Position Paper

SemanticHealthNet
Semantic Interoperability Processes
Semantic Resources

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<tbody>
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<td>In this Annex the EN13606 Association explains its position on generic EHR-Systems, its actors, its context, its components (HISA), and its processes (CONTSYS) and elaborates on the lessons learnt in SemanticHealthNet.</td>
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</table>

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Table of Contents

**Summary**

**Introduction**

Generic Concepts

Data and Information

Primary and secondary uses of an EHR

EHR-system Actors

Generic EHR-System, its context and its components

Generic EHR in its context: Processes: ContSys

Generic EHR-system and its components: HISA

Semantic Interoperability and Interpretability

Semantic Stack/Standards Stack: Semantic Interoperability Artefacts

EHR-systems and ContSys, Clinical Guidelines, Protocols, Actions, Rules sets

**Goal: EHR-systems and Semantic Interoperability**

**Gap analysis: Present and next generation EHR-systems and semantic interoperability artefacts**

SemanticHealthNet Semantic Interoperability: Lessons learned

**SHN: Closing the Gap**

**Discussion: Consequences for Governance and further developments**
1. Summary

This document is an essay. The topic is Semantic Interoperability and its needed shared resources. This essay provides the present points of view on Semantic Interoperability and Interpretability as entertained by the EN13606 Association1. This association endeavors to facilitate the implementation and implementors of the CEN ISO 13606 EHR communication standard.

In the introduction section a set of basic concepts is presented. These are needed to understand the last four sections.

Respectively:

- **Goals** of any EHR-system and Semantic Interoperability are presented. Many healthcare actors (providers and their organisations), but also regional and (inter-)national projects have high expectations of IT-systems and their capabilities as they are marketed.

- The **gap** between the capabilities and expectations is analysed. There is a big gap between the expectations and what is possible with present day, and old, methods and technologies. The ontological methods developed by members of SemanticHealthNet to close the gap are evaluated. The ontological SHN method does not play an essential role in the solution to close the gap as proposed by the EN13606 Association. Current message and document based solutions can not close the gap.

- **Existing standards and methods**, that are deployed and have been demonstrated, make it possible to close the gap. The notion of the Semantic Stack and its components can close the gap without the need to resort to ontological methods. The Semantic Stack can be created using Concurrent Use standards, one or more Reference Terminologies plus standardised methods to produce shared Semantic Interoperability artefacts (clinical models, c.q. archetypes and templates).

With the proposed Semantic Stack standards and artefacts it will be possible for conformant systems to:

- interpret safely and fully data
- exchange data between systems
- create interoperability between co-operating healthcare actors
- create the possibility for plug-and-play EHR-system components such as those for communication, clinical decision support, etc.
- create a common platform, an info- and infra-structure, for all EHR-systems and their components

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1 [http://www.EN13606.org](http://www.EN13606.org)
- In the final discussion section, that is based on the viewpoints of the EN13606 Association, the kinds of Semantic Resources that we need to share, and govern at (at least) the European level are listed.
2. Introduction

SemanticHealthNet (SHN) is a Network of Excellence project (Grant agreement no: 288408)
In SHN experts meet and discuss problems and solutions for semantic interoperability.

In practical terms the challenge that the Semantic Interoperability field is facing, is a wicked problem. It means that it must be possible that: patient data, which is authored by A, using IT-system B, in place C, in context D, for the purpose of E, can be safely and fully understood, by an other person yet to be born, using a system, yet to be produced, in an other place, in an other context, and can be used for a different purpose. To meet these expectations/requirements has been proven to be difficult.

This essay is an effort to create a synthesis of all components/resources that play a role in Semantic Interoperability and Interpretability and describe the kinds of artifacts that are needed and that must be governed and used by all in order to be able to interpret data in and between IT-systems safely and fully. This includes cross health domain, cross border and cross time exchange and re-use of data.

The points of view in the document as presented by the EN13606 Association as SHN-partner depict:
- the worldview based on CEN and ISO standards for Semantic Interoperability and Interpretability of EHR patient data using Structures (Archetypes and Templates) and Codes from Coding Systems.
- the view from the perspective of the Clinical and non-Clinical statement as documented in an EHR and how data is presented on a screen or in a report.

SHN has used real Use Cases (as developed in Wp1 and Wp2) that provide the clinical context for the discussions and work in this European Network of Excellence project. Wp1 developed a Use case for the clinical audit (reporting) of the treatment of Chronic Heart Failure patients. Wp2 was focussing on the Use Case for population research in the context of Chronic Heart Failure. WP3 selected a series of most relevant clinical decision rules that are used in the context of Chronic Heart Failure for diagnosis and treatment. WP4 developed the notion of Semantic Annotations in order to deal with iso-semantic expressions for data as presented on a screen where most contextual data is omitted.
**Generic Concepts**

Too many times words are used in a fuzzy way, leaving room for (mis-) interpretation. Semantic Interoperability is the field of study of the real meaning of things and words we use.

A number of concepts will be defined and used in this document. These concepts present the world-view that is the basis for this document and the way the EN13606 Association thinks about semantic interoperability and interpretability.

Preferably these concepts and terms will be shared and used by all the Semantic Interoperability experts in healthcare.

**Data and Information**

*When it is documented that a patient has Diabetes. Is this ‘data’ or ‘information’?*

*When the diagnostic criteria for the Diabetes diagnosis are documented. Is this ‘data’ or ‘information’?*

The word ‘Data’ is reserved for the bit and bytes inside an EHR-system.

The word ‘Information’ is reserved for the knowledge inside the brains of a person or text books for example.

What is the situation when knowledge inside a human brain is documented inside an EHR-system as bits and bytes?

![Figure 1: Hermeneutic cycle](http://en.wikipedia.org/wiki/Hermeneutic_circle)

The *hermeneutic circle*² depicts this.

Many times the concepts ‘data’ and ‘information’ are used as synonyms. Important differences exist between these two concepts.

The ‘hermeneutic circle’ refers to the idea that one's understanding of the text as a whole is established by reference to the individual parts and one's understanding of each individual part by reference to the

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whole. Neither the whole text nor any individual part can be understood without reference to one another, and hence, it is a circle. However, this circular character of interpretation does not make it impossible to interpret a text; rather, it stresses that the meaning of a text must be found within its cultural, historical, and literary context.

