eHealth Standards and Profiles in Action for Europe and Beyond

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Solutions for a Coexistence of eHealth Standards

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1 Executive Summary

One of the major challenges faced by large-scale eHealth deployment projects is to select the appropriate set of standards for achieving interoperability within the network, and with all legacy systems that need to be connected to the network. There is not a single standard that would cover all needs of a project, and there is a multitude of overlapping and, partly, competing standards that can be employed to define document formats, terminology, communication protocols, etc. It is unlikely that international consensus on a common reference information model, and a common set of standards for eHealth deployment can be reached in a reasonable timeframe and budget. Therefore, eHealth deployment projects need to tackle the important question how the coexistence between competing or overlapping standards and standard options can be achieved in practical terms that ensure sustainability. This document provides a collection of 19 “case studies”, which describe the concepts for managing the coexistence of competing or overlapping standards developed in the research domain on one hand and on the other hand within large-scale eHealth deployment projects:

Solutions for a Coexistence of Standards in International R&D Projects
- Case Study #01: SemanticHealthNet
- Case Study #02: Semantic Mediation in ARTEMIS, RIDE and SALUS
- Case Study #03: IHE Cross-Community Profiles
- Case Study #04: X-Paradigm
- Case Study #05: DICOM SR to HL7 CDA Imaging Report Transformation Guide
- Case Study #06: Trillium Bridge – Bridging Patient Summaries across the Atlantic

Solutions for a Coexistence of Standards in eHealth Deployment Projects
- Case Study #07: eHealth Cross-Border Patient Summary and ePrescription / eDispensation Services: epSOS, EXPAND, and e-SENS
- Case Study #08: Nation-wide EHR System in Romania
- Case Study #09: National eHealth network in Denmark
- Case Study #10: “Documentation at the Source” Programme in the Netherlands
- Case Study #11: EHR Interoperability in Italy
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- Case Study #18: Portuguese eHealth National Contact Point
- Case Study #19: Portuguese National Broker

The case studies describe which standards were used concurrently, which concepts were devised for their concurrent use, and what were the successes, failures, and lessons learned from the individual projects. Many authors from within and outside the eStandards project have contributed case studies, and the different styles, lengths and level of granularity mirror this document’s status as an omnibus.
The main conclusions of all case studies, including lessons learned and pragmatic recommendations derived from the experience of the various projects, have been summarized in a separate chapter. When analysing the set of case studies, we have to conclude that we have found remarkably little evidence for a significant use of competing and overlapping standards in the real-world eHealth deployment projects, other than a mapping between different controlled terminologies, which is used in several projects. Terminology mapping, however, is a critical issue, because a direct mapping is most often possible only for a subset of each terminology. In Trillium Bridge, the percentage of terms for which a correspondence could be found varied from 6% to 87%, depending on the terminology.

The one eHealth deployment project where a use of competing and overlapping standards plays a central role is epSOS, described in case study #07. epSOS developed and evaluated an elaborated concept for converting between a document (patient summary, ePrescription/eDispensation and patient consent) in the sending country’s format and language, to a document in the receiving country’s format and language, based on the concept of a “pivot document”, an intermediate format for the document conversion, for which a mapping from and to each national format has to be defined. Within the epSOS network, only the pivot documents are exchanged, and it is the task of a national contact point to “hide” the conversion process from or to a national format from the other epSOS actors.

When looking at the concepts developed and piloted by international R&D projects, we can state that several powerful and elaborated algorithms for converting between different equivalent representations of messages or clinical documents have been developed. The approaches discussed in the R&D case studies can be summarized as follows:

- **Gateway based approach:** The IHE Cross-Community Profiles define protocols for connecting different Electronic Health Record deployments into a federated network. The profiles cover the protocols required to locate documents, retrieve documents, or submit documents across communities. The profiles imply that a conversion between local value sets and document formats can be performed by the Gateway, but do not specify how such a conversion could be implemented. The approach is nevertheless important, because it is a fully implementable specification for a federated EHR system into which a conversion between formats can be integrated where needed.

- **Semantic mediation based approaches:** Several projects make use of semantic technologies to convert between different equivalent representations of clinical information. This requires the complete content of the messages or documents to be expressed through ontologies, and either the use of a common ontology for both source and target format, or complete bi-directional mappings between ontologies. The strength of these approaches is that they can recognize equivalent clinical information even if different representations are used. The weakness of these approaches is that they require a set of ontologies that can completely represent the full meaning of the clinical documents. Such ontologies are not available today for real-world use cases such as patient summaries.

