 THE RESEARCH LEADING TO THESE RESULTS HAS RECEIVED FUNDING FROM THE EUROPEAN UNION'S SEVENTH FRAMEWORK PROGRAM (FP7/2007-2013) FOR CRYSTAL – CRITICAL SYSTEM ENGINEERING ACCELERATION JOINT UNDERTAKING UNDER GRANT AGREEMENT N° 332830 AND FROM SPECIFIC NATIONAL PROGRAMS AND / OR FUNDING AUTHORITIES.

CRitical S**YST**em Engineering **A**cce**L**eration

State of the art for Healthcare ontology

D407.010

DOCUMENT INFORMATION

Project	CRYSTAL
Grant Agreement No.	ARTEMIS-2012-1-332830
Deliverable Title	State of the art for Healthcare ontology
Deliverable No.	D407.010
Dissemination Level	PU
Nature	R
Document Version	V1.0
Date	2013-01-31
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CHANGE HISTORY

Version	Date	Reason for Change	Pages Affected
0.1	18-11-2013	Creation of Table of Contents (TNO)	All
0.11	06-12-2013	Added preliminary content of chapters, first version of long list (TNO)	7-13, Annex I
0.12	12-12-2013	Added action points for project partners (TNO)	7-13
0.2	23-12-2013	Chapters 3.1, 3.2 (TU/e), added standards to long list (ITI)	9-14, Annex I
0.3	13-01-2014	Elaboration on chapter 3.2 (TU/e, TNO), chapters 3.3, 4 (TNO), added standards to long list (Barco, Philips)	13-21, Annex I
0.9	20-01-2014	Chapters 5, 6, finalized document for review (TNO)	All
1.0	31-01-2014	Chapters 1, 2, 4.1.1, 6, process review comments (TNO)	All

CONTENT

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1 Introduction

This chapter introduces the deliverable and the corresponding task and work package to which this deliverable belongs. Next to describing the role of the deliverable within the CRYSTAL project and its relationship to other CRYSTAL documents, also the structure of the document is clarified.

1.1 Role of deliverable

This document is the first deliverable in CRYSTAL work package WP4.7.1, which is concerned with the specification of a domain-specific ontology for the healthcare domain.

The ontology aims to provide common, unambiguous semantics and a vocabulary for the use cases and deliverables in the healthcare domain. It facilitates interoperability between (ICT) systems and tooling environments in the healthcare domain and extends the generic set of engineering concepts of IOS developed in SP6 by adding healthcare domain specific concepts.

This document provides a state-of-the art list and evaluation of resources, standards and initiatives that are relevant to the scope of CRYSTAL Healthcare Domain. It takes input from the healthcare use cases UC4.01, UC4.02, UC4.03, UC4.04, UC4.05 and UC4.06, from previous, related projects (a.o. CESAR) and desk and literature research. There is strong link with similar work being performed in the other CRYSTAL domains. A cross-domain discussion on the scope and use of ontologies in Crystal further adds to the scope of the deliverable. Its outcome is considered in order to identify common approaches and standardization issues.

The resulting list is classified and evaluated on usability and suitability aspects by applying several quality criteria. The end result serves as basis for the definition of the ontology in task T4.7.2.

1.2 Relationship to other CRYSTAL Documents

The results presented in this document will serve as a basis and starting point for deliverables D407.021 and D407.022. These deliverables will define an initial and second version of an ontology definition for the CRYSTAL healthcare domain.

The use cases in SP4 provide input to the ontology definition by scoping the domain of the ontology. This deliverable is related to use case deliverables D401.010, D402.010 and D403.010, which have all included relevant state-of-the art resources, initiatives.

The three other domains present in CRYSTAL (aerospace, automotive and rail) have similar tasks in collecting state-of-the-art and defining an ontology. This deliverable is related to the other state-of the-art deliverables D209.010 (Aerospace), D308.010 (Automotive) and D504.010, by providing a similar result that lists and evaluates relevant resources.

The deliverable is also related to the output of SP6, most notably to T6.1. The RTP interoperability specifications (D601.021, D601.022, and D601.023) in T6.1 a.o. aim to define semantics for IOS, which is the generic engineering foundation for the scope of WP4.7.

1.3 Structure of this document

After this introduction to the deliverable, the following method is used to come up with the content of the document. Between the brackets the corresponding chapters can be found.

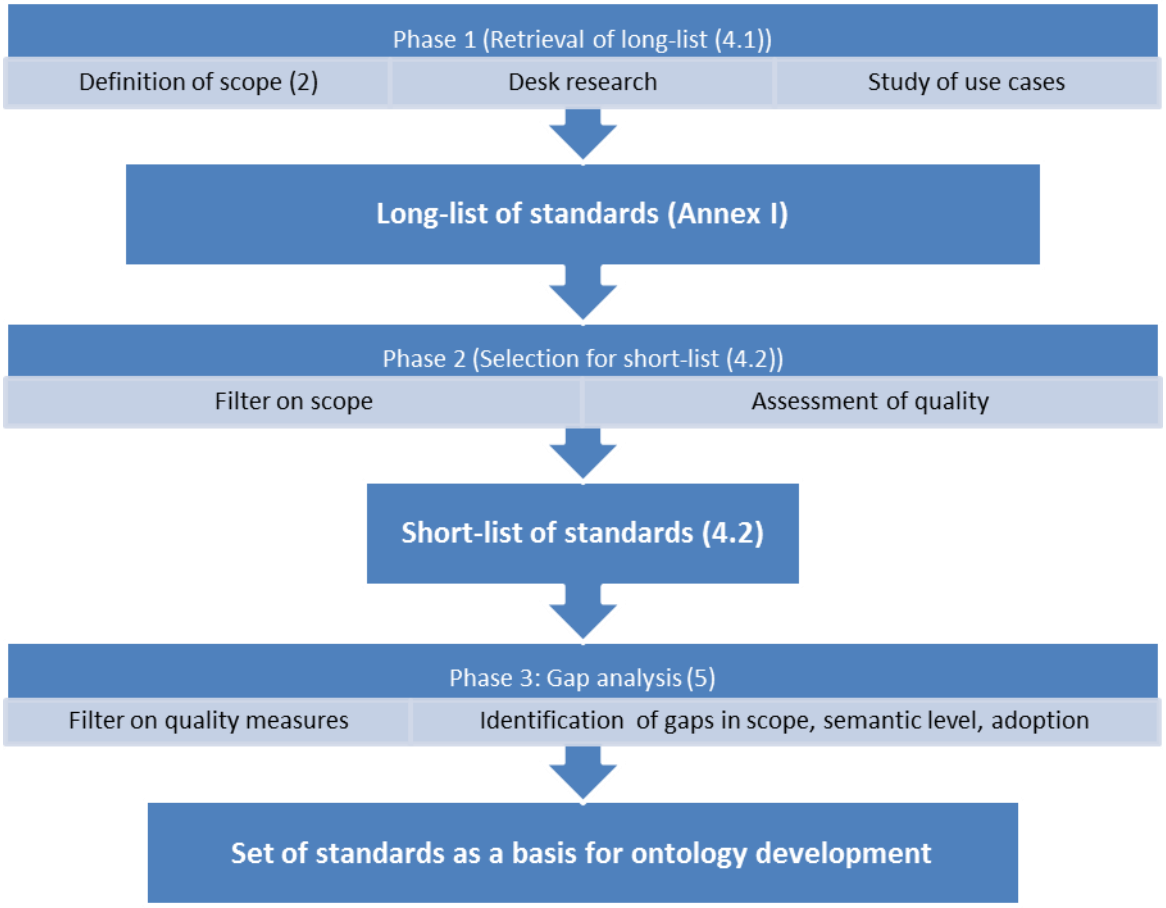


Figure 1-1: Research method

This results in a structure of chapters as follows:

- Chapter two clarifies the scope of the work package of which this deliverable is a result. It reflects on the position of this work related to the work packages in the other domains and the consolidating work package.
- Chapter three gives an introduction to semantics. It gives a classification of semantic models in general and goes into more details about ontologies. The chapter ends with describing specific application possibilities for ontologies within the defined scope.
- Chapter four provides the overview of standards that exist in the healthcare domain. The long-list that is the result of a desk research and studying the use cases is narrowed down to a short-list based on the defined scope. For each standard on the short-list a quality assessment is done.
- Chapter five concludes the deliverable by filtering the short-list on the quality measures. Furthermore, gaps with regards to the standards are identified in terms of scope, semantic level and adoption. This gap analysis is done in order to be able to say whether a solid basis exists for the development of the ontology.

2 Scope definition

The healthcare domain ontology aims to provide common, unambiguous semantics and a vocabulary for the use cases and deliverables in SP4. It facilitates interoperability between (ICT) systems and tooling environments in healthcare systems engineering, in line with the goals of CRYSTAL.

Its generic scope is defined by:

- The domain of systems engineering: the ontology is defined in support of interoperability in the engineering cycle. The ontology has the same role across all four domains defined in CRYSTAL.
- The domain of healthcare systems: the ontology covers healthcare related concepts, systems and devices. The engineering cycle in SP4 targets development of medical systems.

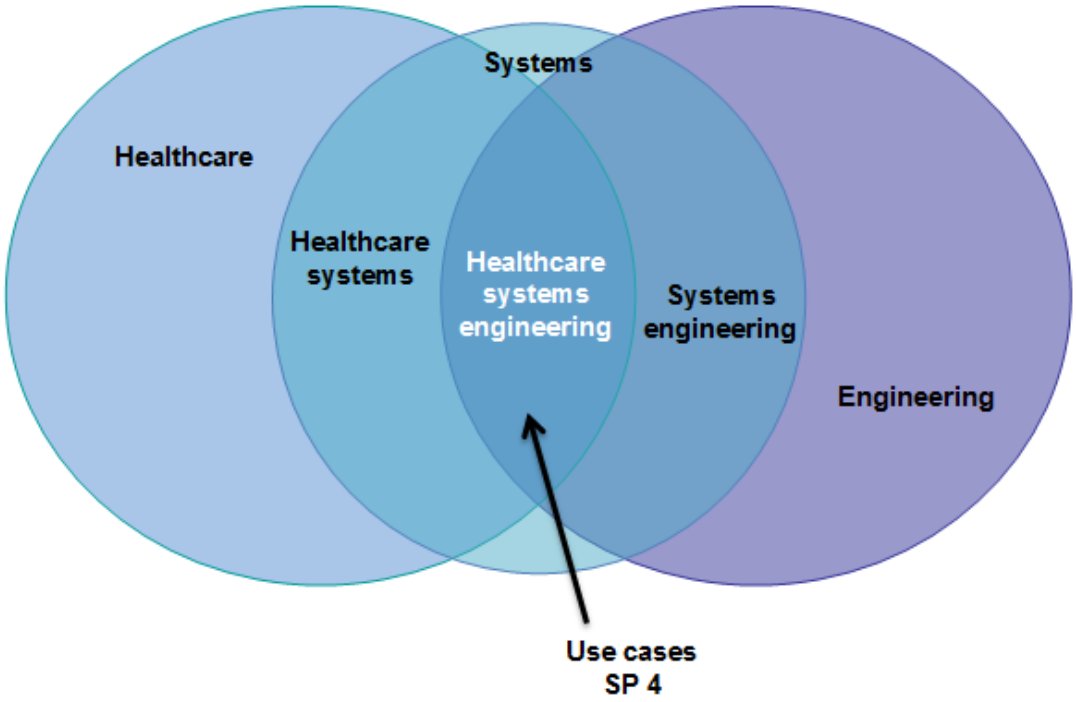


Figure 2-1: Scope of work package 4.7

The domain ontology developed in WP4.7 is thus defined at the intersection of those two domains, as is depicted in Figure 2-1. The use cases in SP4 provide further input to the ontology definition by scoping the application domain of the ontology. Their focus on specific engineering activities and specific healthcare systems, determine the depth and detail of the ontology.