The ‘Hermeneutic cycle’ in the context of the EHR is:
- Phenomena happen.
  This includes processes that come in or get out of existence, material entities that emerge or disappear, qualities that change or dispositions that are realised.
- Phenomena produce signals, either spontaneously or by exposing biological entities to artificial stimuli (e.g. x-ray, lab test etc.).
- These signals are taken in (perceived) by humans using their senses.
- Together with Knowledge and Expertise the signals are interpreted and produce information.
- Information can be documented.
- The documented information becomes a phenomenon again and this closes the first cycle.
- Documented information will create new knowledge that can be used to interpret the signals that were received. This is the second cycle.

EHR-systems documents both data and information about the patient.

We here constrain the meaning of the word "knowledge" to generic knowledge, i.e. generalisations as derived from clinical trials and in medical text books. This is not directly an issue of EHRs. Another kind of knowledge, viz. knowing, whether e.g. some clinical condition exists, matters for clinical documentation. We refer to this as "epistemic information".

**Primary and secondary uses of an EHR**

*What is the major difference between ‘primary data’ and ‘secondary data’ in an EHR-system?*

The primary function of an EHR is to document the provision of health care. All relevant data about a patient and its treatment is stored and can be retrieved.

The European Privacy³ regulations are based on a set of principles:
- Transparency
- Legitimate purpose
- Proportionality
- The legitimate purpose coincides with the primary function of the EHR.

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³ [http://ec.europa.eu/justice/data-protection/]
Primarily the function of an EHR is to serve as:
- legal artefact, with the author as accountable intellectual property holder, used to document the provision of healthcare to the patient
- an aide de memoir for the treating physician (healthcare provider)
- a way to share data with the patient (subject of care)

Secondarily the data in an EHR can be re-used for:
- collaboration with third parties for the joint treatment of the patient
- input for specific supporting services such as Clinical Decision Support services
- clinical and non-clinical research
- reporting, (clinical-) audits
- education

The secondary function most times is the legitimate prime purpose/goal for documentation as seen from the position of the Patient, its healthcare provider, and other associated professionals. Additional rules for the protection of privacy need to be obeyed when data is re-used.

**EHR-system Actors**

<table>
<thead>
<tr>
<th>EHR-system Actors each with a defined role:</th>
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<tbody>
<tr>
<td>Author</td>
</tr>
<tr>
<td>Reader</td>
</tr>
<tr>
<td>Processor</td>
</tr>
<tr>
<td>Committer</td>
</tr>
</tbody>
</table>

What are in general terms the actors around the EHR?
What generic actors play what roles?

The generic EHR-system has only a few generic actors that are involved:
- the Patient as **Subject of Care**
- the **Author** (many times that is the Healthcare Provider, but not always)
- the **Committer** (many times this is the Healthcare Provider, but not always)
- the **Reader** (many times this is the Healthcare Provider, but not always)
- the **Processor** is the person or service that processes the data and many times generating new data to be persisted
- the **Owner** is the legal person or legal organisation is accountable for the the EHR-system operations.

The Patient as **Subject of Care** is the human whose health status and provision of care is documented.

The **Author** is that person or service that submits data to the EHR to be persisted. Always a person is accountable for the content of new data submitted to the EHR. The primary function of an EHR-system is to document the provision of healthcare, as delivered by the Healthcare actor.

The **Committer** is always the person that is accountable for the inclusion of that what is authored by
the Author.

The **Reader** is that person or service that retrieves data from the EHR database and interprets the data. From the point of view of the EHR the Reader is re-using existing, stored, ‘raw data’[^1]. Data that needs to be safely interpreted after storage.

The **Processor** is that person or service that re-uses persisted data from the EHR. It reads, interprets, processes and can generate new data for persistence. Data that is generated by the Processor will be authored and committed by the Author and Committer roles. It means that always a human is accountable. From the point of view of the EHR the Processor is re-using existing, stored, raw patient data. The processing takes place by software and can: present data, check data, annotate data, augment data, insert data, export data, make inferences, etc.

*Examples are: Clinical Decision Support Systems, Communication Engines, a Screen.*

The **Owner** is that person or organisation that is accountable for the correct functioning of the EHR-system and its ethical, legal, organisational, technical and clinical aspects.

**Generic EHR-System, its context and its components**

*What is in generic terms an EHR-system?*

*What are its components?*

In order to answer these questions this chapter presents three standards known under the name: **ConcurrentUse standards**.

These standards play a role in defining the generic EHR-system and the definition and exchange of data inside or outside these EHR-systems:

[^1]: ‘Raw data’ is data as persisted together with its contextual data that is needed for a safe interpretation.
- **ContSys.** EN CEN ISO 13940 System of Concepts for Continuity of Care
- **HISA.** EN CEN ISO12967 Health Information Service Architecture
- **EHR-Com.** EN CEN ISO 13606 EHR Communication

All three together they allow cooperating healthcare actors to be Semantically Interpretable at the Healthcare Process level; the healthcare actors can co-operate, exchange data and they allow the creation of plug-and-play EHR-system Services in EHR-Systems.

**ContSys**

ContSys is a terminological standard with as its scope:

> "This International standard defines a system of concepts for different aspects of the provision of healthcare. The concepts aim to support the continuity of care in healthcare and clinical processes. An additional aim is to enable the reuse of clinical information for other purposes such as secondary use for follow-up and knowledge management.

The general aim for this standard is to provide a comprehensive, conceptual basis for content and context in healthcare services. It should be the foundation for interoperability at all levels in healthcare organizations and for development of information systems in healthcare. The core business in healthcare is the interaction between subjects of care and healthcare professionals. Such interactions occur in healthcare and clinical processes and are the justification for the process approach of this standard. To be able to represent both clinical content and clinical context, this standard is based upon a generic clinical process model as well as comprehensive concept definitions and concept models for the clinical, management and resource aspects of healthcare services.

In practice this standard should be used whenever information in healthcare is specified as a requirement. This will cover all levels of specifications in the development of:

- business or clinical reference models as a common basis for interoperability on international, national or local levels;
- information systems and
- information for specified types of clinical processes.

