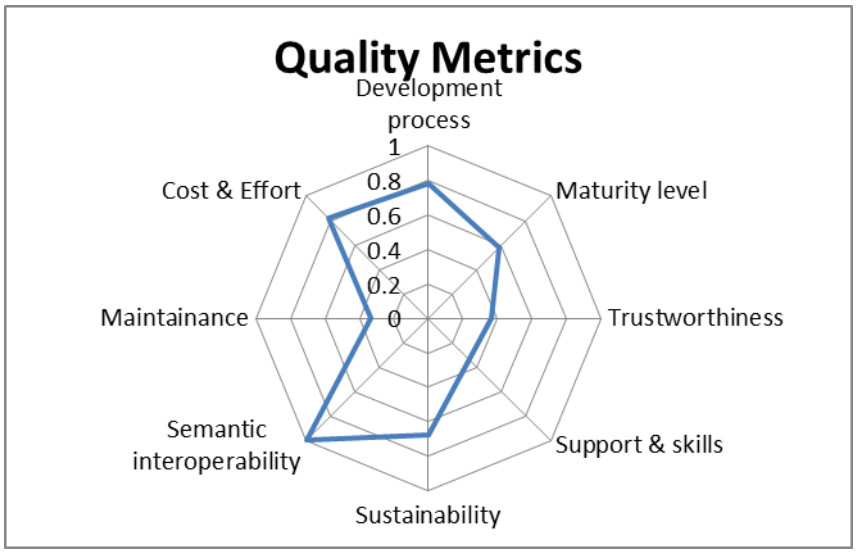


Figure 63. Graphical representation of SemanticHealthNet Heart failure patient Summary quality evaluation

E.6. openEHR allergy archetype

Asset name	openEHR allergy archetype
Asset type	Technical
Use cases supported	Other cross-border or within border use case
Scope/purpose	Structure allergy information for immunology purposes
Domain coverage	Immunology
Targeted user groups	Health informatics experts, IT developers

Quality metrics for Technical assets				
200	**Development process**	0.855	Selection	Free text for additional information
201	**Evidence used**	0.75	2. Literature review and meta-analysis (design or content has been informed by published evidence, in the literature)	
202	**Consultation process**	1	1. An open access consultation process was used, resulting in >50 respondents spanning multiple relevant stakeholder	
203	**Conformance to standards**	1	1. Fully conforms to the following standards:	openEHR
204	**Quality processes used**	0.67	2. External quality control process	
300	**Maturity level**	0.80952	Selection	Free text for additional information
301	**Technical completeness**	1	1. Validated: Final version tested and deployed (production version, has been formally evaluated and/or already usec	
302	**Domain completeness**	1	2. Full coverage of the stated domain	
303	**Adoption scale**	0.42857	5. Incorporated into deployable products - commercial or non-commercial (will only apply to some kinds of asset)	
400	**Trustworthiness**	0.73333	Selection	Free text for additional information
401	**Endorsements**	0.2	9. Non-profit organization	
402	**Reliability of access**	1	1. The asset is held and made available by an organisation that has committed to making it available indefinitely.	
403	**Communities of use**	1	1. This asset has both user and developer communities, available online, to provide support in how to use the asset a	
500	**Support & skills**	0.4875	Selection	Free text for additional information
501	**Extent of documentation and training**	0.75	2. Technical documentation and training program based on the technical specification with a large volume of example	
502	**Extent of tool guidance**	0.5	2. There are available tools able to support the definition and validation of the selected CIM	
503	**Commercial Support**	0.5	2. There is available commercial support on office hours	
504	**Skills required**	0.2	5. Experts in clinical information modeling and IT professionals with certified training program in the selected spec	
600	**Sustainability**	0.80357	Selection	Free text for additional information
601	**Viable business model**	0.85714	2. The organisation holding or productising the asset has a formal business plan for its sustainability and maintenanc	
603	**Extensibility**	0.75	2. Designed to be extended by others including feedback from open consultation into review cycles	
700	**Semantic interoperability**	0.615	Selection	Free text for additional information
701	**Clinical information models**	0.56	5. Based on a open specification and some of their nodes are mapped to international terminologies	
702	**Value sets**	0.67	2. Some the terms were mapped to international terminologies	
800	**Cost & Effort**	0.5425	Selection	Free text for additional information
801	**Validation Cost**	0.67	2. Certification and validation is partially supported by third party organization and there are validation tools and e	
802	**Asset Cost**	0.5	2. Free for non commercial use	
803	**Effort for required implementation**	1	1. The selected implementation requires that system process less than 5 Clinical Entries	
804	**Maintainance effort**	0	3. It is recommended that adopters assign resources to implement new releases regularly that might impact on their sy	
900	**Maintainance**	0.61	Selection	Free text for additional information
901	**Change Management & Problem resolution**	1	1. Change management process based on priorisation according to team leader and open consultation for evaluating	
902	**Updating process**	0.33	3. The update process has not planed regular updates but new releases are foreseen in the future	
903	**response to incidents & problems**	0.5	2. There are enough resources to address incidents and problems in a reasonable time	