This chapter will further clarify the scope of the ontology.

2.1 Extending IOS

Based on results of previous projects (e.g. CESAR, MBAT, iFest), in which the foundation for an Interoperability Standard (IOS) has been laid out, CRYSTAL evolves the IOS towards a widely accepted standard for engineering platforms usable in scenarios and use cases across multiple domains. The IOS standard features a generic set of engineering concepts and semantics that are further developed in SP6.

IOS evolution is strongly related to the Open Services for Lifecycle Collaboration (OSLC). OSLC is an open community creating specifications and standards for integrating tools. These specifications allow conforming independent software and product lifecycle tools to integrate their data and workflows in support of end-to-end lifecycle processes. OSLC specifies (among others) a common vocabulary and semantics for the lifecycle artifacts in domains in the engineering process, such as change management, test management, requirements management and configuration management.

IOS/OSLC thus provide a basis of engineering process semantics for all domains in CRYSTAL. The activities of the domain ontology work package in each of the CRYSTAL domains will result in extensions for the core vocabulary of IOS/OSLC. There are several ways imaginable to extend this core vocabulary:

- New types/concepts: these concepts or (sub) types for existing concepts are not readily available in the IOS specification. Examples are (medical) risk, harm, medical device, etc.
- New properties/attributes: these extensions may add to the scope of specific concepts in IOS. An examples would be healthcare domain specific test management.
- New links/references: extension by referencing to the domain ontology.
- New specifications: new concepts of engineering activities not currently available in IOS. Examples are safety management, variability, etc.

These extensions may exist on two levels:

- They can be domain specific, i.e. they apply only to the specific domain they are developed in. The concept of medical risk may e.g. only be useful in the healthcare domain and will thus only be present in the healthcare domain ontology.
- They can be made available to other domains, by being fed back to the vocabulary of IOS. Some concepts that are relevant in the separate domains may exhibit a more generic character, i.e. they may prove to be useful and applicable to other domains as well. These extensions could, in collaboration with SP6, be provided as input to the development process of the set of core concepts in IOS.

Figure 2-2 depicts the relation between semantics in domains and IOS.

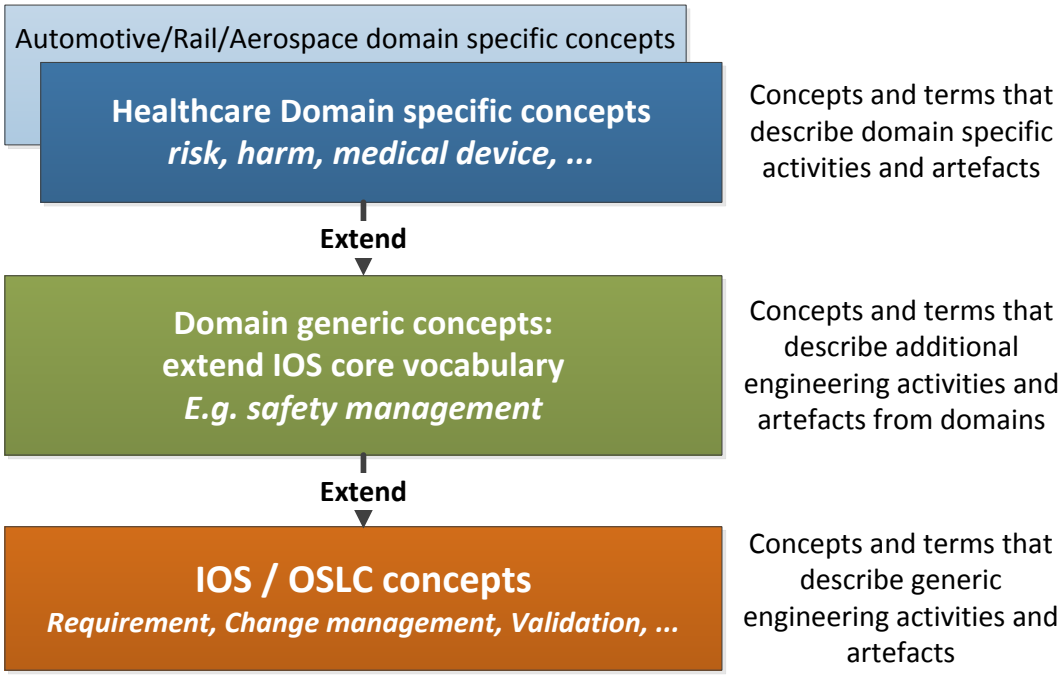


Figure 2-2: Relation between semantics of domains and IOS

2.2 Input from SP4 Use Cases

The domain ontology work packages will look into which concepts play a role in the domain specific systems engineering cycles, with special focus on the use cases in the particular domains. The use cases will deal with artefacts, semantics, activities that are considered in scope for SP4. In other words, they scope the interoperability problem domain the ontology aims to support.

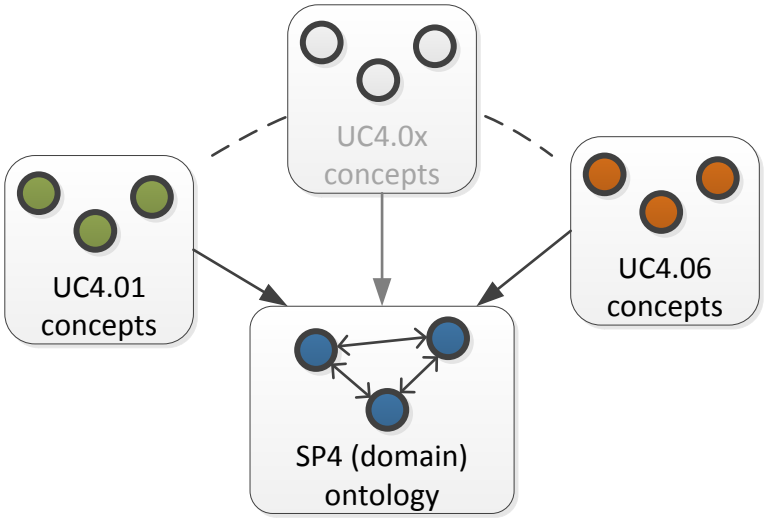


Figure 2-3: Use cases versus domain ontology

For healthcare this means that the ontology work package will focus on:

- The specific systems engineering cycles for the healthcare domain, that are under investigation in use cases UC4.01 to UC4.06.
- Other concepts within the healthcare domain that are related to the systems engineering cycle that may be part of and relevant in the use cases.

3 Introduction to semantics

As the society is getting more and more information-intensive, huge amounts of information are exchanged in order to communicate and collaborate. To get the right results, it must be made sure that everyone and everything understands each other properly. Semantic interoperability is what must be strived for, as this is a state in which it is possible to comprehensively collaborate in the proper context by sharing knowledge. Essential is that the meaning and context, the semantics, associated with a piece of data is made explicit and also recorded explicitly. This makes it possible to provide better and more accurate interpretations and responses, which can be done both by people but also by computers [Verbeek, A., 2009].

Also the healthcare systems engineering world is becoming more information-intensive. Therefore this chapter will give an introduction to semantics and will focus on the multiple semantic models that exist. In more detail the capabilities of the richest form of semantic model, an ontology, will be described, as the purpose of this work package within CRYSTAL is to develop an ontology. This chapter will conclude with an elaboration on the specific application possibilities of ontologies within the healthcare use cases.

3.1 Classification of semantic models

The definition of semantics in the Merriam-Webster Online Dictionary is: “the study of the meanings of words and phrases in language”. In computer science, the term is used to describe the meaning of programming languages or to represent information content in semantic data models. We will be referring to the second meaning within the computer science field in this document.

In relation to semantics, we define controlled vocabularies from the ANSI/NISO Z39.19-2005 standard as a list of terms enumerated explicitly, where at least two rules must be enforced: terms used to qualify different concepts have a name explicitly qualified to resolve the ambiguity and if multiple terms are used to mean the same thing, one of the terms is the preferred term and the others are synonyms or aliases. The most important principles in vocabulary control are: eliminating ambiguity, controlling synonyms, establishing relations among terms where appropriate and testing and validation of terms. The primary purpose of vocabulary control is to achieve consistency in the description of content objects and to facilitate retrieval.

The ANSI/NISO Z39.19-2005 standard is a standard for guidelines for the construction, format, and management of monolingual controlled vocabularies.

There are multiple levels at which we can define semantics and these levels also classify controlled vocabularies. A list of these levels in order of increasing structural complexity is: list, taxonomy, thesaurus and ontology. With the increase in complexity, also the power of the controlled vocabulary increases. A view on the increasing power of the controlled vocabularies is presented in the figure below.

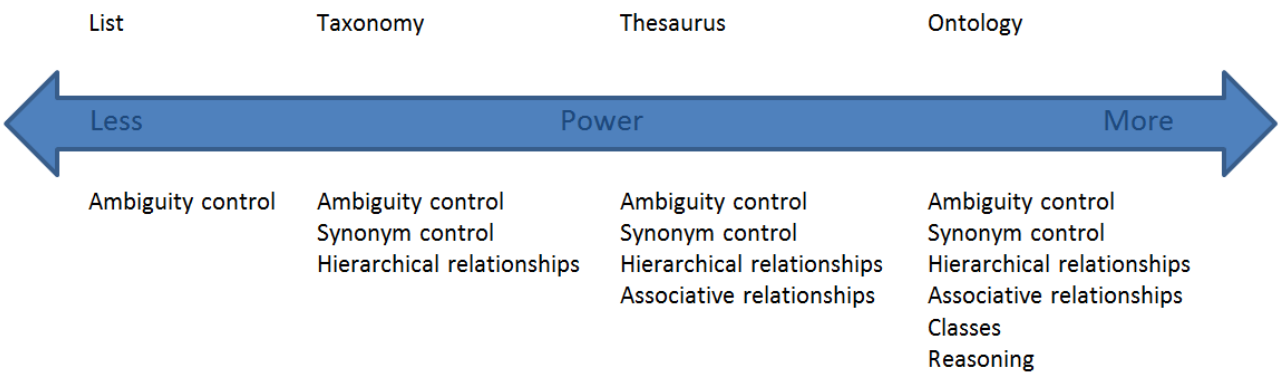


Figure 3-1: Power and complexity of controlled vocabularies

Although there is much debate on the precise definitions and borders between the terms list, taxonomy, thesaurus and ontology, we present the standard definitions and usage.

3.1.1 List

"A list (also sometimes called a pick list) is a limited set of terms arranged as a simple alphabetical list or in some other logically evident way. Lists are used to describe aspects of content objects or entities that have a limited number of possibilities." (from ANSI/NISO Z39.19-2005).

The general structure of a list is depicted in the figure below.

Figure 3-2: General structure of a semantic model - List

Next, we give an example of an alphabetical list and an example of a logical list.