The performance of any specific healthcare and clinical processes, healthcare research processes and healthcare educational processes are not covered in this standard.\(^5\)

**HISA**

HISA is a three part CEN/ISO standard: EN12967 Health Information Service Architecture.

It has as its scope:

\(^5\) EN CEN ISO 13940:2012
This European standard provides guidance for the description, planning and development of new systems as well as for the integration of existing information systems, both within one enterprise and across different healthcare organisations through an architecture integrating the common data and business logic into a specific architectural layer (i.e. the middleware), distinct from individual applications and accessible throughout the whole information system through services.

It defines normalised interfaces for EHR-system Applications and services. It makes use of the viewpoints as presented by ISO RM ODP standard: Enterprise, Information and Computational View Points.

**EHR-Communication**

The EHR-Communication standard has as its scope:

> This part of ISO 13606 specifies the communication of part or all of the electronic health record (EHR) of a single identified subject of care between EHR systems, or between EHR systems and a centralized EHR data repository.

It may also be used for EHR communication between an EHR system or repository and clinical applications or middleware components (such as decision support components) that need to access or provide EHR data, or as the representation of EHR data within a distributed (federated) record system.

This part of ISO 13606 will predominantly be used to support the direct care given to identifiable individuals, or to support population monitoring systems such as disease registries and public health surveillance. Uses of health records for other purposes such as teaching, clinical audit, administration and reporting, service management, research and epidemiology, which often require anonymization or aggregation of individual records, are not the focus of this part of ISO 13606 but such secondary uses might also find this document useful.

This part of the multipart series, ISO13606, is an information viewpoint specification as defined in ISO/IEC 10746-1.

This part of ISO 13606 is not intended to specify the internal architecture or database design of EHR systems.

This standard allows that EHR-systems process normalised EHR data. It is based on the Two Level Modeling principle. Clinical (and other data sets) are expressed in Clinical Data Models. These data models are expressed as archetypes. Archetypes are constraints on a Reference Model. It allows the creation of model driven EHR-systems that are extremely flexible. Implementing EHR exchange solutions takes few resources (time and money). Database conversions and resulting data loss is reduced considerably.

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6 EN CEN ISO 12967-1:2007
8 EN CEN ISO 13606-1:2008
With the standard it becomes possible to create in a region or country or cross border framework where all data is stored and exchanged in a normalised way.

In the world of messages each vendor writes software to integrate a message standard. An Implementation Guide need to be developed, implemented and tested. This is a resource (time and money) intensive process, taking years to many months.

When systems implement the Two Level Paradigm based on EN CEN ISO 13606 all Archetypes and Templates can be deployed instantaneously inside or outside EHR-systems. This creates flexible and model driven systems.

**Generic EHR in its context: Processes: ContSys**

*Is the EHR about data about the patient only, or does the EHR documents the results of executed processes around the patient?*

The generic EHR-system operates in many contexts. Actors in all these contexts have an interaction with, or influence on, the EHR patient data and the EHR-system.

Data Objects are processed by Applications. The operating system and network is running inside the technical hardware. Persons use the system in a physical context. Users and the EHR-system are subjected to various (organisational) policies. Ethical and legal rules and regulations influence the policies of organisations.

For complete Semantic Interoperability to be possible two organisations that exchange data need to be harmonised at many levels. When shared standards are used full and safe semantic interoperability becomes possible.

The circle depicts a set of layers that need standards to document healthcare as delivered by an organisation, that is cooperating with another organisation and its healthcare actors.

The provision of healthcare needs several processes to be active within the organisation:
- the health delivery process, the clinical treatment process where a patient is diagnosed and treated. E.g. investigations, tests, orders, etc.
- the healthcare delivery management of resources, where the various services provided by the healthcare system are co-ordinated. E.g. planning of appointments, etc.
- the healthcare administration, where data generated by the first two processes are processed. E.g. billing, reporting, etc.
- the healthcare knowledge processes. E.g. knowledge extraction, Clinical Guidelines, Protocols, Actions.

The EN CEN ISO 13940 standard for System of Concepts for Continuity of Care is a standard that defines these processes in detail and components of these processes in detail. This ContSys standard makes it possible that organisations and persons can collaborate treating the same patient and exchange data between processes.

The EHR-system is active in a Healthcare Organisation and documents the provision of healthcare as documented most times by the healthcare provider as the result of the Clinical Treatment process, Resource management processes and Administrative processes.

All health actors (patients, healthcare providers, health organisations and healthcare services) interact with each other. This results in actions that are documented in the EHR database.

All actors around the EHR-system can interact with each other but document these acts in the EHR-system Patient Record.

**Generic EHR-system and its components: HISA**

_Wouldn’t it be nice when it was possible to ‘compose’ an EHR-system using various components? Wouldn’t it be nice to be able to swap one service with an other service? Wouldn’t it be nice when one Terminology Server or Clinical Decision Support server or Patient Administration sub-system or database could be swapped with a product from an other vendor?_
The EN12967 CEN ISO Health Information Service Architecture standard is designed to make all that possible.

HISA makes use of the ISO RM/ODP standard. Only the first three layers as defined in that standard are described. The engineering and technical viewpoints are not developed in HISA.

The three viewpoints are:
- Enterprise viewpoint
- Information viewpoint
- Computational viewpoint

Based on the work described in the EN CEN ISO 12967 Health Information Service Architecture (HISA) a generic picture of the generic EHR-system was developed.

HISA describes a real Interface between a set of EHR-system services. These interfaces are defined using (among others) Semantic Interoperability Artefacts such as Information Models, Archetypes and Templates.

These HISA Interfaces exists between:
- EHR Repository Service that persists all data and can be queried. Clinical- (diagnostic and therapeutic), Administrative-, Resource Management- and Audit-log Statements will be persisted.
- EHR-Presentation Service that presents data on a screen or in a report,
- EHR-Data Entry Service that collects data from a keyboard or similar entry device,
- EHR-Data Exchange Service that creates, sends and reads exchanges with other EHR-systems using: messages, EHR-Extracts, etc.
- EHR-Semantic Interoperability Resources that contain all local, and shared, resources that the EHR makes use of: Archetypes/Templates, Value- and Coding sets, etc.
- EHR-Other Services such as Clinical Decision Support service, Case Management Services, Planning services, Demographics service, etc., etc.