Figure 64. Detailed evaluation of the openEHR allergy archetype

- **Development process** good. Based on open participation. It could be improved with external quality assurance. it is based on common practice by guideline (we expect that in future guidelines will promote the use of information models)

- **Maturity** Good. Specification ready to deploy already implemented in some systems, full coverage of the addressed domain
- **Trustworthiness:** Although it is just promoted by an non-profit organisation, this organisation is committed to support it and has a community of support
- **Support & skills:** There are training programs, technical documentation and examples but this documentation is directed for clinical information modelling experts and there is not commercial IT. (Commercial IT support could be provided by Ocean Informatics)
- **Semantic interoperability:** Medium. Not all entries or value sets are mapped to terminology and it is an open specification not international standard
- **Cost & effort:** Medium. This specification is free for not commercial use and certification can be done by third party but it requires to implement a low volume of clinical concepts and it is recommended to include cost for maintenance
- **Maintenance:** change management is directed collecting open consultation from end users for prioritisation, there are not plan regular updates and there is not a maximum time to address incidents and problems with the specification

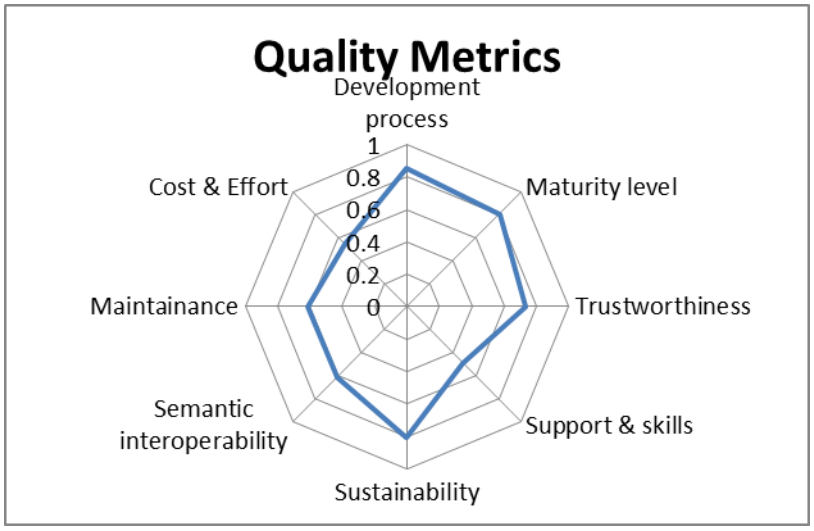


Figure 65. Graphical representation of openEHR allergy archetype quality evaluation

E.7. Intermountain allergy Clinical Element Model

Asset name	Intermountain allergy CEM
Asset type	Technical
Use cases supported	Other cross-border or within border use case
Scope/purpose	Structure allergy information for immunology purposes
Domain coverage	Immunology
Targeted user groups	Health informatics experts, IT developers