Example alphabetical list:
Albania
Andorra
Armenia
Austria
Azerbaijan
Belarus
Belgium

Example logical list:
Mercury
Venus
Earth
Mars
Jupiter
Saturn
Uranus
Neptune
Pluto

3.1.2 Taxonomy

"A taxonomy is a controlled vocabulary consisting of preferred terms, all of which are connected in a hierarchy or polyhierarchy." (from ANSI/NISO Z39.19-2005).

Taxonomies often put together words (controlled terms) in hierarchical view, meaning a broader/narrower navigation tree so that people can browse a tree to find information quickly.

The general structure of a taxonomy is given in the figure below.

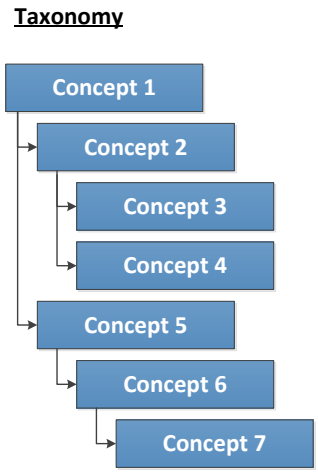


Figure 3-3: General structure of a semantic model - Taxonomy

Next, we give an example of taxonomy.

Example of taxonomy hierarchy:		
Chemistry		
	Physical chemistry	
		Electrochemistry
		Magnetohydrodyamics

3.1.3 Thesaurus

"A thesaurus is a controlled vocabulary arranged in a known order and structured so that the various relationships among terms are displayed clearly and identified by standardized relationship indicators. Relationship indicators should be employed reciprocally." (from ANSI/NISO Z39.19-2005).

All terms in a thesaurus have relations between them. These relationships are typically of three kinds: hierarchical (broader term/narrower term), associative (see also), and equivalent (use/used from or see/seen from). In addition, it is common in thesauri that some or all terms have scope notes, brief explanations of how the term should be used in indexing. Term history notes may also be present.

The general structure of a thesaurus is given in the figure below.

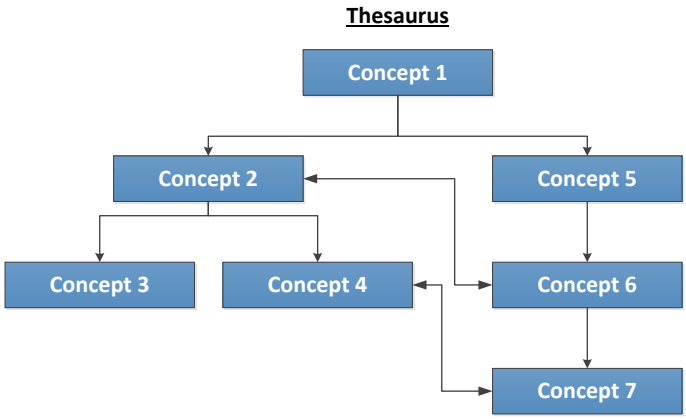


Figure 3-4: General structure of a semantic model - Thesaurus

Next, we give an example of a thesaurus (from ANSI/NISO Z39.19-2005). In the example, BT means broader term, NT means narrower term and UF means used for.

Example thesaurus:	
ABSORPTION	
The retention and conversion into another form of energy rays, waves or particles by a substance.	
UF	**ABSORPTIVE PROPERTIES**
BT	**SORPTION**
NT	**BIOLOGICAL ABSORPTION**
	RESONANCE ABSORPTION
	TWO PHOTON ABSORPTION
	X RAY ABSORPTION ANALYSIS

3.1.4 Ontology

An ontology is an explicit specification of a shared conceptualization, as defined by Gruber in 1993 [Gruber T., 1993]. An ontology consists in a set of definitions of basic categories (things, relations, properties) which enables to describe the things of the domain of interest, their properties and the relations the things maintain among each other.

Ontologies are the most complex structures compared to lists, taxonomies and thesauri. They are more powerful too, in the sense that they have reasoning/inference capabilities. These capabilities will be further described in Section 3.2.

There are many ontology specification languages [Corcho O., 2000] and they differ in the way they deal with readability, expressiveness and inference of the represented information.

The general structure of an ontology is given in the figure below.

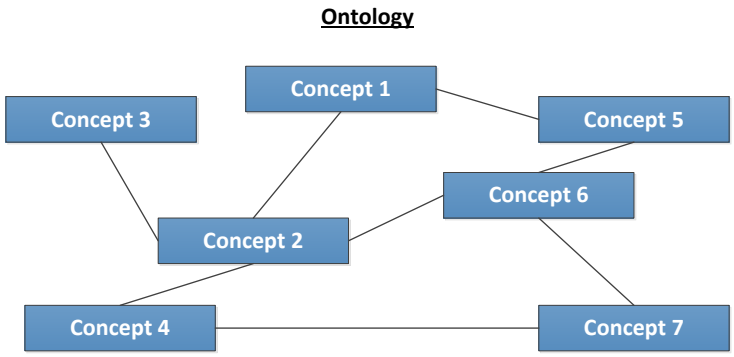


Figure 3-5: General structure of a semantic model - Ontology

Next we present an example of a vehicle ontology [Madsen B.N., 2009].

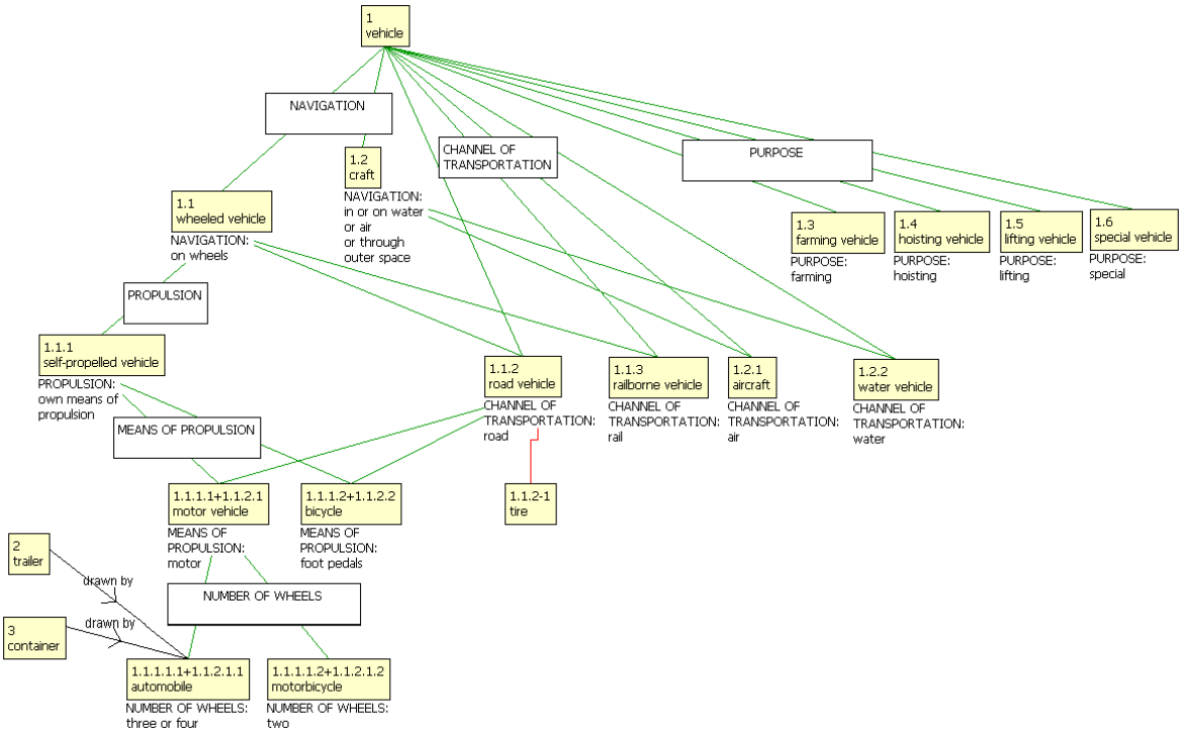


Figure 3-6: Example of a vehicle ontology [Madsen B.N., 2009]

3.2 Basics of ontologies

As the task of this work package is to come up with an ontology, we will further elaborate on the purpose and capabilities of ontologies. This sub chapter will describe in generic sense what possibilities one haves with an ontology of a certain domain [Corcho, O., 2000; Guarino, N., 2009, Obitko, M., 2007]. Next sub chapter will give examples of the application of ontologies within the healthcare systems engineering domain.

The original definition by Gruber as mentioned in the previous sub chapter was extended by Struder et al into: “An ontology is a formal, explicit specification of a shared conceptualization” [Struder, R., 1998]. The three main parts of this definition, ‘conceptualization’, ‘formal, explicit specification’ and ‘shared’ will be explained below in order to give more information about the ideas behind an ontology.

- ‘shared’: as an ontology represents knowledge that exists in a domain, the concepts that are in the ontology must be understood and agreed upon by all or at least most of the stakeholders in the domain. The stakeholders must commit to the meaning of the concepts and the relations, as only with this shared understanding the benefits of ontologies can be utilized.
- ‘conceptualization’: an ontology must represent a selected part of the world, and this is done by an abstract, simplified view called a conceptualization. It consists of objects, concepts and other entities together with the relationships that exist between them that are all assumed to be of interest in the corresponding domain. A prerequisite is that this conceptualization should not change when the (state of the) world it describes changes.
- ‘formal, explicit specification’: a language is needed to describe the concepts in the domain. Ontology languages make sure that the conceptualizations are not only in the mind of people but

that they are explicitly specified. In order to be machine readable the language in which the ontology is written must be formal. Mostly these languages are based on first-order logic or description logic.

Generally, the purpose of an ontology is to capture the knowledge in a domain and to identify specific classes of objects and relations that exist in that domain. They enable knowledge sharing and clarify the structure of knowledge. Due to the fact that ontologies are written in a formal language based on logic, it not only offers the ability to represent data, but also to reason about and infer from the data. This means that knowledge that is not explicitly recorded in the ontology can be derived. Automatic processing of an ontology can in this way result in new facts. This section will further elaborate on the reasoning/inference capabilities of ontologies.

A semantic reasoner (inference system) is a piece of software capable to infer information from a set of facts and axioms. An inference system is said to be sound if it only allows you to generate logical consequences and it is said to be complete if it allows you to generate all logical consequences. A reasoner that is sound and complete can make the representation in that language more complicated.

There are two main methods of reasoning when using inference and production rules, one is forward chaining and one is backward chaining. In the forward chaining technique the starting point is the available data and the software uses inference rules to extract more data until a goal is reached, while in backward chaining the starting point is the goal and the software works backwards from the consequent to the antecedent to see whether there is any antecedent that supports the consequent. Thus, forward chaining is data-driven, while backward chaining is goal-driven. An advantage of forward chaining over backward chaining is that forward chaining is better suited to dynamic situations where conditions change because the reception of new data in this scheme produces new inferences.

The reasoning capabilities we will discuss next are consistency checking, transitive relations, value partitions, automated classification, inheritance, constraint checking and exception handling.

Consistency checking ensures that the ontology, and thus the knowledge recorded about the domain, does not contain any contradictory facts. The inconsistencies that can be checked are terminology inconsistencies, designation inconsistencies, structure inconsistencies, strong conflicts and weak conflicts [Van Lamsweerde A., 2009]. An example of a strong conflict is that in which there are classes where no individual can fulfil its definition. Via reasoning engines such a definition can be found also in big ontologies.