The HISA interfaces must treat all applications, services and databases behind these interfaces as black boxes. According to the EN CEN/ISO 13606 scope the EHR-system software providers will have to be fully responsible and accountable for their software behind these interfaces.
Each of these HISA Interfaces has different requirements. For example: data that is shown on a screen is transformed in such a way that it is what the user expects or needs. Raw data from the persistence database is transformed. The data is processed; much of the existing contextual data is left out; many times the numeric data is presented using a classification. A Blood pressure measurement with a result that was precisely measured (‘Blood serum Glucose concentration = 12 mM/l at 2 hours after a glucose challenge and ...’) is documented as raw data including its full context. The same data will be presented on a screen as: ‘Glucose: 120/80’ or even as ‘Glucose: normal’ on a screen for a Healthcare Provider. But the layperson/patient will see the same data as: ‘Blood glucose was normal’.

An other example is that data that flows via the HISA Interfaces inside an EHR-system can use (refer to) existing resources that are available inside that EHR-system. But when the data about the patient is exchanged with a system outside the originating EHR-system then all of these references need to be resolved and exported together with the raw data.

**Semantic Interoperability and Interpretability**

*Is semantic interoperability the capability that a healthcare provider, yet to be born, understand fully and safely what was documented many years ago? And using an IT-system, yet to be developed?*

Many definitions exist for the term ‘*semantic interoperability*’. The definition that will be used in this essay is: ‘*ability of computer systems to exchange data with unambiguous, shared meaning*’ with the addition that *the exchange and interpretation needs to be done by the IT-system*. This means that data can be exchanged in such a way that receivers can understand that what is received fully and safely without any misinterpretation.

For real semantic interoperability in healthcare to exist it is essential that it must be possible that the clinical data is stored and retrieved in such a way that the same person 50 years later must be able to interpret the data in an EHR-system he documented 50 years before. Observe that the correct interpretation is possible only when all implicit data is documented as well. Even for data that never left the EHR-system, data that was never exchanged between EHR-systems, the data in its complete context needs to be documented explicitly.

It is for this reason that I introduced the notion of ‘*safe and full interpretability*’.

**Examples:**

- A diagnosis ‘*xyz*’ about the patient is not the same as a diagnosis ‘*xyz*’ about his mother.
- A finding observed and reported by the patient is not the same as one reported by the treating physician or when reported by a nurse. This notion is important in the context of eHealth and mHEALTH\(^9\).

- A diagnosis documented in a process about inferencing is not the same as when documented as a reason for encounter or to perform more diagnostics, or used in the context of billing, etc., etc.

Without the full context of the data, as documented in the EHR-system, any reader/receiver will be unable to interpret the data fully and safely.

Without complete explicit knowledge, Who documented, What, Where, When, Why, How in what context, the reader can not interpret the data safely and fully.

The figure depicts at the left side the present situation where Healthcare Providers (HcP’s) store and retrieve data but can only do so because they share a lot of implicit data. This implicit data can be shared by the persons because they made agreements or because of many years of medical training or because the implicit knowledge is part of the software code. At the right side all (as much as possible) implicit data is stored and retrieved explicitly.

Most systems and data set specifications (archetypes) today need a large amount of implicit knowledge about the context. That knowledge is many times not made interoperable, interpretable, via EHR-systems Interfaces, or messages, etc.

**Semantic Stack/Standards Stack: Semantic Interoperability**

**Artefacts**

What is the set of semantic interoperability artefacts that we need in order to create semantic interoperability and interoperability?

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\(^9\) Mobile Health (mHealth) is a sub-segment of eHealth and covers mobile devices. It especially includes the use of mobile communication devices for healthcare purposes as well as mobile health applications. [http://ec.europa.eu/digital-agenda/en/mhealth](http://ec.europa.eu/digital-agenda/en/mhealth)
The Semantic Stack is a layered set of components that are minimally needed to create Semantic Interoperability in and between EHR-systems.

Each of the layers has preferably one model that defines that layer. Each layer in the model is analogous to the ‘layers’ we use in our day to day languages. Each of the layers preferably does not overlap with other layers.
<table>
<thead>
<tr>
<th>Function</th>
<th>Layer</th>
<th>Standards involved</th>
<th>Models of ...</th>
<th>Language analog</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>Storage and retrieval</td>
<td>Database</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>Documentation / archiving</td>
<td>EN13606 Middleware</td>
<td>EN13606-1 Model of documentation structure</td>
<td>Syntax</td>
</tr>
<tr>
<td>2</td>
<td>Archetypes/Templates</td>
<td>(non-)Clinical statements</td>
<td>EN13606-2 Model of use</td>
<td>Generic Phrases</td>
</tr>
<tr>
<td>3</td>
<td>Reference Archetypes</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>Disambiguating codes</td>
<td>Reference Coding system</td>
<td>EN13606-3 SNOMED-CT LOINC ATC ICDx ICPC-2 ...</td>
<td>Model of meaning</td>
</tr>
<tr>
<td>5</td>
<td>Ontologies</td>
<td>Reference Ontology</td>
<td>SNOMED Ontology ...</td>
<td>Model of Knowledge</td>
</tr>
<tr>
<td>6</td>
<td>Plug-and-play EHR-system components</td>
<td>EHR-system services</td>
<td>EN12967 HISA EHR-system architecture</td>
<td>-</td>
</tr>
<tr>
<td>7</td>
<td>Diagnostic and therapeutic healthcare delivery</td>
<td>Healthcare delivery process</td>
<td>SIAMM / ContSys Model of medical treatment</td>
<td>treatment of patients</td>
</tr>
<tr>
<td>8</td>
<td>Supporting processes, surgery, lab, medication dispensing, pathways</td>
<td>Organisational health and care services</td>
<td>ContSys Clinical Pathways, protocols, etc/</td>
<td>Recipes, agreements</td>
</tr>
<tr>
<td>9</td>
<td>Planning, agenda’s, reporting, billing, etc.</td>
<td>Organisational, administrative and financial services</td>
<td>ContSys Commercial IT-systems</td>
<td>Agenda’s</td>
</tr>
<tr>
<td>10</td>
<td>Legal, rules and ethical</td>
<td>Medico- and legal and ethical processes, organisational management</td>
<td>Law, etc.</td>
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Next to these layers of the Semantic Stack there are more such as: EHR-technical systems level, knowledge domains, and environment. But the 10 mentioned are the most important in the context of this document.