Quality metrics for Technical assets

200	**Development process**	0.6075	Selection	Free text for additional information
201	**Evidence used**	0.5	3. Regional/National practice (design or content reflects the consensus of existing practice within a health region or co	
202	**Consultation process**	0.6	3. At least one representative from most stakeholder groups who might be users or impacted by the asset's use were co	
203	**Conformance to standards**	1	1. Fully conforms to the following standards:	CEM
204	**Quality processes used**	0.33	3. Internal quality control process	
300	**Maturity level**	0.90476	Selection	Free text for additional information
301	**Technical completeness**	1	1. Validated: Final version tested and deployed (production version, has been formally evaluated and/or already use	
302	**Domain completeness**	1	2. Full coverage of the stated domain	
303	**Adoption scale**	0.71429	3. Deployed and used in multiple healthcare providers in a region or country	
400	**Trustworthiness**	0.56667	Selection	Free text for additional information
401	**Endorsements**	0.5	6. Regional Healthcare provider	
402	**Reliability of access**	1	1. The asset is held and made available by an organisation that has committed to making it available indefinitely.	
403	**Communities of use**	0.2	5. The original development group, or the present asset holder, is available to provide support and guidance to down	
500	**Support & skills**	#N/A	Selection	Free text for additional information
501	**Extent of documentation and training**	#N/A	4. Technical documentation based on the technical specification	
502	**Extent of tool guidance**	0	3. There are available tools able to support the definition of the selected CIM	
503	**Commercial Support**	0	3. There is not commercial support for the implementation	
504	**Skills required**	0.2	5. Experts in clinical information modeling and IT professionals with certified training program in the selected spec	
600	**Sustainability**	0.46429	Selection	Free text for additional information
601	**Viable business model**	0.42857	5. Multi-stakeholder value propositions have been developed for this asset, indicating why it should be successfully a	
603	**Extensibility**	0.5	3. Designed to be extended by others without including feedback from open consultation into review cycles with mai	
700	**Semantic interoperability**	0.835	Selection	Free text for additional information
701	**Clinical information models**	0.67	4. Based on a open specification and all of their nodes map d to international terminologies	
702	**Value sets**	1	1. All the terms were mapped to international terminologies	
800	**Cost & Effort**	0.8325	Selection	Free text for additional information
801	**Validation Cost**	0.33	3. There are validation tools but there is not example of models (e.g. schematrons) available to support validate the l	
802	**Asset Cost**	1	1. The selected asset is free of charge for any purpose	
803	**Effort for required implementation**	1	1. The selected implementation requires that system process less than 5 Clinical Entries	
804	**Maintainance effort**	1	1. It is not required to include maintainance effort to adopt this asset	
900	**Maintainance**	0.44333	Selection	Free text for additional information
901	**Change Management & Problem resolution**	0.5	2. Change management process based on priorisation according to team leader for evaluating complexity, gravity and	
902	**Updating process**	0.33	3. The update process has not planed regular updates but new releases are foreseen in the future	
903	**response to incidents & problems**	0.5	2. There are enough resources to address incidents and problems in a reasonable time	

Figure 66. Detailed evaluation of the Intermountain allergy CEM

- **Development process Fairly good**. It could be improved with external quality assurance and open consultation. Moreover it is based on common practice but not supported by guideline (we expect that in future guidelines will promote the use of information models)

- **Maturity High** level based on the implementation on multiple health centers in a region, full coverage of the multiple domains addressed
- **Trustworthiness: Medium.** It has the support of regional healthcare providers that will support this asset in the future and there is not a community of support
- **Support & skills: Low** There are limited training programs, technical documentation and examples but this documentation is directed for experts in the selected specification and there is not commercial IT support for the selected specification
- **Semantic interoperability:** High level since value sets and entries are mapped to terminologies but it is considered a local specificarion not international standard
- **Cost & effort:** This specification is free and certification can be provided by a third party. It requires to implement a low volume of clinical concepts and it is recommended to include cost for maintenance
- **Maintenance:** change management is directed without collecting open consultation from end users for prioritisation, release process has not planed regular updates and there is not a maximum time to address incidents and problems with the specification

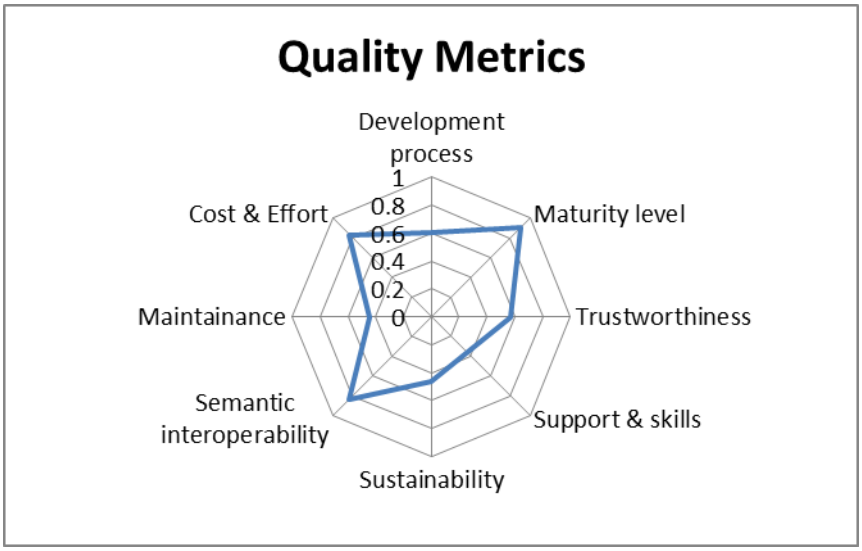


Figure 67. Graphical representation of Intermountain allergy CEM quality evaluation