- **Model driven approaches:** In this approach, first a clinical information model is developed, which represents the clinical knowledge to be exchanged, independent from a concrete implementation in any EHR standard, and then mappings to real-world EHR standards are defined. Based on these mappings and the understanding of the common clinical information
model, transformation rules can be specified that can be used to drive the conversion of documents from one format to the other.

When comparing the three approaches, it becomes clear that they are not mutually exclusive, but actually complement each other. Both case studies on semantic mediation have identified the clinical information model, represented by a set of archetypes or templates, as the level on which semantic mediation should be defined, which means that semantic mediation can be seen as an extension (or implementation technique) for the model-driven approaches. Furthermore, both approaches are independent from the actual communication protocol used to locate and access clinical documents in an EHR “network of networks”. This is a gap that is filled by the Gateway-based approach.

The lessons learned from the case studies, and a number of pragmatic recommendations derived from the project experience, can be found in a summarized form in sections 5.1 and 5.2, respectively.

Within the eStandards project, this document will serve on one hand as a source from which recommendations for future large-scale eHealth implementation projects will be derived, and on the other hand as part of the “baseline” (i.e., documentation of the state of the art) for the draft “eStandards Roadmap for Essential Standards Development Strategic Options and Policy Instruments” that will be defined by the project in early 2016.
2 Introduction

2.1 Purpose of this Document

The convergence towards a fully harmonized set of eHealth interoperability standards at international or European level is a long-term vision, but far from the reality today. Different approaches in terms of technical solutions, standards and profiles used, terminologies adopted, etc., are the natural consequence of the many factors influencing architectural decisions in eHealth deployment, including culture, domain, country, implementation timeline and the interoperability layers addressed. It seems unlikely that international consensus on a common reference information model for eHealth deployment can be reached in a reasonable timeframe and budget and we need eHealth interoperability now! To support large-scale eHealth deployment, we need to tackle the important question how coexistence between competing or overlapping standards and standard options can be achieved in practical terms that ensure sustainability.

The purpose of this document is to provide evidence on concepts for managing the coexistence of competing or overlapping standards in large-scale eHealth deployment nationally and cross-border. The evidence is organised as a collection of case studies about technical concepts (e.g. research works) and real-world eHealth deployment projects where solutions for the concurrent use of overlapping or competing standards have been developed. The case studies describe which standards and profiles were used concurrently, which concepts were devised for their concurrent use, and what were the successes, failures, and lessons learned from the individual projects.

Many authors from within and outside the eStandards project have contributed case studies, and the different styles, lengths and level of granularity mirror this document’s status as an omnibus. Within the eStandards project, this document will serve on one hand as a source from which recommendations for future large-scale eHealth implementation projects will be derived, and on the other hand as part of the “baseline” (i.e., documentation of the state of the art) for the draft “eStandards Roadmap for Essential Standards Development Strategic Options and Policy Instruments” that will be defined by the project in early 2016.

2.2 How to Read this Document

The main body of this document, following the introduction chapter, is the collection of case studies in chapter 3 (covering research work) and 4 (covering real-world deployments). Each case study can be read independently from the others. The main conclusions of all case studies, including lessons learned and pragmatic recommendations derived from the experience of the various projects, are summarized in chapter 5, which can be read by the urgent reader without a need to read the case studies first.

All case studies follow a similar structure, which was provided to the author as a “case study template” document shown in the Annex. Each case study begins with overview information, such as name and e-mail address of the author, name and type of the project, project status, countries/regions involved, project partners and the scale of deployment. This is followed by a section
called “Project Overview” that provides a brief, non-technical overview of the project. The section “Approach” then discusses the technical approach taken by the project in detail, and describes the standards and profiles used by the project. This presentation is structured along the “Layers of Interoperability” defined by the ANTILOPE project [vPS14] as shown below. The case study collection mostly covers the lower four layers, i.e. care process, information, applications, and IT infrastructure.

The four lower layers of this model are defined in [vPS14] as follows:

- **Care Process**: “After the organisations have agreed to work together, specific care processes are analysed and aligned, resulting in integrated care pathways and shared workflows. This level handles the tracking and management of the workflow processes”.

- **Information**: “This level represents the functional description of the data model, the data elements (concepts and possible values) and the linking of these data elements to terminologies that define the interoperability of the data elements.”

- **Applications**: “On this level, agreements are made about the way import and export of medical information are handled by the healthcare information systems. The technical specification of how information is transported is at this level (communication standards). The information systems must be able to export and import these communication standards.”

- **IT Infrastructure**: “The generic communication and network protocols and standards, the storage, backup, and the database engines are on this level. It contains all the “generic” interoperability standards and protocols.”