In an ontology, terms can be related directly via an asserted relation or they can be related indirectly via inferred relations. Through this process, new information is logically discovered. The inferred relations are discovered traversing transitive asserted relations. For example, the *is_a* relationship is a transitive relationship. If A *is_a* B and B *is_a* C, then A *is_a* C. Having the first two relationships asserted in the ontology, the third one is inferred from the first two ones.

A frequent requirement in ontologies is to model the attributes of an element. For example, we assume that the height of a person in an ontology can have one of the three values: “small”, “medium” and “tall”. The only possible heights are considered to be only these three in the given ontology. To represent such features and their specified values, one way is to represent them as partitions of classes. A class is said to be partitioned by a group of subclasses if the subclasses are mutually exclusive and they completely cover the parent class. The partitions can be furthered sub partitioned.

Ontologies can also compute the subclass relations between named classes to create the complete class hierarchy. The class hierarchy can subsequently be used to answer queries such as all the subclasses of a class or the direct subclasses of a class. One can also find the most specific class an individual belongs to or all the types of an individual (from the class hierarchy). This is called automated classification.

In an ontology, a distinction is being made between single inheritance and multiple inheritance. In a single inheritance scheme, a class can have only one parent and in a multiple inheritance scheme, a class can have multiple parents. An important property of the inheritance relationship is that properties from the parent class are inherited by child classes. Inheritance can also give rise to conflicts in the inherited attribute values (multiple inheritance) or default values (single inheritance). Another distinction is made between monotonic inheritance and non-monotonic inheritance. In a monotonic inheritance, types inherited from a superclass are never overwritten, but accumulated instead. On the other hand, in a non-monotonic inheritance scheme, types can be overwritten by explicit or derived information for subclasses.

Constraints in an ontology are used to restrict the existing knowledge. Constraint checking checks the entered information for inconsistencies. There are multiple types of constraints: integrity constraints (check correctness of arguments' values), type constraints (for attributes), cardinality constraints (constraint the minimum and maximum values of an attribute), etc.

Exception handling refers to analysing whether the value of attribute A in concept C2 overrides the value of attribute A in concept C1 when concept C2 is a subclass of concept C1.

3.3 Application of ontologies in the healthcare systems engineering domain

The sub chapters above describe the applicability of ontologies in general. This sub chapter will elaborate on how ontologies could be helpful in the healthcare systems engineering domain.

As a starting point the engineering cycle is taken. Due to the fact that healthcare systems are subject to strict regulations, the engineering process of such systems is typically well-defined, according to the V-model (see the figure below).

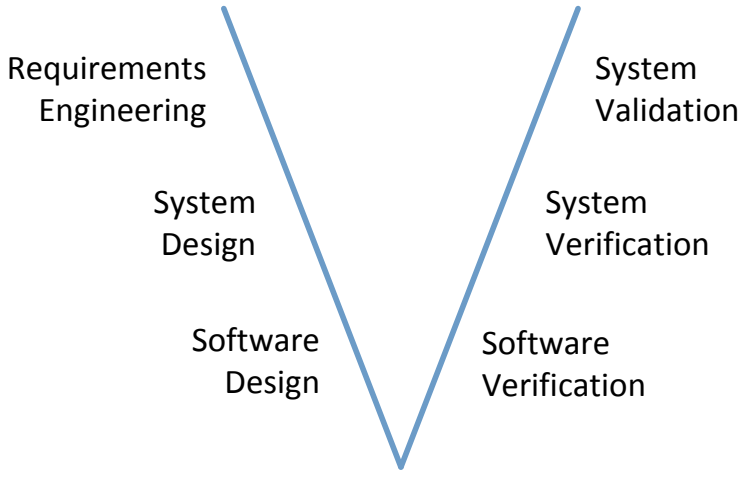


Figure 3-7: V-Model for system engineering

In various parts of a development process according to the V-model benefits could be gained from the use of an ontology:

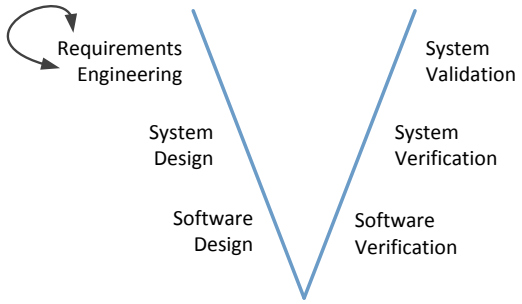
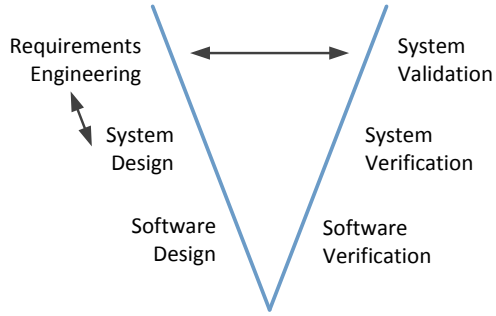
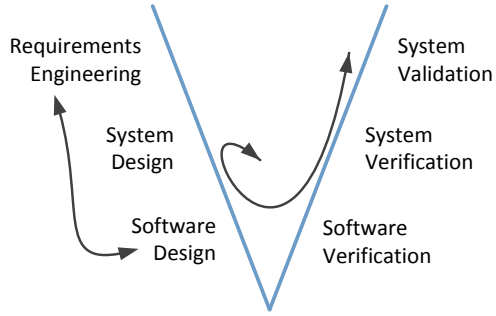
	• Formalization of concepts within one stage of the engineering cycle, for example user requirements engineering. ○ Formalization of concepts allows for automated inference and reasoning on inconsistencies. ○ Also automated discovery of contradictions within the used vocabulary is facilitated.
	• Formalization of concepts that exist in two related stages and their mutual relationship. This can be applied on both horizontal and vertical relations. ○ This results in a common set of concepts used in both stages. ○ Attributes that exist in the specific phases stay specific for that particular phase.
	• Formalization of the whole engineering cycle. Concepts and their mutual relations are specified for all stages, which creates a shared understanding throughout the engineering cycles. ○ Traceability of artefacts is established, the relations between them can be automated. ○ Impact of changes in any part of the process can be analysed throughout the whole cycle.

Table 3-1: Application of ontologies within the engineering cycle

3.3.1 Example application from use cases

To concretize the applicability of ontologies within the healthcare systems engineering domain, we will focus on one of the use cases of the healthcare domain to illustrate the possibilities.

Use case 4.2, which is about the safety layer of an interventional X-ray system, aims at improving the safety risk management process, which runs parallel to the development process. In short, the safety risk management process takes into account the system requirements and the system design and analyses whether additional risk control measures need to be implemented to fulfil safety requirements. When changes in the system design occur, the impact of these changes must be determined. Currently, this process asks for a number of manual steps to be executed, for example to identify what test evidence for risk control measures needs to be renewed [Cruts, H.E.P., 2013]. The picture below depicts the process of impact analysis of design changes.

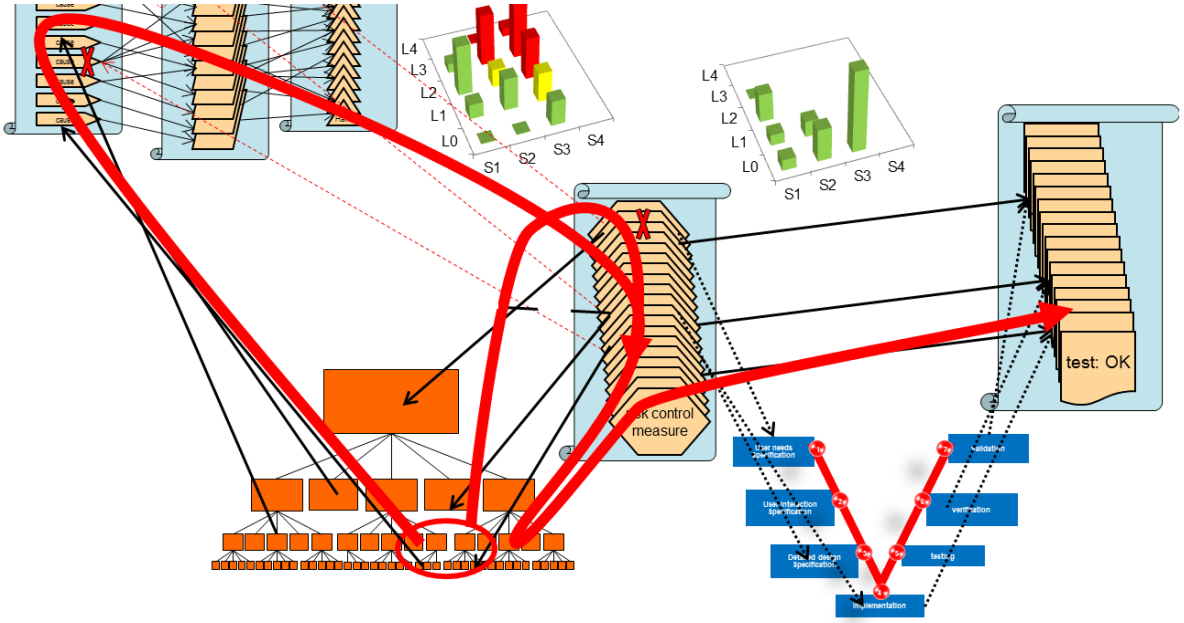


Figure 3-8: Impact analysis of design changes [Cruts, H.E.P., 2013]

The figure depicts that when components change due to the development of a new version of a product, parts of the risk analysis has to be redone, as the cause-hazard-harm relations may have changed. This results in the definition and implementation of new risk control measures or a different implementation of existing risk control measures [Cruts, H.E.P., 2013].

An ontology could formalize the relations between design, cause, hazard, harm, risk control measures, test evidence and experience. In this way the maintenance of these relations can be automated by making use of the ontology. This is an example of the third application possibility that is described in Table 3-1.

4 Overview of standards within healthcare domain

This chapter gives an overview of standards that are relevant within the healthcare domain. At first, a long-list of standards on a variety of topics within this domain is gathered. From this long-list, a selection is made according to the defined scope of this work package. Standards that are considered relevant for the healthcare systems engineering domain are put on a short-list.

4.1 Long-list

An extensive search was executed in order to come up with a list of standards that exist in the healthcare domain. Two ways of information gathering were used to retrieve the list:

- Desk and literature research was done; a search on relevant topics and a look into the standards databases of important standardization organizations (such as ISO and IEC).
- Use case owners within the healthcare domain of CRYSTAL were contacted and their use case descriptions were studied in order to identify standards that are relevant in the domain.

At first, the scope of this search was not limited to healthcare systems engineering, but healthcare in broader sense was chosen. This has resulted in a list of standards with a variety of topics, which are depicted in the figure below. More statistics about the standards on the list will follow in the next sub chapter.

Figure 4-1: Topics of standards on long-list

See Annex I for the long-list standards that are identified within the Healthcare domain. For each standard the following aspects are described:

- Full name: The complete name of the standard, elaboration on the identifying short name
- Semantic level: The richness of the standard in terms of semantics
- Topic: One or more subjects where the standard is about
- Description: Short summary of purpose of standard
- More info available at: A reference to where more information about the standard be found

4.1.1 Statistics of long-list

In total, 87 standards are discovered that cover parts of the healthcare domain. As the aim of this CRYSTAL work package is to develop an ontology, it would be beneficial when already ontologies exists that can serve as a basis. This does not say that standards that are classified as other than ontology cannot be valuable input for the development of the ontology. The following table shows the semantic levels of the standards on the long-list.