The HISA EHR-system defines the interfaces between EHR-system services. The artefacts, that are created using the Semantic Stack, define the Information View point of these interfaces inside the EHR-system.

The level zero is outside the Semantic stack and consists of the layer where data is persisted in a database.

The additional layers that impact the Semantic Stack are:

1. In the Healthcare Delivery process the patient is receiving healthcare provided by the healthcare provider.
2. The patient and healthcare provider make use of various services inside the healthcare organisation. These services give rise to patient data and administrative and resource management data that can be recorded as part of the EHR.
3. Within the organisation all kinds of rules and regulations inform the actors how to use the organisation services.
4. Finally Regional and National ethical and legal rules and regulations inform the healthcare actors how to deliver and report the quality of the provision of healthcare and the quality of the healthcare delivery organisation.
5. All these layers influence requirements posed on Archetypes and Templates that are used inside EHR-system Interfaces.

A list of standards is needed as part of the Semantic Stack.

ConcurrentUse standards as a set of co-ordinated CEN/ISO standards:
- EN 13606: EHR-communication
- EN 19340: ContSys
- EN 19267: HISA

Codes are from Reference Coding Systems:
- SNOMED-CT
- LOINC
- ATC
- etc.

Other important standards are for example:
- Identification of Subjects of Care,
- Healthcare providers
- Devices
- Time
- Countries
- Languages
- Scales
- etc.
Standards Stack

Next to the standards listed as part of the Semantic Stack numerous other standards define concepts that are needed in an EHR. These standards are part of the Standards Stack needed for Semantic Interoperability and Interpretability in healthcare.

Examples of these standards are listed on the left side of the figure 9.

Important remark.

ERS B.V. (member of the EN13606 Association) uses a document (Semantic Interoperability Artefact Modeling Method, SIAMM) that defines standardised archetype patterns and modeling styles. These archetype patterns reduce the number of degrees of freedom to create archetypes. SIAMM is harmonised with ContSys and HISA. Initial thoughts on the modeling method were published. SIAMM is the missing link in the Semantic Stack and results in a Reference Archetype Library that

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can be used to create clinical models that can be shared as a common public semantic interoperability resource.

Clinical Model / Template / Data set
With the standards associated with the Semantic Stack it is possible to translate data set descriptions based on Use Cases in a computer processable resource, that when used by a conformant EHR-system, can define what data can be stored, retrieved, presented on a screen, entered via a keyboard and used for exchange with other (non-)proprietary IT-systems. A data set describing the content of a Patient Summary can be represented in a Template making use of predefined archetypes from the Reference Archetype Library. Reference Archetypes are specialized using clinical models. Clinical models are a shared resource and have as characteristic that they can be used in multiple technical expressions (e.g. European Interoperability Framework Base Standards like EN CEN ISO 13606 and HL7 v3 CDA). Clinical Models / Templates could be derived from work done in the Clinical Information Modeling Initiative (CIMI11). and/or a European resource as part of the Connecting Europe Facility12 (CEF). The CEN EN14822 standard on General Purpose Information Components (GPICS) can be an important resource because it lists the data requirements for 15 years of message development in Europe.

Since all these supporting standards are needed these standards must be governed as one coherent package. This package of harmonised open public standards is called the EHR Standards Stack.

EHR-systems and ContSys, Clinical Guidelines, Protocols, Actions, Rules sets

ContSys is a CEN ISO standard (EN 13940) System of Concepts for Continuity of Care (ContSys) Together with EN13606 (EHR-communication) and EN12967 (HISA) it forms the suite called ConcurrentUse.

CEN/tc251 is in the process of creating a more extensive harmonisation of these three standards.

The System of Concepts for Continuity of Care (ContSys) standard provides definitions and relationships for healthcare processes, actors and objects that play a role in the provision of healthcare in and between organisations.

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11 [http://informatics.mayo.edu/CIMI/index.php/Main_Page](http://informatics.mayo.edu/CIMI/index.php/Main_Page)

ContSys defines concepts in their ContSys system of concepts ranging from processes to objects that play a role inside processes:
- Actor (User) related concepts
- Health issues related concepts
- Time related concepts
- Process related concepts
- Concepts related to the use of clinical knowledge and decision support in continuity of care
- Concepts related to activity
- Concepts related to responsibility in continuity of care
- Health information (data) management in continuity of care

Examples of processes are: clinical care provision process (see figure), documentation process, knowledge management process, executed guidelines, executed pathways, executed complex plans for one patient, executed by more than one or one healthcare providers plus the assessment of the execution of these plans.

ContSys has a series of concepts going from guidelines, via pathways, Care plans, down to individual plans and healthcare activities. All these activities can be described as parts of processes that can be ordered, executed, assessed and the generated data can be collected. All aspects can be documented in an EHR using defined Information Models.

Part of ContSys is the healthcare (clinical) delivery model. It describes in general the diagnostic and therapeutic parts of the clinical process.

The ContSys defined processes define to a large extend the context of any documented clinical and non-clinical fact about the Patient System.

Processes in healthcare have as a feature that they can be nested. (Guidelines, Clinical Pathways, Protocols). In the end atomic Activities are planned at the patient level and executed. This means that EHR-systems and Information Models must be able to deal with nested structures. Most common modeling methods are about snap-shots in time (screens, reports, messages, documents). But the data as documented inside and EHR-system database has to reflect the fractalness created by all the nested processes. SIAMM (as did ContSys) recognised this fact.

A second characteristic feature of processes (Clinical Guidelines, Clinical Pathways, Protocols) is that they must be able to deal with many exceptions. Patients, healthcare providers and their organisations appear to be part of a chaotic system. The accepted procedures try to unify all the actions, but real life is always more complex than complex procedures can be designed. This means that EHR-systems
must be able to flexible deal with all exceptions. This means that Rules based systems when based on Workflow methods need to be more ‘forgiving’ and look like Case Management systems.