The next section, “Concurrent Use of Standards and Specifications (De-facto Standards)” explains where in the project the concurrent use of standards played a role, and how this task was addressed in the project, for example by providing gateways converting or mapping (transformation) between terminologies, documents or messages. A section named “Governance” then describes the organisation and governance the project has established in order to continuously maintain the specifications (e.g. mapping rules) for the concurrent use of standards and specifications as described in the previous section.

Finally, “Lessons learned” discusses what future large-scale eHealth deployment projects learn from this case study – the successes, pitfalls and remedies encountered by the project. Each case study
ends with a list of resources a project has produced and made available resources that might be used by other projects, either freely or commercially, and a list of references for further information about the project.

Figure 2: ANTILOPE layers discussed in each case study

Figure 2 provides an overview of which of the layers of interoperability are discussed in which case study. The mark “X” refers to a layer of interoperability discussed in depth in the case study, whereas “(x)” refers to a layer only discussed briefly. As discussed above, this collection of case studies focuses on the four lower layers.

2.3 Background: The eStandards Project

The eStandards CSA is proposed by HL7, CEN TC251, & IHE, leading Standards Organizations (SDOs), and is supported by the eHealth Network, ISO TC215, GS1, IHTSDO, IEEE11073, and IMIA to advance eHealth interoperability and global alignment of standards with seven objectives:

1. Join up with Stakeholders in Europe and globally to build consensus on eHealth standards, accelerate knowledge-sharing, and promote wide adoption of standards.
2. Deliver an evidence-based Roadmap for alignment, iterative consolidation, and broad acceptance of eStandards that is endorsed by SDOs, the eHealth Network, the providers, and the industry.
3. Contribute to the eHealth Interoperability Framework use cases focusing on clinical content modelling for different paradigms and embed a Quality Management System for interoperability testing and certification of eHealth systems.
4. Collect evidence and provide guidance on the coexistence of competing or overlapping
standards in large-scale eHealth deployment nationally and cross-border.

5. Participate in EU/US MoU roadmap actions as the international patient summaries standard.

6. Explore socio-economic aspects of eHealth interoperability, revisiting the language for user-vendor interaction that embodies ‘co-making’ in trust, collaboration and long-term engagement.

7. Align across PHC-34 to nurture innovation, sustainability & growth under CEF and beyond contributing to Key actions of the Digital Agenda 2020.

The proposal’s ambition is to strengthen Europe’s voice and impact, while reinforcing the bridges established with the EU Patient Summary guideline across the Atlantic in Trillium Bridge and among member states with epSOS, eSENS, Antilope, and EXPAND. The eStandards Roadmap and associated evidence base, a white paper on the need for formal standards, and two guidelines addressing how to work with: (a) clinical content in profiles and (b) competing standards in large-scale eHealth deployments will be pragmatic steps toward alignment and convergence.

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3 Solutions for a Coexistence of Standards in International R&D Projects

3.1 Case Study #01: SemanticHealthNet

- Author of case study within the eStandards project: Marco Eichelberg <eichelberg@offis.de>
- Project name: SemanticHealthNet
- Project type: Concept / limited deployment for experimental use
- Project status (in 10/2015): Completed
- Countries / Regions: Not applicable
- Project partners: RAMIT (BE), Imperial College London (UK), University of Hull (UK), University Hospitals of Geneva (CH), World Health Organization (CH), Medical University of Graz (AT), IHTSDO (DK), INSERM (FR), Ocean Informatics (UK), HL7 International (BE/US), EN 13606 Association (NL), EMPIRICA (DE), COCIR (BE), Whittington NHS Trust (UK), EuroRec (BE), Data Mining International (CH).
- Scale of deployment: Not applicable

3.1.1 Project Overview

SemanticHealthNet, the “Semantic Interoperability for Health Network” [SHN15], was a thematic network, partly funded by the European Commission in the 7th Framework Programme, operating from 12/2011 to 05/2015. The central topic of the project was Semantic Interoperability in the context of patient-centred care and advanced clinical and biomedical research. The project aimed at developing a scalable and sustainable pan-European organisational and governance process to achieve this objective across healthcare systems and institutions, with a clinical focus on chronic heart failure and cardiovascular prevention. [SHN1.1] The project partners represented medical researchers, computer science and medical informatics researchers, as well as standardization bodies and industry representatives.