Semantic level	Count
Taxonomy	32
Ontology	25
List	11
To be determined[1]	9
Thesaurus	8
Not applicable[2]	2

Table 4-1: Semantic levels of standards on the long-list

To make a choice which standards are relevant for further research, the topics of the standards must be considered. The following table shows the top five of topics of the standard that are present on the list.

Topic	Count
Procedures/actions	23
Devices/products	20
Health record	13
Diseases	12
Drugs	8

Table 4-2: Top five of topics on the long-list

[1] These standards are not publicly available to determine their semantic level
[2] Two standardization organizations are on the list, so a semantic level is not applicable

4.2 Short-list

The defined scope of the work package will be used to select standards from the long-list as being useful for the ontology development. In line with this defined scope, standards that are directly concerned with healthcare systems engineering will be on the resulting short-list, which can be found in the table below. The specific standards that are considered useful in the use cases are by all means put on the short-list. Furthermore, all standards that are classified with the topic devices/products, supplemented with standards classified with the topics of the use cases, are studied for their applicability and the suitable ones are also placed on the list.

Abbreviation	Relevant UCs	Full name
DICOM GSDF	Barco	Digital Imaging and Communications in Medicine -- Grayscale Standard Display Function
GMDN		Global Medical Device Nomenclature
ICPS		International Classification for Patient Safety
IEC 60601-1	Philips	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
IEC 60601-2	Philips	Medical electrical equipment – Part 2: Particular standards for basic safety and essential performance
IEC 62304	Barco Philips	Medical device software – software life cycle processes
IEC 62366	Philips	Medical devices -- Application of usability engineering to medical devices
ISO 13485	Philips	Medical devices -- Quality management systems -- Requirements for regulatory purposes
ISO 13606	RGB	Health informatics - Electronic Health Record Communication
ISO 14971	Philips	Medical devices -- Application of risk management to medical devices
ISO 15225		Medical devices -- Quality management -- Medical device nomenclature data structure
ISO/IEEE 11073	RGB	Health informatics -- Point-of-care medical device communication
UMLS		Unified Medical Language System

Table 4-3: Short-list

One important aspect to mention about the standards on the short-list is that a large part of them are mandatory to apply according to the regulations that hold in Europe and the USA. In the European Union, the Medical Device Directive (MDD) holds, which intension it is to harmonize laws relating to medical devices. It states that compliance with the European Norms gives presumption of conformity with the essential requirements of the MDD. In the USA a comparable construction is known, as the Code of Federal Regulations states that applicants may utilize FDA recognized standards. The following table compares the standards that are on the short-list with the standards that are mentioned in both the MDD and the FDA.

MDD (European Union)		FDA (USA)
EN 60601-1	**IEC 60601-1** **Safety requirements**	AAMI ANSI ES 60601-1
EN 60601-2	**IEC 60601-2** **Particular safety req.**	
EN 62366	**IEC 62366** **Usability**	AAMI ANSI IEC 62366
EN 62304	**IEC 62304** **SW life cycle processes**	AAMI ANSI IEC 62304
EN ISO 14971	**ISO 14971** **Risk management**	AAMI ANSI ISO 14971
EN ISO 13485	**ISO 13485** **Quality management**	

Table 4-4: Comparison between MDD, standards on short-list and FDA

5 Analysis of short-list

In order to be able to say something about the usefulness of the standards for the development of the ontology, this chapter will do an analysis of the overlaps in scope between the standards on the short-list. Furthermore, the standards will be measured against a couple of quality measures and the semantic level. This will help us in identifying the usability and suitability of the standards as input for the ontology development.

5.1 Scope

For analysing the first aspect, in the table that follows next, a classification of the standards on the short-list can be found. In this way a quick overview can be given of the relation between the various standards. A distinction is made between standards that are product oriented and process oriented. Moreover, the topics of the standards are related to each other, from specific healthcare standards, to specific medical devices standards on to specific medical devices standards.

Generic healthcare standards	Specific healthcare standards	Generic medical devices standards	Specific medical devices standards	
UMLS			DICOM GSDF Imaging requirements	**Product**
	ICPS Patient safety	IEC 60601-1 Safety requirements	IEC 60601-2 Particular safety req.	
		IEC 62366 Usability		
	ISO 13606 EHR Communication	ISO/IEEE 11073 Communication		
		IEC 62304 SW life cycle processes		**Process**
		ISO 14971 Risk management		
	ISO 15225 GMDN Quality management	ISO 13485 Quality management		

Table 5-1: Classification of standards on short-list (inspired by [Gerber, C., 2008])

5.2 Quality measures and semantic level

The aspects that we will focus on in the analysis of the quality of the standard are:

- The adoption of the standard: National versus international user groups
- Licence: Terms of use and intellectual property rights related to the standard
- Last update: Year in which the latest stable version of the standard was released
- Semantic level: Richness of the standard in terms of semantics; does the standard provides input on a vocabulary, on relationships between concepts?

The details for each standard can be found in Annex II. The following figure summarized the results. The semantic level is plotted on the vertical axis, the year of last update on the horizontal axis and the €-sign before a standard means that one must pay to get access to the standard.

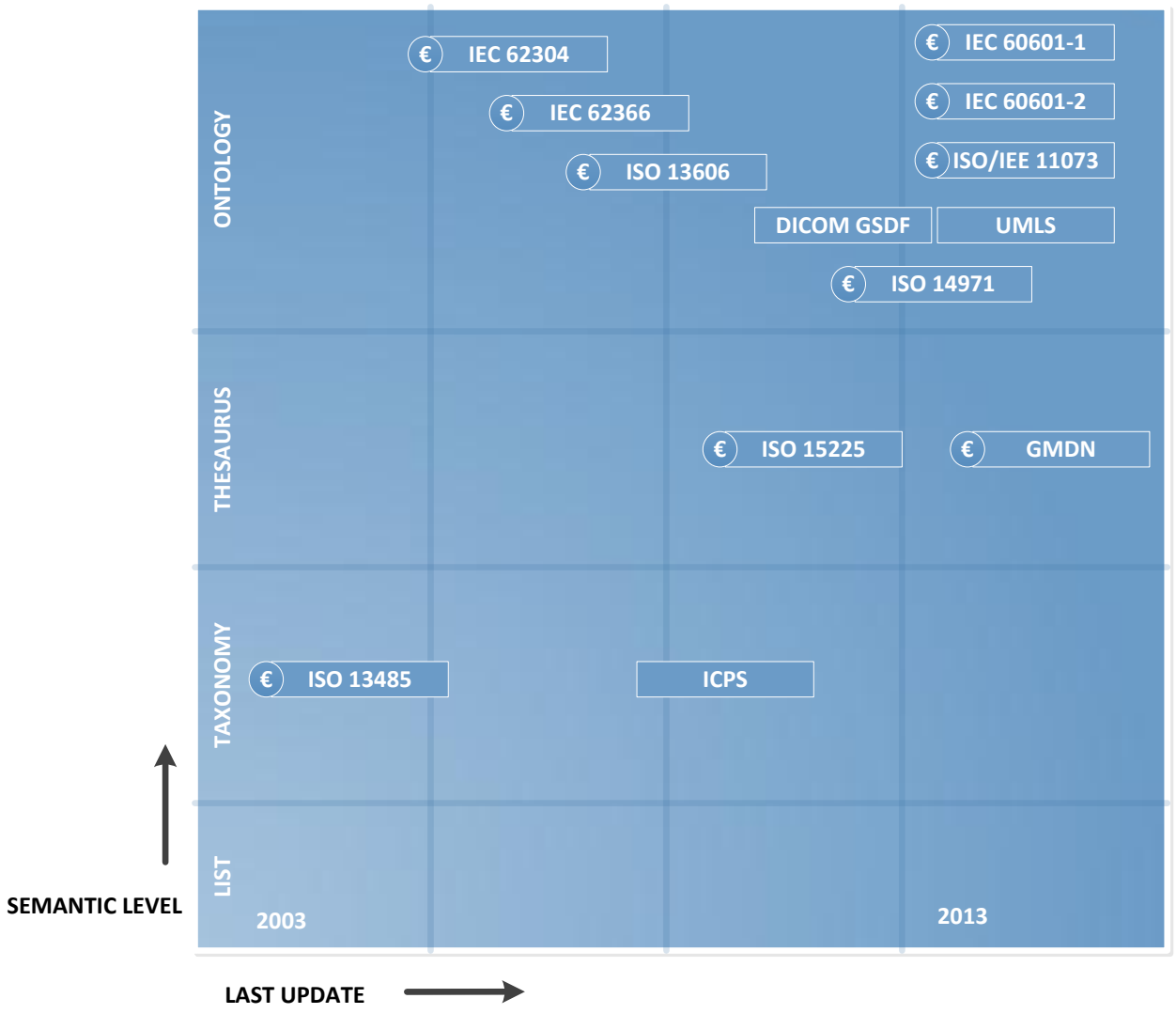


Figure 5-1: Standards of short-list plotted at semantic level and year of last update*

* As all standards turn out to have a global scope, this aspect is left out of the figure.

6 Evaluation

The purpose of this document was to give an overview of the state of the art for a healthcare ontology. Therefore a study is done of the existing standards within the healthcare domain. A set of 87 standards is put on a long-list. The defined scope of this work package has restricted the resulting set of standards, resulting in a short-list. The standards on the short-list are analysed on their scope, quality measures and semantic level.

The following conclusions can be drawn for the standards that are on the short-list:

- The scope is ranging from generic and specific healthcare standards to generic and specific medical devices standards. Topics that are included are, amongst others, safety management, risk management, quality management and communication.
- Most standards on the list are classified as ontologies, due to the fact that they consist of sets of concepts with names relations between them. Because the standards are not written in a formal specification language, they are however not able to offer the reasoning capabilities that are described in chapter 3.2.
- A lot of standards are not publicly available, because one must pay to get IPR free access. Although this implies that the standard scores somewhat weak on openness, it is probably not problematic for the development of the ontology.
- The relevant regulations related to medical devices that are imposed by both the MDD/FDA are all on the short-list.

7 Terms, Abbreviations and Definitions

AAMI	Association for the Advancement of Medical Instrumentation
ANSI	American National Standards Institute
BT	Broader Term
CO	Confidential, only for members of the consortium (including the JU).
CRYSTAL	CRitical SYSTem Engineering AcceLeration
D	Demonstrator
EN	European Norm
FDA	Food and Drug Administration
IEC	International Electro technical Commission
IEEE	Institute of Electrical and Electronics Engineers
IOS	Interoperability Specifications
ISO	International Organization for Standardization
MDD	Medical Devices Directive
NISO	National Information Standards Organization
NT	Narrower Term
O	Other
OSLC	Open Services for Lifecycle Collaboration
P	Prototype
PP	Restricted to other program participants (including the JU).
PU	Public
R	Report
RE	Restricted to a group specified by the consortium (including the JU).
SP	Subproject
UF	Used For
WP	Work Package

Table 7-1: Terms, Abbreviations and Definitions

8 References

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[Struder, R., 1998]	Studer, R., Benjamins, R. & Fensel, D.; *Knowledge engineering; Principles and Methods*, Data & Knowledge Engineering 25(1–2):161–198, 1998
[Van Lamsweerde A., 2009]	Van Lamsweerde A.; *Requirements Engineering, From System Goal to UML Models to Software Specification,* John Wiley & Sons Ltd, 2009
[Verbeek, A., 2009]	Verbeek, A.; *Semantic interoperability – From metadata to ontology*, BeInformed, 2009

Table 8-1: References

9 Annex

Annex I: Long-list of standards within the healthcare domain

The following list consists of standards that exist in the healthcare domain. Focus is on standards from the USA and Europe, with special attention for standards that are present in the Netherlands, as most of the use cases within the CRYSTAL Healthcare work package are from here.