E.8. Spanish patient summary

Asset name	Spanish patient summary
Asset type	Technical / Information model
Use cases supported	Patient summary, chronic diseases, continuity of care
Scope/purpose	Support the
Domain coverage	Family Medicine
Targeted user groups	IT developers

Descriptors

Quality metrics for Technical assets				
200	**Development process**	0.6575	Selection	Free text for additional information
201	**Evidence used**	0.5	3. Regional/National practice (design or content reflects th	onsensus of existing practice within a health region or co
202	**Consultation process**	0.8	2. A wide multi-organisation and multi-stakeholder consultation process was adopted at some point in the developmen	
203	**Conformance to standards**	1	1. Fully conforms to the following standards:	HL7 CDA, ISO 13606
204	**Quality processes used**	0.33	3. Internal quality control process	
300	**Maturity level**	0.86905	Selection	Free text for additional information
301	**Technical completeness**	0.75	2. Published: Final version ready to deploy (production version, suitable for use in real world settings, but not formal	
302	**Domain completeness**	1	1. Full coverage for multiple domains	
303	**Adoption scale**	0.85714	2. Deployed in the majority of sites in one country	
400	**Trustworthiness**	0.73333	Selection	Free text for additional information
401	**Endorsements**	1	1. Governmental policy or strategy or law	
402	**Reliability of access**	1	1. The asset is held and made available by an organisation that has committed to making it available indefinitely.	
403	**Communities of use**	0.2	5. The original development group, or the present asset holder, is available to provide support and guidance to downs	
500	**Support & skills**	0.2875	Selection	Free text for additional information
501	**Extent of documentation and training**	0.25	4. Technical documentation only, based on the technical specification	
502	**Extent of tool guidance**	0.5	2. There are available tools able to support the definition and validation of the selected CIM	
503	**Commercial Support**	0	3. There is not commercial support for the implementation	
504	**Skills required**	0.4	4. IT professionals with specialised training program in the selected specification and experienced in previous SOA/	
600	**Sustainability**	0.67857	Selection	Free text for additional information
601	**Viable business model**	0.85714	2. The organisation holding or productising the asset has a formal business plan for its sustainability and maintenanc	
603	**Extensibility**	0.5	3. Designed to be extended by others without including feedback from open consultation into review cycles with mai	
700	**Semantic interoperability**	0.78	Selection	Free text for additional information
701	**Clinical information models**	0.89	2. Based on standard specification and some of their nodes were mapped to international terminologies	
702	**Value sets**	0.67	2. Some the terms were mapped to international terminologies	
800	**Cost & Effort**	0.4325	Selection	Free text for additional information
801	**Validation Cost**	0.33	3. There are validation tools but there is not example of models (e.g. schematrons) available to support validate the l	
802	**Asset Cost**	1	1. The selected asset is free of charge for any purpose	
803	**Effort for required implementation**	0.4	4. The selected implementation requires that system process less than 50 Clinical Entries	
804	**Maintainance effort**	0	3. It is recommended that adopters assign resources to implement new releases regularly that might impact on their sys	
900	**Maintainance**	0.55333	Selection	Free text for additional information
901	**Change Management & Problem resolution**	0.5	2. Change management process based on priorisation according to team leader for evaluating complexity, gravity and	
902	**Updating process**	0.66	2. The update process has a regular updating process with new releases every year or less	
903	**response to incidents & problems**	0.5	2. There are enough resources to address incidents and problems in a reasonable time	

Figure 68. Detailed evaluation of the Spanish patient summary

- **Development process** Fairly good. It could be improved with external quality assurance and open consultation. Moreover it is based on common practice but not

supported by guideline (we expect that in future guidelines will promote the use of information models)