The concept of Semantic Interoperability is defined as follows: “Beyond the ability of two or more computer systems to exchange information, semantic interoperability is the ability to automatically interpret the information exchanged meaningfully and accurately in order to produce useful results as defined by the end users of both systems. To achieve semantic interoperability, both sides must refer to a common information exchange reference model. The content of the information exchange requests are unambiguously defined.” [EN13a] In brief this can be expressed as “Semantic Interoperability: What is sent (or shared) is the same as what is understood.” [SHN2.2]

The work of the project was organized in three different “work streams”

- The first work stream exercised the development of a minimal data set (patient summary) for heart failure shared care, based on the European clinical guidelines for heart failure treatment. This data set was first expressed in tabular form (spreadsheet), then converted into EN 13606 archetype format, and then implemented as “mock-up” application that had a user interface permitting data entry directly equivalent to the EN 13606 structures defined. This mock-up was used by clinicians to identify inconsistencies and shortcomings in the dataset or its conversion to EN 13606. Furthermore, the work stream identified various public
health use cases related to heart failure, and identified data elements required for these use cases, which can be seen as extensions of the minimal data set enabling public health research based on a set of these patient summaries.

- The second work stream analysed the challenges in achieving semantic interoperability in fully structured clinical data, such as Electronic Health Records (EHRs) or the patient summaries developed in the first work stream. The solution proposed is to “annotate” each statement in the health record or patient summary with a semantic annotation that makes the “meaning” of this statement clear by defining it in a formal manner that can be processed by a reasoning engine. The “semantic language” (ontologies) required for a semantic annotation of the minimal dataset from the first work stream was developed, using existing ontologies where possible. In this context the suitability of SNOMED-CT for this purpose was examined. The possibilities enabled by the semantic annotation were demonstrated in small-scale examples.

- The third work stream dealt with the adoption and sustainability of the approach developed by the project, through means of a “European Virtual Organisation”. This is further discussed in section 3.1.4.

### 3.1.2 Approach

When analysing the technical approach of the project following the “Layers of Interoperability” defined by the ANTILOPE project [vPS14], it can be noted that most of the work of the project was on the “Information” layer. The project did not address the legal/regulatory and policy layers. The care process layer was addressed in that existing clinical guidelines for the treatment of heart failure were analysed in order to identify the information and documentation needs corresponding to these processes. However, there was no “alignment of care processes”, i.e. no work on care process interoperability\(^1\). The “applications” layer was addressed in a limited way by developing a stand-alone mock-up application that offered a user interface for creating heart failure summary data sets. The IT infrastructure layer was also not a topic of the project. The following detailed description, therefore, focuses on the information layer.

#### 3.1.2.1 Information Layer

As described in the project overview, there were two work streams in the project addressing interoperability at the information layer: Development of a minimal data set (patient summary) for heart failure, and Development of an approach for achieving semantic interoperability. These two work streams will be described in more detail below.

##### 3.1.2.1.1 Clinical Information Model: The Heart Failure Dataset

As described in the project summary, the project developed a minimal data set (patient summary) for heart failure shared care, based on the European clinical guidelines for heart failure treatment. This data set was first expressed in tabular form (spreadsheet), then converted into EN 13606 archetype format, and then implemented as “mock-up” application with a user interface permitting data entry directly equivalent to the EN 13606 structures defined. This mock-up was used by clinicians to identi-
fy inconsistencies and shortcomings in the dataset, or its conversion to EN 13606. No attempt was made to map the same clinical information model to another EHR standard such as HL7 CDA. Further details can be found in [SHN1.2] and [SHN1.3]. The most important result of this work – besides the clinical information model for the heart failure patient summary itself – is a set of guidelines, derived from this process, on the development of clinical information models suitable for publication as standards (see section 3.1.6).

3.1.2.1.2 Approach to Semantic Interoperability

In [SHN5.1], the concept of “Clinical Information Models” is explained as follows: “Numerous research projects have addressed the need to describe the content and the structure of EHR systems in a comparable and consistent way, enabling structured representation of the content, standardised exchange between systems and decision support when interacting with formalised knowledge. Over the years “competing” models of structuring were developed. The main ones to be considered are Archetypes (developed by openEHR and standardised through CEN and ISO (EN ISO 13606), the Clinical Data Architecture (CDA) created by HL7 and the Detailed Clinical Model (DCM) also supported by HL7. They are commonly named Clinical Information Models (CIM).”