**Clinical Guidelines** are consensus texts produced by healthcare providers. These narratives describe how in the ideal case diseases or disorders are diagnosed and treated. (E.g. Chronic Heart Failure)

**Clinical Pathways** are translations of the Clinical Guideline and enable various healthcare actors to cooperate in the treatment of patients with a specific disease or disorder. Clinical Pathways are local agreements who will do what, when, and how patient data is recoded and exchanged.

**Protocols.** (E.g. Measure weight) are individual parts of these Clinical Pathways.

Protocols consist of one or more steps (Actions) that are to be scheduled specifically per patient, executed and documented.

In short, there are nested components (procedures) that can be ordered, scheduled, executed by one or more healthcare actors. Each of these processes and the data generated needs to be documented in the EHR-system.

One characteristic, that Procedures (Guidelines, Pathways and Protocols) share, are sets of Rules that are executed as part of a work flow process or case management process. These rules operate on variables that are associated with relevant patient data. Several methods exist to represent sets of Rules. Several standards/languages exist that can be used by EHR-system Services (Clinical Decision Support, Workflow engines, Case management). These kinds of services are from the point of view of the EHR black boxes that accept patient data and generate suggestions that become part of the EHR.

These services interoperate via EHR-system Interfaces. Templates (Archetypes) define the data content of these interfaces.

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13 CDS Methods: [http://www.openclinical.org/gmm_proforma.html](http://www.openclinical.org/gmm_proforma.html)
3. Goal: EHR-systems and Semantic Interoperability

Many times each EHR vendor has its proprietary solution to store and expose patient data and deal with Rules-engines. Each implementation is unique. Would it be nice when for example Rules sets can be exchange between EHR-systems because they all use the same normalised data in a common EHR-system interface? In such case Rules-Engine services can be swapped.

Healthcare providers and their organisations expect that their systems have a lot of essential features:
- supporting innovations in healthcare
- full and safe storage and retrieval of patient related clinical and non-clinical data
- safe interpretation of old data or data from a different context
- safe and full re-use of existing patient related data for: education, reporting, research, clinical audits, etc.
- supporting full and seamless integration with one or more feeder systems
- supporting plug-and-play system components
- controlled access for those actors that qualify
- no data loss
- full trustworthy audit logs
- flexibility, adaptability: no database conversions, fast and cheap implementation of new concepts, new rules for clinical decision support systems, new screens and reports, etc.
- resilience and capable to deal with the many exceptions that are naturally occurring in healthcare

These features are supported by the Semantic Stack, and its accompanying Standards Stack as presented in this document including the ConcurrentUse standards plus one or more Reference Coding systems.

The deployment of the components, as mentioned in the Semantic Stack, will lead to EHR-systems that handle clinical and non-clinical data internally (as raw data) inside the normalized EHR-system Interfaces. These interfaces are defined by Templates consisting of one or more standardised Archetypes from a Reference Library. The Archetypes and Templates use a collection of codes and concepts from one or more Reference Terminologies.
How the EHR-system components behind the interfaces operate is a matter for the software community and vendors to decide.


The EHR-system Architecture, that the EN13606 Association advocates uses the ConcurrentUse standards as part of the Standards Stack, can create an Health-IT Services Framework, a complete ecosystem, such as the Apple iTunes for content, or App store for applications. Shared normalised data, shared applications with normalised application interfaces as EHR-system services make it possible. This is needed for swift eHealth and mHealth infrastructures deployment.

4. Gap analysis: Present and next generation EHR-systems and semantic interoperability artefacts

What can present EHR-systems deliver?
How are these present ‘old’ EHR-systems coping with semantic interoperability and exchanges with other EHR-systems?
What do healthcare providers and their organisations expect?

Present EHR-system databases

Present EHR-systems make use of proprietary database schemas. The result is that database conversions are necessary when the data requirements change. Database conversions result often in data loss. Many times each implementation of the same solution becomes a unique site specific implementation. Present deployed EHR-systems are all unique and inflexible.

Present EHR-system Clinical and Non-Clinical Models

Clinical data models describe what gets documented and presented. Many times these models are hardwired in the database schema and the software. Any changes, any new requirements, can only be realised by changing software and the database schema.

For example each system defines in a proprietary way Subject of Care identifying data. Most systems record only part of the complete context needed from full and safe interpretation of the data. Database conversions result many times in data loss. Many times each implementation of the same solution gets a unique site specific implementation. Present EHR-systems are complex in design, resource intensive to maintain, inflexible and cover part of the relevant requirements for semantic interoperability.

Present EHR-system Services

Existing services need proprietary software to be able to use data from the proprietary database. Data can not be exchanged plug-and-play. For instance Rules engines need proprietary integrations. Present EHR-systems lack support of the ConcurrentUse standards and are inflexible.

Present EHR-system Interoperability: messages and documents.

Present EHR-systems can exchange data between databases using message standards. By their nature these message standards need shared Implementation Guides and testing. Integrating the Health En-
terprise (EHI) is an organisation that provides the implementation guides and does the testing of applications that claim conformance. This process takes years to be completed. Any change in the implemented requirements needs again much time. Present EHR-systems semantically interoperate in a time consuming, inflexible and expensive way.

**SemanticHealthNet Semantic Interoperability: Lessons learned**

SHN relies on the Chronic Heart Failure Use cases as provided by the clinicians involved. Using these use cases data sets were derived for direct patient care and documenting clinical auditing and population research.

The representatives of Standards Development Organisations, implementers of standards, and specification development organisations, were all asked to transform these requirements into artefacts. It appeared, as could be expected, that each modeled the same requirement but ended up with different iso-semantic solutions.

In order to create transformations between these iso-semantic expressions of the same data set ontological methods were used. It proved possible to create Semantic Annotations (pointing at the selected BioTopLight Ontology\textsuperscript{15}) of parts of the various iso-semantic artefacts and create these transformations.

Questions that can be posed and that need to be answered:

1. These semantic annotations are created and added to the parts of the artefacts by humans. Is this manual process scalable?

2. These humans need a lot of background knowledge to interpret the parts of the artifacts in order to select the correct ontological semantic annotations. Is it scalable? And trustworthy?

3. Semantic annotations are created by hand and placed next to nodes in the Semantic Artefacts. Isn’t this fully equal to having one standardised way to create these artifacts and use the codes from the same Reference Terminology?