- **Maturity** High level. Specification ready to be deployed in most of the centers of a country, full coverage of the multiple domains addressed
- **Trustworthiness:** Based on a national law and Spanish ministry of that is committed to support this asset in the future but there is not community of support more than their contact.
- **Support & skills:** There are certified training programs, technical documentation but documentation is directed for experts in the selected specification and there is not many examples or commercial IT support for the selected specification
- **Semantic interoperability:** Medium level since there are many entries just in free text and they are only partially mapped to terminologies
- **Cost & effort:** This specification is free and there are not many models for validation in tools by third party but it requires to implement a large volume of clinical concepts and it is recommended to include cost for maintenance
- **Maintenance:** change management is directed without collecting open consultation from end users for prioritisation, the project will include regular updates not declared and there are resources to address incidents and problems with the specifications in reasonable amount of time

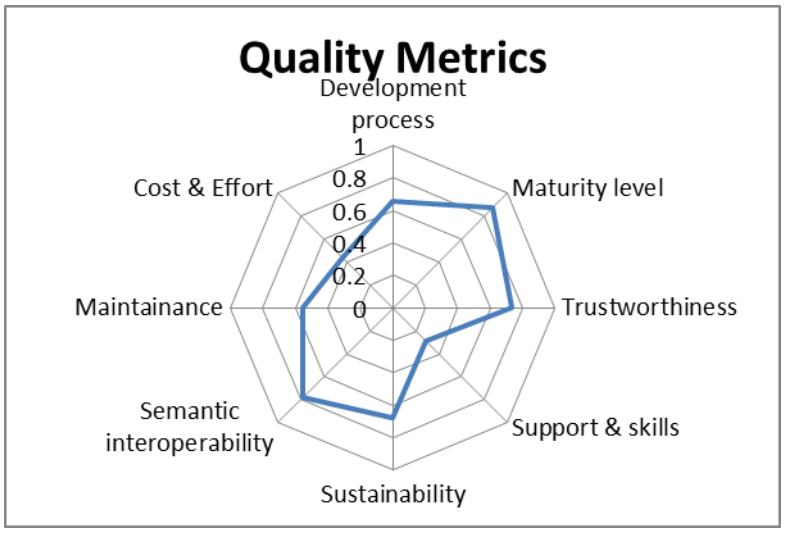


Figure 69. Graphical representation of Spanish patient Summary quality evaluation

Appendix F. Interoperability Asset register architecture

This section details the technological architecture applied to develop the Interoperability Asset register:

- **Adobe ColdFusion** a commercial web application development platform that was designed to make it easier to connect simple HTML pages to a database. The programming language used with that platform is also commonly called ColdFusion, though is more accurately known as ColdFusion Markup Language (CFML). The implemented IA register was based on version 10 of this software.
- **Microsoft SQL Server** a commercial relational database management system. This database server is a software product with the primary function of storing and retrieving data for other software applications. The implemented IA register is based on the version 2005 of the MSSQL server.

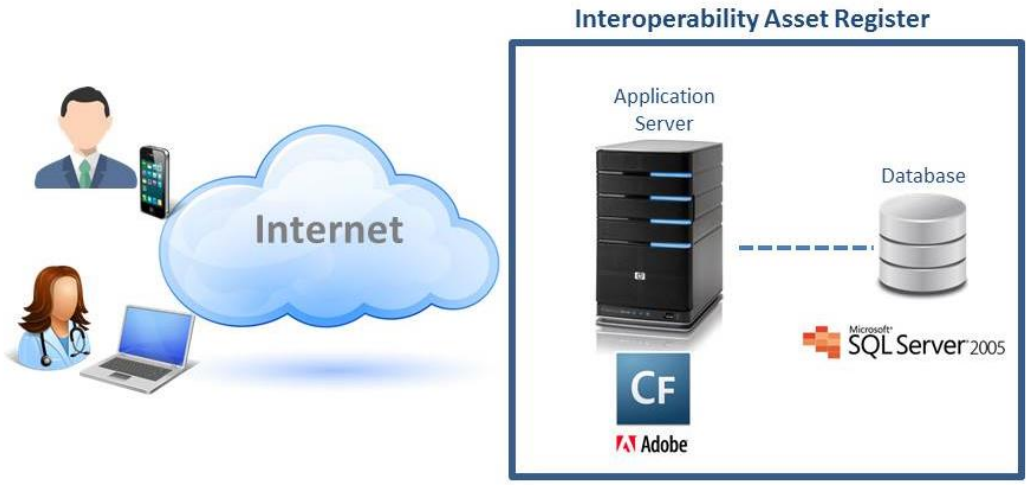


Figure 70. Architecture of the IA register