When Clinical Information Models are expressed as a template or archetype of one of the EHR standards mentioned above, the meaning of clinical information is represented using three layers of artefacts, as [SHN4.1] explains:

1. Generic information models for representing EHR data such as the provided by ISO 13606, openEHR and the HL7 Clinical Statement Pattern (HL7 CSP).
2. Clinical element definitions like ISO 13606/openEHR archetypes, Detailed Clinical Models (DCMs) or Intermountain CEMs that are re-usable models that describe all the items around a topic such as blood pressure measurement or a laboratory analysis test result; and clinical data set definitions or templates such as HL7 CDA or ADL templates, consisting of specific combinations of clinical element definitions, for a particular use case or purpose, tailored to the needs of structured data acquisition, use and exchange.
3. Clinical vocabularies such as LOINC, ICD and SNOMED CT, the latter being increasingly based on formal-ontological principles and logic.

This layered approach to EHR standards can be described as the current state of the art. Nevertheless, it causes certain problems with regard to semantic interoperability. First of all, it is possible to describe the same clinical concept in different ways, leading to different clinical information models (e. g. archetypes or templates) for the same information – these are called “iso-semantic models”. This means that semantic interoperability is not guaranteed even if all parties use the same underlying generic information model for representing EHR data, e.g. ISO 13606 or HL7 CDA! [SHN4.1] states that “semantic interoperability is not only an issue when using different EHR standards but also when using the same one, in which many different iso-semantic models can be built. In practice the greater heterogeneity will not be between two different information models but between different clinical models that have been created by different teams with overlapping scope.”

A second, related problem, is the overlap between EHR information models and clinical vocabularies. [SHN4.1] explains: “EHR standards had been devised to structure and organize clinical information in a way that would be easy to communicate and process. But they allow many different ways of repre-
senting the same clinical information, not only between different information model standards but also within the same standard. The binding of information entities to clinical vocabularies is meant to provide explicit semantics to the clinical content represented by these structural models. Bindings were developed to comply with different kinds of vocabularies, and clinical vocabularies can be used within multiple different information model frameworks. There are two consequences. Firstly, present EHR standards include their own vocabulary, with mostly hidden (non-explicit) ontological assumptions. Secondly, vocabularies include context-laden concepts, which correspond to complex clinical statements rather than to terms. As a result there is a zone of overlap between EHR information models and clinical vocabularies, and that leads to different representations for exactly the same clinical information. This is one of the main barriers to semantic interoperability, i.e. the lack of a strict separation between the information represented by clinical vocabularies and by EHR information models.”

The goal of achieving semantic interoperability is defined in [SHN3.1] as follows: “For semantic interoperability a linkage (binding) between information models (models of use) and terminologies (models of meaning) is indispensable. This includes both the fixed elements in an information model and the values, i.e. the variable components. Therefore the goal of semantic interoperability is to be able to recognize and process semantically equivalent information homogeneously, even if instances are heterogeneously represented with great variety by using different combinations of (1) information models; (2) terminologies/ontologies; 3) different encodings within the same [information model] or [terminology/ontology], e.g. pre- versus post-coordinated expressions in SNOMED CT.”

The approach taken by the project is to annotate clinical documents with semantic annotation based on formal ontologies that describes the meaning of the clinical statements in an unambiguous way. [SHN3.1] explains: “Formal ontologies consist of logical axioms that convey the meaning of terms for a particular community. The set of logical axioms that define a representational unit (concept, class, represented by a unique preferred name) is named intentional definition. Dependable exchange of clinical data requires that there is only one intentional definition per representational unit. In this way, ontologies are based on the understanding of the members of a community and help to reduce ambiguity in communication.” In order to express the content of clinical documents in a semantically unambiguous manner, the project uses three ontologies, which [SHN4.1] describes as follows:

- **Top-level ontology**: as top-level ontology, BioTopLite [SB13] is used. It will help to constrain the way in which information and domain ontologies combine.
- **Domain ontology**: as ontology for representing the healthcare domain, parts of SNOMED CT will be used. Its concepts are treated as classes in the sense of OWL. Classes aggregate individual entities according to their invariant features. They inherit their basic properties from top-level ontology categories like Process, Quality, Condition.
- **EHR Information entity ontology**: information entities are outcomes of clinical actions, such as observations, investigations, or evaluations. They refer to clinical concepts and represent the epistemic and contextual aspects of the information (e.g. past history, confirmed). The concepts of this ontology will be represented as subclasses of the top-level category Information object of BioTopLite. This category is disjoint from all other categories, i.e. nothing can be both an information entity and, e.g. a process, quality, or a material entity.