4. The SHN use cases and data sets were about highly abstracted data without the, as full as possible, context information. Therefor the Semantic Interoperability Artefacts produced in SHN, needed to be enriched ex post with semantic annotations without certainty about the original meaning of the author. It was needed to make guesses about the original meaning in the data sets as provided. In SHN we were dealing with data as presented in a particular context for clinical auditing and thereby we were not dealing with focussing on what do we need to capture during data entry as raw data; meaning statements plus context. Shouldn’t SHN have focused on raw data, defined as a statement including its full context, in order to give proof of the semantic annotation capability to be able to safely interpret the data and make the transformation to the printed audit report or screen report?

5. When it has not been proven that SHN Semantic Annotations fully cope with the meta-data describing the complete context of each statement, is in that case the proposed method unripe?

\textsuperscript{15} http://www.imbi.uni-freiburg.de/ontology/biotop/
6. Part of the present problems with the artefacts used (archetypes, templates, documents, SNOMED-CT codes) stem from the fact that there are too many degrees of freedom to create these artefacts. In addition there is an overlap between what the structure and what the codes represent. The Semantic Annotations solve a problem partially but do not prevent it from happening. Can the proposed SHN method of Semantic Annotations, in engineering terms, be seen as a very expensive workaround to implement, at best? The SHN Semantic Annotation is not a solution that prevents the problem to occur. Isn’t a real engineered solution based on the Semantic Stack to be recommended?

7. Is it worth investing in Semantic Annotations that will take large amounts of resources and will deliver unproven, partial improvements, work arounds for semantic interoperability problems that can be prevented?

8. Can we allow to expose healthcare actors to data that is semantically enriched ex post, by making guesses about the Authors intend, and therefor will be potentially unsafe to use?

When Vendors can not give warranties on the safe use of semantically enriched data and therefor can not insure their operations, is it possible to impose the use of semantic annotations to EHR Vendors to achieve partial semantic interoperability?

Answers to these questions are:

1. When humans need to interpret the full meaning, the full context, the method is not scalable.
2. A method that needs interpretation by humans is an indication that the data has lost a lot of its contextual information. That data is not semantically interoperable, or interpretable, without human intervention post hoc.
3. At the level of semantic artefacts such as archetypes, templates and documents the nodes plus the codes attached to it are not distinguishable from semantic annotations that refer to an ontology. Both are strings of text that disambiguate that node and its associated data. The difference is that the SIAM Method is scalable because those strings of text are based on fixed modeling complete (sub) patterns and entered data.
4. SHN Use Case and its derived data sets with highly abstracted data collected by a group of specialists for a specific purpose gave different requirements for their data repository than the generic EHR-system that records and that holds patient data; raw-data that must be stored and retrieved (queried) in such a way that this data can be interpreted fully and safely when reused. SHN paid too much attention to this abstracted data collected for a specific purpose to be used by a defined group of specialist instead of paying attention to raw-data. The SHN Ontological approach used for Semantic Interoperability Artefacts based on screen data inevitably leads semantic annotations that have to be applied in an ad-hoc way; not leading to a scalable solution.

5. SHN Semantic Annotations depend on SNOMED-CT for the use of codes from a Reference Coding system and run-time defined contextual data such as: involved actors, locations, times, reasons, and confounding factors. SNOMED-CT and its driving ontology partially cover all the needed non-clinical terms. Present ontologies that the SHN method makes use of do not cover the
complete context of any documented statement. It can be argued that when Models of Documentation, Models of Meaning and Models of Knowledge need to work together, we must make use of second or perhaps third order logic. OWL-DL deals partially with first order logic. When OWL-DL is used work-arounds need to be used.

6. SHN Semantic Annotations solve a problem and do not prevent the problem from happening. Therefor it is, in engineering terms, a workaround and not a solution.

A solution based on standardised structures (reference archetypes, templates, clinical models, documents) and Reference Terminologies based on the CEN/ISO ConcurrentUse standards and one or more clinical and non-clinical Reference Terminologies is a complete, scalable, affordable, and reasonably correct, solution.

Ten Key Issues in Health and Social Care Systems

1. How to define and create a citizen’s Health and Social Care record
2. How to build a lifelong history for a citizen from information held in multiple, diverse systems
3. How to identify citizens or Health and Social Care professionals uniquely and reliably
4. How to manage citizen consents and professional authorities to ensure privacy and confidentiality
5. How to create a “seamless” user experience
6. How to “join up” diverse systems on diverse platforms with diverse data and make them interoperable
7. How to manage business processes that span multiple systems and multiple domains
8. How to enable legacy systems to participate in new, wider, integrated scenarios
9. How to achieve flexibility and agility to cope with rapid change
10. How to achieve performance and scalability as user populations, transaction numbers, and data volumes grow

Present EHR-systems are not addressing the ten key issues as presented by Microsoft:

1. EHR’s and there structures are not uniformly defined.
2. Part of the context of any statement is recorded in the database. Overtime the data can not be interpreted safely and fully by present EHR-systems.
3. Subjects of Care and healthcare providers and their organisations are not uniformly defined and be identifiable when data is exchanged between present EHR-systems.
4. Present EHR-systems have ‘hardwired’, inflexible or absent ways to express access rights to parts of the EHR under control by Subjects of Care.
5. Present EHR-systems are not based on an EHR architecture that allows plug and play services and flexible, easy, definition of, and changes in, clinical and non-clinical data models.
6. Present EHR-systems rely on messages and do not handle data inside EHR-systems in a normalised way. Joining up EHR-systems is resource intensive.
7. Present EHR-systems document primarily data as part of documents/screens. They have no facilities to support clinical, administrative and resource management processes based on CEN and ISO standards, because they rely on proprietary solution.

8. Present EHR-systems store data in proprietary formats without proper codes from Reference Terminologies. Messages are used to exchange data between EHR-system databases. After the fact, post hoc, codes are attached and the database fields and ‘hardwired’ data is interpreted and added during the creation and processing of messages.

9. Present EHR-systems are not based on the layers of the semantic stack. The Semantic Stack makes model driven systems possible. Present EHR-systems are not model driven using CEN and ISO standards.