AGB-code

Full name	Algemeen GegevensBeheer Zorgverleners
Semantic level	List
Topic	Healthcare providers
Description	Identification, contact details and competencies of healtcare providers (individuals, practices and institutions)
More info available at	http://www.agbcode.nl/MainPage/agb-code.aspx

ATC

Full name	Anatomical Therapeutic Chemical Classification System
Semantic level	Taxonomy
Topic	Drugs
Description	Pharmaceutical coding system: classification of drugs, organ/system, therapeutic and clinical characteristics, defined daily dose
More info available at	http://www.who.int/classifications/atcddd/en/

AZN

Full name	Ambulance Zorg Nederland
Semantic level	List
Topic	Ambulance care
Description	Ambulance care, conceptual framework is present, also tables exist
More info available at	http://www.ambulancezorg.nl/download/downloads/1372/uniform-begrippen-kader-2013.pdf

AZR

Full name	AWBZ-brede Zorg Registratie
Semantic level	List
Topic	Patients
Description	The AWBZ-brede zorgregistratie (AZR, Exceptional Medical Expenses Act care registry) is a systematics to trace patients through all phases in the chain: the indication, the allocation and supply of care and the enforcement of the own contribution of patients. The AZR is a systematics aimed at the digital exchange of data (on patient level) between organizations in the Exceptional Medical Expenses Act chain.

	https://www.zorgregistratie.nl/web/zorgregistratie/tabellen
More info available at	https://www.zorgregistratie.nl/web/zorgregistratie/werken-met-azr

BEP-model

Full name	Bedrijfsregels, EI (Externe Integratie)-standaarden en Processen
Semantic level	Ontology
Topic	Operational process
Description	The BEP-model visualizes the operational processes in the Exceptional Medical Expenses Act care and shows how AZR-messages are applied here. Records specifications of the AZR.
More info available at	https://www.zorgregistratie.nl/web/zorgregistratie/bep-model

BIG-register

Full name	Beroepen in de Individuele Gezondheidszorg
Semantic level	List
Topic	Healthcare providers
Description	The BIG-registry clarifies the qualifications of care providers.
More info available at	https://www.bigregister.nl/

CAS Codes

Full name	Classificaties voor Arbo en SV
Semantic level	Taxonomy
Topic	Diseases
Description	Diagnoses for occupational health, derived from ICD
More info available at	http://www.arbokennisnet.nl/images/dynamic/Dossiers/Arbobeleid/Overzicht_CAS_codes.pdf

CCAM

Full name	Classification Commune des Actes Médicaux
Semantic level	Thesaurus
Topic	Procedures/actions
Description	French medical classification for clinical procedures
More info available at	http://www.ameli.fr/accueil-de-la-ccam/index.php/

CCR

Full name	Continuity of Care Record
Semantic level	Taxonomy
Topic	Health record
Description	The CCR data set contains a summary of the patient's health status

	including problems, medications, allergies, and basic information about health insurance, care documentation, and the patient's care plan (Header, Patient Identifying Information, Patient Financial and Insurance Information, Health Status of the Patient, Care Documentation, Care Plan Recommendation)
More info available at	http://www.astm.org/Standards/E2369.htm

CDISC

Full name	CDISC Clinical Research Glossary
Semantic level	List
Topic	Clinical research
Description	The purpose of the CDISC Glossary is to harmonize definitions and to serve the community of clinical researchers by selecting and defining terms pertaining to clinical research, particularly eClinical investigations, sponsored by the pharmaceutical industry or a federal agency.
More info available at	http://www.cdisc.org/stuff/contentmgr/files/0/08a36984bc61034baed3b019f3a87139/misc/act1211_011_043_gr_glossary.pdf

CLIQ

Full name	Classificatie implementeer Qualiteit
Semantic level	Taxonomy
Topic	Devices/products
Description	Refinement of the international classification for assistive products for persons with disability. Based on CEN-ISO 9999.
More info available at	http://cliq.vektis.nl/

CMSV

Full name	Classificatie van Medisch Specialistische Verrichtingen
Semantic level	Taxonomy
Topic	Procedures/actions
Description	The 'Classificatie van Medisch Specialistische Verrichtingen' (CMSV, Classification of Medical Specialized Acts) is used by hospitals to record the acts concerning internal information supply and also to record the acts fitting in with the Landelijke Medische Registratie (LMR, National Medical Registry). Based on ICPM.
More info available at	http://www.rivm.nl/who-fic/cmsv.htm

CPT

Full name	Current Procedural Terminology
Semantic level	Taxonomy
Topic	Procedures/actions

Description	The CPT code set describes medical, surgical, and diagnostic services and is designed to communicate uniform information about medical services and procedures among physicians, coders, patients, accreditation organizations, and payers for administrative, financial, and analytical purposes.
More info available at	http://www.ama-assn.org/ama/pub/physician-resources/solutions-managing-your-practice/coding-billing-insurance/cpt.page

CSEM

Full name	Semantische Standaard Verrichtingen in de Medische Microbiologie en Medische Immunologie
Semantic level	To be determined
Topic	Procedures/actions
Description	Microbiologics, immunology
More info available at	http://old.nvmm.nl/open/documents/csem1_50.xls

DBC

Full name	Diagnosebehandelcombinatie
Semantic level	To be determined
Topic	Diagnoses, procedures/actions
Description	Is being replaced by DOT - DBC's op weg naar Transparantie (Diagnosis – Treatment Combinations on the way to transparancy)
More info available at	http://www.dbconderhoud.nl/

DCM

Full name	Detailed Clinical Models
Semantic level	Ontology
Topic	Health record, Diseases, Devices
Description	Descriptions of medical concepts, in which medical expert knowledge, a detailed data specification, meaning of these data and used terms are brought together.
More info available at	http://www.detailedclinicalmodels.nl/

Diagnose thesaurus

Full name	Diagnose thesaurus
Semantic level	Thesaurus
Topic	Diagnoses
Description	Is being developed in order to come up with a national list of diagnoses. Behind the scenes coding schemes such as SNOMED CT, ICD10 and DBC are linked. In this way a 'unity of language' arises.

More info available at	http://decor.nictiz.nl/art-decor/dhd-thesaurus

DICOM

Full name	Digital Imaging and Communications in Medicine
Semantic level	Ontology
Topic	Imaging
Description	Standard for handling, storing, printing, and transmitting information in medical imaging
More info available at	http://medical.nema.org/

DICOM GSDF

Full name	Digital Imaging and Communications in Medicine – Grayscale Standard Display Function
Semantic level	Ontology
Topic	Imaging
Description	The Digital Imaging and Communications in Medicine (DICOM) Grayscale Standard Display Function (GSDF) was developed to provide an objective, quantitative mechanism for mapping digital image values into a given range of luminance values in order to produce better visual consistency in the way images appear on diverse display devices.
More info available at	http://medical.nema.org/Dicom/2011/11_14pu.pdf

DSM

Full name	Diagnostic and Statistical Manual of Mental Disorders
Semantic level	Taxonomy
Topic	Diseases (Psychical)
Description	Common language and standard criteria for the classification of mental disorders
More info available at	http://www.psychiatry.org/practice/dsm

EDIFACT

Full name	Electronic Data Interchange For Administration, Commerce and Transport
Semantic level	Taxonomy
Topic	Health insurance
Description	Healthcare claims, services review
More info available at	http://www.unece.org/trade/untdid/welcome.html

eLab

Full name	Elektronisch laboratoriumonderzoek

Semantic level	To be determined
Topic	Lab (requests), Outcomes
Description	With e-Lab GPs are able to electronically request for lab tests at Medlon en to look through the results of both own requests and requests of other care providers such as specialists.
More info available at	http://www.nictiz.nl/module/360/110/09003_e-Lab_Rapport_Semantische_Standaard.pdf

GALEN/OpenGALEN

Full name	Generalised Architecture for Languages, Encyclopedia and Nomenclature in Medicine
Semantic level	Ontology
Topic	Procedures/actions (surgical)
Description	The GALEN CORE Model for representation of the Common Reference Model for Procedures contains the building blocks for defining procedures - the anatomy, surgical deeds, diseases, and their modifiers used in the definitions of surgical procedures.
More info available at	http://www.opengalen.org/

GMDN

Full name	The Global Medical Device Nomenclature
Semantic level	Taxonomy
Topic	Devices/products
Description	System of internationally agreed generic descriptors used to identify all medical device products. Such products include those used in the diagnosis, prevention, monitoring, treatment or alleviation of disease or injury in humans.
More info available at	http://www.gmdnagency.org/

GO

Full name	Gene Ontology
Semantic level	Thesaurus
Topic	Gene and gene attributes
Description	A unified ontology for representing the gene attributes across all species and providing a controlled vocabulary and annotate gene information. Is part of the Open Biomedical Ontologies.
More info available at	http://www.geneontology.org/

GS1

Full name	Global Standards One
Semantic level	To be determined

Topic	Identification, Traceability, Products
Description	GTIN Allocation Rules for Healthcare, Global Traceability Standard for Healthcare, EPCglobal Pedigree Messaging Standard, GDSN Trade Item Extension: Healthcare
More info available at	http://www.gs1.org/healthcare/standards

G-Standaard

Full name	G-Standaard
Semantic level	Thesaurus
Topic	Drugs, devices/products
Description	A database which supports the prescription, delivery, ordering, declarations and compensation of care products in a integrated manner.
More info available at	http://www.z-index.nl/g-standaard

HCPCS

Full name	Healthcare Common Procedure Coding System
Semantic level	List
Topic	Procedures/actions, devices/products
Description	Level I of the HCPCS is comprised of CPT. Level II of the HCPCS is a standardized coding system that is used primarily to identify products, supplies, and services not included in the CPT codes, such as ambulance services and durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) when used outside a physician's office
More info available at	http://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/index.html?redirect=/MedHCPCSGenInfo/

HL7

Full name	Health Level 7
Semantic level	Ontology
Topic	Health record, Business (Administrative, Financial)
Description	International standard for the electronic exchange of medical, financial and administrative data between care information systems.
More info available at	http://www.hl7.org/

HPRIM

Full name	Harmonie et PRomotion de l'Informatique Médicale
Semantic level	To be determined
Topic	Lab (requests), Outcomes
Description	Standard for the exchange of medical and biological data. The standard defines, amongs others, a format for data exchange between medical

	labs, based on the ASTM-format, such as requests and results of analyses.
More info available at	http://www.interopsante.org/interopsante