The **EHR information entity ontology** is a development of the project, adapted to the requirements of
the heart failure patient summary, while BioTopLite and SNOMED CT are existing specifications. Based on these foundations, the project proposes a five-layer architecture for semantic interoperability, as shown in Figure 3:

![Figure 3: Layered architecture of SemanticHealthNet [MKS14]](image)

Layer 1 is comprised of the classical EHR documents, while Layer 2 contains the semantic annotation that unambiguously defines the semantics (meaning) of each clinical statement. The project proposes the use of re-usable “content ontology patterns” to simplify the process of defining the semantic annotation for each archetype or template of the underlying EHR standard. On Layer 3, a reasoning engine based on description logics is used to determine iso-semantic models. [SHN4.1] explains: “The framework proposed will make use of description logics (OWL-DL) […]. In this way, by means of using a DL reasoner the equivalence between the different DL expressions can be computed. For instance, if we want to obtain the past history of some disease from some patient, and there are three possible encodings for representing that information, we want to obtain it independently of the encoding used. This means that the use of a DL reasoner should tell us if they have the same or similar meaning.” Layer 4 presents a “virtual” homogeneous database against which client applications (Layer 5) can execute queries.

Another use case, which is discussed in chapter 7 of [SHN4.1], is the transfer of clinical information between systems using different representations (EHR standard, clinical information model, terminology) for the same clinical concept. This approach uses three phases:

- **Phase 1: Semantic clinical information extraction**: In this phase, the equivalence (iso-semantic property) of two clinical information models (e.g. archetypes) is determined using semantic annotation, and a reasoner that classifies the different semantic statements.
- **Phase 2: Clinical data exchange**: In this phase, clinical information with semantic annotation is exchanged, and the reasoned determines the appropriate clinical information model (ar-
• **Phase 3: Syntactic clinical information mapping:** In this phase, the content of the clinical statement is mapped to the syntactic structure expected by the receiver. This mapping seems to have been developed manually. Furthermore, [SHN4.1] explains that “in phase three, when syntactic mappings are applied in order to represent the clinical data from a system B into the corresponding representation in a system A, not always will [it] be possible to do the mapping without information loss and the rules needed to implement the mapping of the specific clinical data when they are represented at different granularity levels in the corresponding systems are not obvious.”

### 3.1.3 Concurrent Use of Standards and Specifications (De-facto Standards)

The concurrent use of standards and specifications in the SemanticHealthNet project has been outlined in the previous section. In brief, it can be summarized as follows:

- **Mapping between controlled terminologies (coding systems):** Not addressed by the project. The project recommends the use of terminology servers for managing synonyms and mappings.
- **Mapping between identifiers:** Not addressed by the project.
- **Mapping between clinical concepts:** This is the core of the project, which proposes the use of semantic annotation to enable a reasoning engine to automatically determine the equivalent meaning (iso-semantics) of different clinical information models (archetypes, templates). It should be noted, though, that the mapping is performed at the information level; no mapping to a common system of concepts (i.e. a common conceptual basis) takes place, and there is no mapping to the clinical process context.
- **Mapping between document formats:** The project relies on the semantic annotation of clinical statements to derive their meaning, independent from the document format or EHR standard used. The mapping between document formats is shown in chapter 7 of [SHN4.1], albeit only on a toy problem.
- **Mapping between messages (e.g. notifications, queries and responses):** The project proposes a five-layer-architecture establishing a layer of virtually homogeneous data against which semantic queries can be executed (see previous section). Mapping between messages is not further discussed.
- **Mapping between different reference information models:** Not addressed by the project.

Little information is available about the tools used by the project. The language used for the semantic annotation is description logic represented in OWL-DL, or, in the case of SNOMED-CT, in EL++, which is a subset of OWL-DL. Protégé is mentioned as the editor for ontology creation, and Fact++, Pellet, and HermiT as reasoning engines for OWL-DL. SPARQL is proposed as the query language for semantic queries against the “virtual homogeneous data layer” in the SemanticHealthNet architecture, but it is not clear whether this concept was actually implemented in the project.

### 3.1.4 Governance

The semantic interoperability specifications developed by the project are clearly academic in nature. They defined a method for achieving semantic interoperability within and across eHealth standards,
but do not cover all requirements of a real-life use-case. Therefore, the project has actively examined possible structures for continuing and expanding the work of the project towards a set of re-usable semantic interoperability assets. The project summary states that “one of the most important objectives of the project has been to define and put into place a sustainability approach that can grow the scale, support and resources for [the] stakeholder communities – who inevitably must work together to align their interests and capabilities – to design, implement, adopt and productively use interoperable capability. [...] The project has joined forces with other European projects to establish a new European not-for-profit Institute as the permanent approach to its sustainability: the **European Institute for Innovation through Health Data (i~HD)**. This new Institute has emerged as the most appropriate and welcomed solution to the challenges of sustaining the momentum and community developing solutions for semantic interoperability. Multiple stakeholders from across Europe were involved in workshops and business modelling sessions in order to arrive at this conclusion. i~HD will initially focus its efforts on developing further semantic interoperability resources through an Alliance of relevant stakeholders and experts (including SDOs and industry), establishing a register of interoperability assets and developing an evidence base of benefits from richer interoperability.