10. Performance and scalability are ever present requirements needing proper software engineering. More important is the possibility to store and exchange statements and their full context making full and safe Semantic Interoperability and Interpretability possible. Well designed model based EHR-systems allow full and safe Semantic Interoperability and Interpretability.

What is missing is the shared deployment of well governed Semantic Artefacts that find their basis in the Semantic Stack and Standards Stack. The stack of standards behind the layers in the Semantic Stack need to be created and maintained in parallel in a coherent way.
Organisational Health and Care services

Figure 12: Semantic Stack and standards (ERS B.V.)

EHR Semantic Stack

- Ontological Models
- Terminology-Classification-Models (WHO, IHTSDO, ...)
- EN13606-9 SIAMM Semantic Pattern Model
- CEN/ISO 13606-4 Archetype Object Model
- EN13606-1 Documentation/Archiving Model
- Database
- Protocols
- Tasks
- Clinical Pathway/Study

Models of Knowledge
- Encyclopedia
- Model of Meaning Terms
- Dictionary
- General Models of Use
- Specific Phrases
- Model of Documentation
- Syntax
- Real use
- Storage
- Archetypes
- Reference archetypes
- Templates
- Protocols
- Clinical Pathway/Study

5. Registry
4. Semantic Services
3. Archetypes
2. Reference archetypes
1. EN13606 Metadata
5. SHN: Closing the Gap

The gap can be bridged using existing ConcurrentUse standards and a standardised way to create Archetypes and Templates. Much of the requirements for Archetypes and Templates do not have to be re-invented. They are available, already.

The gap between present IT-Architectures and standards can be closed.

What is needed is a limited amount of governed Semantic Interoperability Artefacts based on the Semantic Stack and Standards Stack that we all must share.

The basis for Semantic Interoperability and Interpretability is formed by Semantic Interoperability Resources as defined by the Semantic Stack:

- **ConcurrentUse CEN and ISO standards** that are used to create Reference Archetypes to document data that is part of dynamic processes and static documents. These standards belong to the foundational standards for Semantic Interoperability.

- **Reference Archetypes and Templates** as Semantic Interoperability Artefacts based on the foundation standards provide the basic shared building blocks to construct Templates that describe what needs to be exchanged in EHR-system Interfaces between EHR-system Services, to be stored and retrieved, to be presented on a screen or entered by keyboard, to be exported to, or imported from, other systems.

- **Standardised archetype and template patterns.** Patterns that need to be standardised. SI-AMM (Semantic Interoperability Artefact Modeling Method) defines a set of patterns and is a candidate for standardisation.

- **Clinical Models.** A collection of Clinical Models based on data requirements expressed by the healthcare actors will define what can/must be used in these Interfaces using the Reference Archetypes.
- **Data Requirements / data sets.** Healthcare actors will define the data sets as one of the Semantic Interoperability Artefacts. Data sets that are converted into shared Clinical Models.

- **Reference Terminology codes to disambiguate structure labels.** Users of the Semantic Interoperability Artefacts at the local, regional level, very likely will use their own local code lists and coding systems. Via a localisation process they will map their local codes to the international codes from the Reference Terminology.

  The codes from the Reference Terminology are used in all Semantic Interoperability Artefacts. The Reference Coding system for clinical and non-clinical concepts is one of the founding Semantic Interoperability standards (EU Base Standards).

  In many places predefined code lists are needed in Archetypes and Templates. These are additional Semantic Interoperability Artefacts that need to be governed.

- **Document management.** All defined Semantic Interoperability Artefacts need to be governed.

  Each artefact can exist in more than one exchange format (Word, Pdf, UML model, ADL, MInd-Map, XML, etc.). In addition more supporting documents will exist: data sets, use cases, implementation guides, etc.). This means that a repository is needed where all artifacts, their versions and supporting materials are managed in a coherent, consistent, way. At the international level we need one standards based Document Management system\(^\text{16}\) that acts as the governed (managed) registry of European Semantic Interoperability Artefacts.

- **Other supporting services / tools.** Finally various international, regional, national or local supporting services need to be in place. At the various levels one will have the need to create lists of available resources like: local thesauri, list with common health delivery services (lab tests, surgery and other procedures, workflow agreements, case management agreements, clinical decision support services, language translation, code translation, etc.).

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\(^{16}\) Standards are: ISO 13119:2012 Health informatics -- Clinical knowledge resources -- Metadata
6. Discussion: Consequences for Governance and further developments

What Semantic Interoperability artifacts are needed as shared Semantic Interoperability resources?

How can they be governed?

Wouldn’t it be nice when new developments in healthcare that lead to new requirements for the data stored in EHR-systems can be implemented in a short period of time instead of years?

Governance of Semantic Interoperability Artifacts.

The Semantic Stack defines layers that can produce Semantic Interoperability Artefacts that need to be shared and therefore governed in the public domain.

In addition these Artefacts have supporting documents that need to be managed together with the Semantic interoperability artefacts.

This implies one accountable European organisation.

That organisation must oversee the governance for various domains and at various levels of detail:

1. Governance of applicable rules,
2. Governance process execution,
3. Governance of Foundation Standards Stack,
4. Governance of Reference Archetypes,
5. Governance of shared Clinical Models,
6. Governance of supporting materials,
7. Governance of Code lists (value sets) needed in Semantic Interoperability Artefacts,
8. Governance of common shared services and supporting tools

Observe that the proposed solution is not dependent directly on Ontologies.

Based on one European Governance system, Member States, regions, and local Healthcare actors can localise and govern their specific Semantic Interoperability Artefacts as one Semantic Interoperability Resource.

Shared, common, Semantic Interoperability Resources need to be governed in the public domain. One International organisation, supported by regional, or national Content Service Points, is accountable for:

- the common rules and regulations for the governance process
- the production, maintenance of all common Semantic Interoperability Artefacts (Reference Archetypes, Clinical Models/archetypes/templates, code sets, value sets, etc.)
- the production, maintenance of all supporting Semantic Interoperability Services: repositories, registries, document managers
- the shared maintenance in SDO’s of the Standards Stack with foundational standards that constitute the Semantic Interoperability Stack
The EN13606 Association firmly believes that the Semantic Interoperability Resources provide the next level of needed Semantic Interoperability and Interpretability at the local up to the European level and beyond.