IBM HIF

Full name	IBM Health Integration Framework
Semantic level	Not applicable
Topic	Not specified
Description	Health Integration Framework provides healthcare-specific reference architectures. It also provides a suite of tools, transformation engines and application adapters built on healthcare standards, such as HIPAA EDI, HL7 and IHE integration profiles, that can help reduce development time and lower costs.
More info available at	https://www-304.ibm.com/partnerworld/wps/servlet/ContentHandler/isv_com_ind_frameworks_healthcare

ICD

Full name	International Statistical Classification of Diseases and Related Health Problems
Semantic level	Taxonomy
Topic	Diseases
Description	The ICD is designed as a health care classification system, providing a system of diagnostic codes for classifying diseases, including nuanced classifications of a wide variety of signs, symptoms, abnormal findings, complaints, social circumstances, and external causes of injury or disease.
More info available at	http://www.who.int/classifications/icd/en/

ICECI

Full name	International Classification of External Causes of Injuries
Semantic level	Taxonomy
Topic	Injuries (causes of)
Description	A medical classification providing codes for external injuries. It is designed to aid professionals and researchers in the statistical tracking and prevention of injury.
More info available at	http://www.rivm.nl/who-fic/ICECIeng.htm

ICF

Full name	International Classification of Functioning, Disability and Health
Semantic level	Taxonomy

Topic	Human functioning
Description	A classification of the health components of functioning and disability. The ICF is structured around the following broad components: Body functions and structure; Activities (related to tasks and actions by an individual) and participation (involvement in a life situation); Additional information on severity and environmental factors
More info available at	http://www.who.int/classifications/icf/en/

ICF-CY

Full name	International Classification of Functioning, Disability and Health for Children and Youth
Semantic level	Taxonomy
Topic	Human functioning (children)
Description	ICF-CY is a classification by which the functioning of children and youth can be described in detail from different perspectives, such as body functions, anatomical characteristics, activities and participation. ICF-CY also contains a classification of external factors, the immediate and wider environment of a child.
More info available at	http://www.rivm.nl/who-fic/icf-cy-english.htm

ICHI

Full name	International Classification of Health Interventions
Semantic level	Taxonomy
Topic	Procedures/actions
Description	A system of classifying procedure codes. Designed to replace ICPM.
More info available at	http://www.who.int/classifications/ichi/en/

ICNP

Full name	International Classification for Nursing Practice
Semantic level	Taxonomy
Topic	Nursing (patient data, procedures/actions)
Description	ICNP classifies patient data and clinical activity in the domain of nursing and can be used for decision-making and policy development aimed at improving health status and health care delivery.
More info available at	http://www.who.int/classifications/icd/adaptations/icnp/en/

ICPC

Full name	International Classification of Primary Care
Semantic level	Taxonomy
Topic	Health record, Procedures/actions (Primary care)

Description	A classification method for primary care encounters. It allows for the classification of the patient's reason for encounter (RFE), the problems/diagnosis managed, primary or general health care interventions, and the ordering of the data of the primary care session in an episode of care structure.
More info available at	http://www.who.int/classifications/icd/adaptations/icpc2/en/

ICPM

Full name	International Classification of Procedures in Medicine
Semantic level	Taxonomy
Topic	Procedures/actions
Description	Replaced by ICHI.
More info available at	http://books.google.nl/books?hl=nl&lr=&id=sSKVX1CTzr0C&oi=fnd&pg=PA7&dq=International+Classification+of+Procedures+in+Medicine&ots=4zkvNu5vCx&sig=ZzHoPzzgO1CWwQ1nVIR0R2zI58E#v=onepage&q=International%20Classification%20of%20Procedures%20in%20Medicine&f=fa

ICPS

Full name	International Classification for Patient Safety
Semantic level	Taxonomy (being developed)
Topic	Patient safety
Description	Provides a common language for sharing information about patient safety incidents and for measuring the impact of change.
More info available at	http://www.who.int/patientsafety/implementation/taxonomy/en/

IEC 60601-1

Full name	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
Semantic level	Ontology
Topic	Devices/products
Description	A widely accepted benchmark for medical electrical equipment. Compliance with IEC60601-1 has become a requirement for the commercialization of an electrical medical equipment in many countries.
More info available at	http://www.medical-ecodesign.com/files/Use%20of%20IEC%2060601%20in%20supporting%20medical%20device%20approval.pdf

IEC 60601-2

Full name	Medical electrical equipment - Part 2: Particular requirements for basic safety and essential performance

Semantic level	Ontology
Topic	Devices/products
Description	Requirements of 60601-1 may be overridden or bypassed by specific language in the standards for a particular product. These particular standards define the requirements for specific products. Particulars may have their own revisions which are different from the General Standard.
More info available at	http://webstore.iec.ch/webstore/webstore.nsf/mysearchajax?Openform&key=60601-2&sorting=&start=1&onglet=1

IEC 62304

Full name	Medical device software – software life cycle processes
Semantic level	Ontology
Topic	Devices/products
Description	A standard which specifies life cycle requirements for the development of medical software and software within medical devices. It is harmonized by the European Union (EU) and the United States (US), and therefore can be used as a benchmark to comply with regulatory requirements from both these markets.
More info available at	http://www.spiq.com/abs/JF200809IEC62304%20SPIQ%20Rev004.pdf

IEC 62353

Full name	Medical electrical equipment - Recurrent test and test after repair of medical electrical equipment
Semantic level	Ontology
Topic	Devices/products
Description	This International Standard applies to testing of medical electrical equipment and medical electrical systems, or parts of such equipment or systems, which comply with IEC 60601-1, before putting into service, during maintenance inspection, servicing and after repair or on occasion of recurrent tests to assess the safety of such ME equipment or ME systems or parts thereof.
More info available at	http://www.rigelmedical.com/Includes/get_download.php?id=80

IEC 62366

Full name	Medical devices -- Application of usability engineering to medical devices
Semantic level	Ontology
Topic	Devices/products
Description	Specifies a process for a manufacturer to analyse, specify, design, verify and validate usability, as it relates to safety of a medical device. This usability engineering process assesses and mitigates risks caused by usability problems associated with correct use and use errors, i.e. normal use. It can be used to identify but does not assess or mitigate risks

	associated with abnormal use.
More info available at	http://www.hfes.org/web/hfesmeetings/hcspresentations/israelskistandardsppt.pdf

IHE

Full name	Integrating the Health Enterprise
Semantic level	Ontology
Topic	Diseases, IT, Lab, Devices/Products
Description	Integration profiles for domains: Anatomic pathology, cardiology, dental, endoscopy, eye care, it infrastructure, laboratory, patient care coordination, patient care device, pharmacy, quality/research/public health, radiation oncology, radiology
More info available at	http://www.ihe.net/

IHTSDO

Full name	International Health Terminology Standards Development Organisation
Semantic level	Not applicable
Topic	Not specified
Description	Owns and maintains SNOMED CT.
More info available at	http://www.ihtsdo.org/

ISO 13485

Full name	Medical devices -- Quality management systems -- Requirements for regulatory purposes
Semantic level	Taxonomy
Topic	Devices/products
Description	ISO 13485:2003 specifies requirements for a quality management system where an organization needs to demonstrate its ability to provide medical devices and related services that consistently meet customer requirements and regulatory requirements applicable to medical devices and related services.
More info available at	http://www.iso.org/iso/catalogue_detail?csnumber=36786

ISO 13606

Full name	Health informatics - Electronic Health Record Communication
Semantic level	Ontology
Topic	Health record
Description	The overall goal of the ISO 13606 standard is to define a rigorous and stable information architecture for communicating part or all of the electronic health record (EHR) of a single subject of care (patient). Related to OpenEHR.

More info available at	http://www.en13606.org/

ISO 14971

Full name	Medical devices -- Application of risk management to medical devices
Semantic level	Ontology
Topic	Devices/products
Description	ISO 14971:2007 specifies a process for a manufacturer to identify the hazards associated with medical devices, including in vitro diagnostic (IVD) medical devices, to estimate and evaluate the associated risks, to control these risks, and to monitor the effectiveness of the controls. The requirements of ISO 14971:2007 are applicable to all stages of the life-cycle of a medical device.
More info available at	http://www.iso.org/iso/home/store/catalogue_tc/catalogue_detail.htm?csnumber=38193

ISO 15225

Full name	Medical devices -- Quality management -- Medical device nomenclature data structure
Semantic level	Thesaurus
Topic	Devices/products
Description	ISO 15225:2010 provides rules and guidelines for a medical device nomenclature data structure, in order to facilitate cooperation and exchange of data used by regulatory bodies on an international level between interested parties, e.g. regulatory authorities, manufacturers, suppliers, health care providers and end users.
More info available at	http://www.iso.org/iso/iso_catalogue/catalogue_tc/catalogue_detail.htm?csnumber=50728

ISO 17115

Full name	Health informatics -- Vocabulary for terminological systems
Semantic level	To be determined
Topic	Not specified
Description	ISO 17115:2007 defines a set of basic concepts required to describe formal concept representation systems, especially for health sciences, and describes representation of concepts and characteristics, for use especially in formal computer-based concept representation systems. Not focused on healtcare, but more on terminology in general.
More info available at	http://www.iso.org/iso/home/store/catalogue_tc/catalogue_detail.htm?csnumber=32881

ISO 17117

Full name	Health informatics -- Controlled health terminology -- Structure and high-

	level indicators
Semantic level	To be determined
Topic	Not specified
Description	This Technical Specification specifies the principal ideas which are necessary and sufficient to assign value to a controlled health terminology. It is applicable to all areas of healthcare about which information is kept or utilized. Not focused on healtcare, but more on terminology in general.
More info available at	http://www.iso.org/iso/iso_catalogue/catalogue_tc/catalogue_detail.htm?csnumber=32883

ISO 9999

Full name	Assistive products for persons with disability - Classification and terminology
Semantic level	Taxonomy
Topic	Devices/products
Description	Classification and terminology of assistive products for persons with disability.
More info available at	http://decor.nictiz.nl/art-decor/iso-9999

ISO/IEEE 11073

Full name	Health informatics -- Point-of-care medical device communication
Semantic level	Ontology
Topic	Devices/products
Description	ISO/IEEE 11073 Health informatics - Medical / health device communication standards enable communication between medical, health care and wellness devices and with external computer systems. They provide automatic and detailed electronic data capture of client-related and vital signs information, and of device operational data.
More info available at	http://www.iso.org/iso/search.htm?qt=11073&searchSubmit=Search&sort=rel&type=simple&published=true

Kmehr

Full name	Kind messages for electronic healthcare record
Semantic level	Taxonomy
Topic	Health record
Description	Belgian medical data standard, introduced in order to enable the exchange of structured clinical information. Transactions: reports, requests, notifications
More info available at	https://www.ehealth.fgov.be/standards/kmehr/

LBZ

Full name	Landelijke Basisregistratie Ziekenhuiszorg
Semantic level	Ontology
Topic	Health record, Business (Administrative)
Description	Medische, administratieve en bekostiging gegevens van patiënten die klinisch of in dagverpleging opgenomen of poliklinisch (incl. buitenpoli) behandeld zijn geweest in een ziekenhuis.
More info available at	http://www.dutchhospitaldata.nl/registraties/LBZ/Paginas/default.aspx

LinkBase

Full name	LinkBase
Semantic level	Ontology
Topic	Diseases, Drugs, Human functioning
Description	An ontology for medical natural language understanding
More info available at	http://www.ifomis.org/Downloads/Ceusters.ppt