### 3.1.5 Lessons learned

This section summarizes the “lessons learned” from the project in terms of successes as well as pitfalls and remedies, i.e. problems the project has identified that the architects of future projects need to keep in mind when designing their solution, and remedies the project has developed or proposed.

#### 3.1.5.1 Successes

**3.1.5.1.1 Semantic Interoperability at Work**

The most important achievement of the SemanticHealthNet project with regard to the concurrent use of standards is that it has demonstrated, albeit on a small scale, how clinical statements (such as a blood pressure or the information that a patient is known to not be diabetic) can be expressed with semantic expressions that enable an application receiving and processing the information to draw the right conclusions even if a) different EHR standards are used and b) different archetypes/templates within a given EHR standard are used to express the same clinical concept.

The approach chosen by the project is to extend the “classical” EHR standards with semantic annotation that defines the meaning of each piece of information in the document in an unambiguous, machine-processable way. This was achieved by combining three ontologies: BioTopLite [SB13] as the top-level ontology, an “**EHR Information entity ontology**” based on BioTopLite, specifically developed by the project, and SNOMED-CT as domain ontology.

The project has also demonstrated that such semantic annotations can be developed for a complete “heart failure patient summary” dataset / document template.

**3.1.5.1.2 Use of a Mock-up Application in the Development of Clinical Information Model**

One of the tasks of the project was the development of a minimal data set (patient summary) for heart failure shared care. The development of such minimal data sets, represented as EHR document templates, are a recurring requirement in many eHealth deployment projects, therefore, the experiences of SemanticHealthNet in this area are useful for future projects. One particular “success story” was the use of a mock-up implementation, i.e. a simple piece of software that offered a graphical
user interface directly corresponding to the data structures of the minimal data set. The following quotes from [SHN1.3] explain the concept, and experiences:

“Early attempts to engage other clinicians have shown that a written data set specification is very hard to appraise properly. We therefore decided to develop a tool that presents the heart failure summary as if it were a clinical application, so that clinicians can do more than just look at a list of data items: they can practice entering example data to verify that provision has been made to capture the data items they feel are important.”

“There is considerable learning to be gained from the communication between clinicians using the written word and the translation into an application and the semantics which underpin the application, alongside ensuring semantic interoperability. At the same time the development of an application allows clinicians and others to explore the facility with which a dictionary of, in this instance Heart Failure terms can be of use on a day to day basis by bringing that dictionary to life. There, then, begins an iterative process to ensure the dictionary is specific and detailed enough to be accurately coded, and applicable to the required domain of practice.”

“The very process of developing the tool, not unexpectedly, revealed to the original authors of the summary data-set that their specification contained some errors, inconsistencies and ambiguities. This has in itself been useful learning, and cautions about the methods that should in future be adopted in the future to develop clinical data set specifications.”

3.1.5.2 Pitfalls and Remedies

3.1.5.2.1 SNOMED-CT Suitable as Domain Ontology?
In order to express the content of clinical documents in a semantically unambiguous manner, SemanticHealthNet uses three ontologies, a top-level ontology, a domain ontology, and an EHR information entity ontology (see section 3.1.2.1.2). The project has chosen parts of SNOMED-CT as the domain ontology. This may be a major pitfall. SNOMED-CT is a terminology including a huge amount of terms and codes for representation of clinical concepts. However, it is not primarily a system of concepts but a repository of categorized terms and codes representing a clinical content from the real world. SNOMED-CT is used by the project as a “model of meaning”. A model of meaning should be a concept model fulfilling the requirements for definitions of concepts and relations between them in a system of concepts, and not just a terminology. The transformation from real world clinical phenomena to semantic interoperable information need to be unambiguously traceable. SNOMED-CT does not warrant this, since concept modelling based on a clinical process model for clinical context and a system of concepts for clinical content are lacking. Both aspects may be considered necessary for developing high level semantic interoperability. A main lesson learned from SemanticHealthNet could be that an “ontological approach”, based on a clinical domain ontology, is a method of choice for achieving the needed paradigm shift in e-health where the clinical perspective is the base. An alternative to SNOMED-CT that was discussed in SemanticHealthNet, but ultimately rejected, would be to choose the Contsys system of concepts (ISO 13940) as the domain ontology.