LOINC

Full name	Logical Observation Identifiers Names and Codes
Semantic level	Ontology
Topic	Lab (observations)
Description	A database and universal standard for identifying medical laboratory observations. Applies universal code names and identifiers to medical terminology related to electronic health records. The purpose is to assist in the electronic exchange and gathering of clinical results (such as laboratory tests, clinical observations, outcomes management and research). LOINC has two main parts: laboratory LOINC and clinical LOINC. Clinical LOINC contains a subdomain of Document Ontology which captures types of clinical reports and documents.
More info available at	http://loinc.org/

MedDRA

Full name	Medical Dictionary for Regulatory Activities
Semantic level	Thesaurus
Topic	Drugs, devices/products
Description	MedDRA is available to all for use in the registration, documentation and safety monitoring of medical products both before and after a product has been authorised for sale.
More info available at	http://www.meddra.org/

MeSH

Full name	Medical Subject Headings
Semantic level	Taxonomy
Topic	Diseases, drugs, procedures/actions, devices/products
Description	NLM (National Library of Medecine) Controlled vocabulary thesaurus used for indexing articles in PubMed.
More info available at	http://www.ncbi.nlm.nih.gov/mesh

NANDA

Full name	North American Nursing Diagnosis Association
Semantic level	Taxonomy
Topic	Diagnoses (nursing)
Description	Develops, researches, disseminates and refines the nomenclature, criteria, and taxonomy of nursing diagnoses.
More info available at	http://www.nanda.org/

NHG-standaarden

Full name	Nederlands Huisartsen Genootschap
Semantic level	List
Topic	Diseases, Procedures/actions (GP)
Description	These guidelines intend to support the medical policy in the daily practice of a GP.
More info available at	https://www.nhg.org/nhg-standaarden

NIC

Full name	Nursing Interventions Classification
Semantic level	Taxonomy
Topic	Procedures/actions (nursing)
Description	Classifies ‘each treatment a nurse carries out based on her knowledgeable judgement and clinical knowledge in behalf of a patient. Elementary physiological functions, complex physiological functions, behaviour, safety, family, health care system.
More info available at	http://www.ncvhs.hhs.gov/970416w4.htm

NOC

Full name	Nursing Outcomes Classification
Semantic level	Taxonomy
Topic	Outcomes (nursing)
Description	Classification of nursing care results, which describes the condition, behaviour and belevingen van een patiënt beschrijven die het gevolg zijn van verpleegkundige interventies. Functionele gezondheid, fysiologische

	gezondheid, psychosociale gezondheid, gezondheid: kennis en gedrag, waarneembare gezondheid, gezondheid: gezin en familie
More info available at	http://www.nursing.uiowa.edu/cncce/nursing-outcomes-classification-overview

NTS

Full name	Nederlandse Triage Standaard
Semantic level	List
Topic	Injuries, Diseases, Procedures/actions (Triage)
Description	Definitions, advices, triage criteria.
More info available at	http://www.de-nts.nl/

ODM

Full name	Operational Data Model
Semantic level	To be determined
Topic	Clinical Research
Description	ODM is a vendor neutral, platform independent format for interchange and archive of clinical study data. The model includes the clinical data along with its associated metadata, administrative data, reference data and audit information.
More info available at	http://www.cdisc.org/odm

OMAHA system

Full name	OMAHA system
Semantic level	Taxonomy
Topic	Health record, Procedures/actions, Outcomes
Description	The system offers a structure to documents problems, investigations, interventions and results of a patient. A standardized health care terminology consisting of an assessment component (Problem Classification Scheme), an intervention component (Intervention Scheme), and an outcomes component (Problem Rating Scale for Outcomes).
More info available at	http://omahasystem.org/

openEHR

Full name	Open Electronic Health Record
Semantic level	Ontology
Topic	Health record
Description	openEHR is an open standard specification in health informatics that describes the management and storage, retrieval and exchange of health data in electronic health records (EHRs). In openEHR, all health data for

	a person is stored in a "one lifetime", vendor-independent, person-centred EHR. The openEHR specification is not concerned with the exchange of data between EHR-systems as this is the primary focus of other standards such as EN 13606 and HL7.
More info available at	http://www.openehr.org/

OPS-301

Full name	Operationen- und Prozedurenschlüssel
Semantic level	Taxonomy
Topic	Procedures/actions
Description	German procedure classification, modification of the ICPM, official classification of operational procedures for power control, the performance record and basis for the claims processing (for inpatient services for G-DRG) of the German hospitals and physicians.
More info available at	http://www.dimdi.de/static/en/klassi/ops/index.htm

Oracle HDM

Full name	Orable Healthcare Data Model
Semantic level	Ontology
Topic	Procedures/actions, Business (Financial)
Description	The Oracle Healthcare Data Model provides an integrated view of enterprise-wide clinical and operational healthcare data that is optimized for healthcare business intelligence.
More info available at	https://www.db.bme.hu/files/Manuals/Oracle/Oracle11gR2/doc.112/e18026/intro_hdm.htm

OZIS

Full name	Open Zorg Informatie Systeem
Semantic level	Taxonomy
Topic	Not specified
Description	A Dutch collaboration between suppliers of information systems in healthcare, which has the goal to build implementation standards in the information systems that they release.
More info available at	http://www.ozis.nl/

Palga

Full name	Pathologisch-Anatomisch Landelijk Geautomatiseerd Archief
Semantic level	Taxonomy
Topic	Lab, Outcomes (Histo- and cytopathology)
Description	A database with all pathology results and a computer network for data exchange with all pathology labs in the Netherlands.

More info available at	http://www.palga.nl/palga-pathologie-uitslagen-archivering-sinds-1971.htm

PWD

Full name	Perinataal Webbased Dossier
Semantic level	Taxonomy
Topic	Health record (Pregnancy, birth)
Description	Digital data exchange in the perinatal care. The PWD (Perinatal Webbased Dossier) supports digital information exchange between obstetricians, gynaecologist, paediatrician, nurses and researcers who are directly involved with caring for a pregnant woman and her child, and who are involved with the quality improvement of obstetric care.
More info available at	http://www.pwdinfo.nl/

RADLEX

Full name	Radiology Lexicon
Semantic level	Taxonomy
Topic	Procedures/Actions (Radiology)
Description	Comprehensive lexicon—a unified language of radiology terms—for standardized indexing and retrieval of radiology information resources
More info available at	http://www.radlex.org/

RDC

Full name	Referentiedomeinenmodel Care
Semantic level	Taxonomy
Topic	Procedures/Actions, Business (Administrative, Financial, Planning), Devices/Products
Description	Gives a reference overview of the link between business activities and information objects. The domains are building blocks for the organization of the information services of a care institution.
More info available at	http://www.nictiz.nl/module/360/908/Referentiedomeinenmodel%20care%20versie%201.0.pdf

RxNorm

Full name	RxNorm
Semantic level	Ontology
Topic	Drugs
Description	RxNorm is a normalized naming system for generic and branded drugs; and a tool for supporting semantic interoperation between drug terminologies and pharmacy knowledge base systems. This is produced by The National Library of Medicine (NLM) and contains the names of

	prescription and many over-the-counter drugs available in the United States.
More info available at	http://www.nlm.nih.gov/research/umls/rxnorm/

SMART

Full name	SMART Data Model
Semantic level	Ontology
Topic	Lab, Procedures/Actions, Health record
Description	SMART provides a unified mechanism for diverse applications to interact with medical record data.
More info available at	http://docs-v06.smartplatforms.org/reference/data_model/#section6

SNOMED CT

Full name	Systematized Nomenclature of Human Veterinary Medicine International, Clinical terms
Semantic level	Ontology
Topic	Health record, Diseases, Procedures/actions, Human functioning
Description	SNOMED CT (Clinical Terms) is a systematically organized computer processable collection of medical terms providing codes, terms, synonyms and definitions used in clinical documentation and reporting
More info available at	http://www.ihtsdo.org/snomed-ct/

Sumehr

Full name	Summarized Electronic Health Record
Semantic level	To be determined
Topic	Health record
Description	Summarizes the minimal set of data that a physician needs in order to understand the medical status of the patient in a few minutes and to ensure the continuity of care. Is a Kmehr message.
More info available at	http://www.health.belgium.be/eportal/Healthcare/Telematics/HealthNetworks/Sumehr:healthpicture/?fodnlang=nl

Thesaurus Zorg en Welzijn

Full name	Thesaurus Zorg en Welzijn
Semantic level	Thesaurus
Topic	Diseases, Drugs
Description	A keyword system with over 20.000 terms from the sector care and well-being. The terms describe a broad area of topics in overlapping sectors: from voluntary work to local social policy, from youth care to elderly care, from societal services to medical care, from education to leisure activities.

More info available at	http://www.thesauruszorgenwelzijn.nl/

TMO

Full name	Translational Medicine Ontology
Semantic level	Ontology
Topic	Drugs
Description	The Translational Medicine Ontology (TMO) is a high-level, patient-centric ontology that extends existing domain ontologies to integrate data across aspects of drug discovery and clinical practice.
More info available at	http://www.w3.org/wiki/images/c/c9/Presentation_20100421_TMO4BioIT_Pichler.pdf

UMLS

Full name	Unified Medical Language System
Semantic level	Ontology
Topic	Procedures/actions, Diseases, Devices/products
Description	The UMLS integrates and distributes key terminology, classification and coding standards, and associated resources to promote creation of more effective and interoperable biomedical information systems and services, including electronic health records.
More info available at	http://www.nlm.nih.gov/research/umls

UZI

Full name	Unieke Zorgverlener Identificatienummer
Semantic level	List
Topic	Healthcare providers
Description	Identification
More info available at	http://www.uziregister.nl/

UZOVI

Full name	Unieke ZorgVerzekeraarsIdentificatie Register
Semantic level	List
Topic	Health insurance
Description	Identification, registry
More info available at	http://uzovi.vektis.nl/

WESP

Full name	Webapplicatie EI-standaardisatieproducten
Semantic level	Taxonomy

Topic	Healthcare providers, Health insurance, Devices/products
Description	WESP stands for WEb application for Standardization Products. With the help of this web application external integration standards for electronic messages, data elements and code lists can be consulted online. Multiple related products can be downloaded, such as message specifications, descriptions of standards, code tables, fill-in instructions and text files.
More info available at	http://ei.vektis.nl/WespCodelijstenDetail.aspx

Zorg register

Full name	Zorg register
Semantic level	List
Topic	Healthcare providers
Description	Registry
More info available at	http://www.zorgregister.nl/

Annex II: Details on quality measures of short-list

Standard	Adoption	License	Last update	Semantic level
DICOM GSDF	International	Publicly available	2011	Ontology
GMDN	International	Paid membership	2014	Thesaurus
ICPS	International	Publicly available	2009	Taxonomy
IEC 60601-1	International	Fee, no IPR	2013	Ontology
IEC 60601-2	International	Fee, no IPR	2013	Ontology
IEC 62304	International	Fee, no IPR	2006	Ontology
IEC 62366	International	Fee, no IPR	2007	Ontology
ISO 13485	International	Fee, no IPR	2003	Taxonomy
ISO 13606	International	Fee, no IPR	2008	Ontology
ISO 14971	International	Fee, no IPR	2012	Ontology
ISO 15225	International	Fee, no IPR	2010	Thesaurus
ISO/IEEE 11073	International	Fee, no IPR	2013	Ontology
UMLS	International	Free membership	2013	Ontology

Table 9-1: Quality measures for standards on short-list