3.1.5.2.2 Semantic Non-Interoperability Instead of Syntactic Non-Interoperability?
The most important limitation of the SemanticHealthNet approach to semantic interoperability, from the perspective of the author of this case study, is that it requires the use of a single, harmonized ontology language to work. In the past, standards developing organisations have never managed to
produce a single, harmonized EHR standard on a syntactic level, and even developments starting from common ground (such as EN ISO 13606 and OpenEHR) are diverging, and not converging. Furthermore, as the studies of the project point out, there is significant overlap between what can be expressed using the structures of EHR standards, and what can be expressed with post-coordinated codes within a coding system like SNOMED-CT. The expectation that “the world” should suddenly manage to agree on a common “language” on the semantic level is unrealistic, and the fact that the upper-level ontology used by the project, BioTopLite, is a development of one of the authors of the semantic annotation concepts in SemanticHealthNet, confirms this. Therefore, there is a high risk that the approach taken by SemanticHealthNet simply shifts the non-interoperability problem to a different level: Instead of being incompatible due to different syntactic structure, EHR documents may very well end up being incompatible due to different semantic languages.

3.1.5.2.3 Semantic Annotation: How?
The project suggests to annotate EHR content with semantic annotation unambiguously defining the “meaning” of each clinical statement. While this concept is appealing, the project has not examined how such annotations could be placed into the document structures of the existing EHR standards, or if extensions to the standards like HL7 CDA, or EN ISO 13606 would be required, which is rather likely. Therefore, the concept is not immediately implementable.

3.1.5.2.4 Iso-semantic Models are Possible Within a Single EHR Standard
One important pitfall that the SemanticHealthNet project has identified, and solved within their approach, is that non-interoperability on a semantic level is possible not only between users of different EHR standards, but also between users of the same EHR standard, if they use different clinical information models (templates, archetypes) to represent the same clinical concept – something that is quite likely to happen if different teams and domains develop their datasets and document templates. Such “incompatible” clinical information models are called “iso-semantic models”: They carry the same meaning, but use different ways of expressing it.

The solution proposed by the project is to annotate each clinical statement in an EHR document with semantic annotation that unambiguously defines the “meaning” of the statement. In that case, a reasoning engine can automatically determine that two different clinical information models are equivalent, or that one statement can be derived from the other.

3.1.5.2.5 Versioning of Terminology Standards is Important
[SHN2.2] discusses the problem that controlled terminologies or ontologies such as SNOMED-CT change over time, which can introduce subtle (or less subtle) changes in the meaning of individual terms: “In an earlier paper, Lee et al. [LCL11] described various problems associated with the versioning of SNOMED CT and concluded that ‘Of the 5182 concepts in the problem list subset, 2135 (41.2%) underwent some form of change ... Keeping track of these changes is important as they are not well published and have an impact in patient case queries and the accuracy of patient records’”.

The obvious consequence of this observation is that whenever terms from a controlled terminology are used within a clinical document, the version of release of the terminology should also be stored. Only the version information enables the reader to clearly determine the meaning of the encoded information. The project does not discuss how semantic interoperability could be achieved in a situation where multiple versions of a controlled terminology are in use in parallel; however, from the
field of public health, where statistics on ICD-10 codes have been evaluated for many years, it is well-known that there are situations where datasets using different versions of a coding system cannot be converted or compared easily, because codes have been split or merged, or shifted their meaning.

3.1.5.2.6 Performance and Scalability Issues

[SHN4.2] mentions performance (“the response time of an application that implements the approach proposed”) and scalability (“the wide implementation of a system that follows the approach proposed should not result in bad performance”) among the success criteria for the approach proposed by SemanticHealthNet. The problem here is that description logic languages that can be executed efficiently (within polynomial time) are quite limited in their expressive power. As an example, [SHN4.5] points out that EL++, which is the description logic used by SNOMED-CT, does not support negation (“not”), disjunction (“or”) and value restrictions (“only”). More powerful description logics, such as OWL-DL as used by SemanticHealthNet, cannot guarantee efficient execution: “The performance of description logics based representation languages decreases dependent of size and language expressivity. It is still open how the performance of the technologies used for the implementation of the proposed approach (e. g. OWL, RDF, SPARQL), can be kept within reasonable values. This directly affects scalability.”

3.1.5.2.7 Human Aspects: Different Professional Cultures and Expectations

The SHN project summary states that “we have learned how difficult it is for the conceptions of clinical information and interoperability amongst clinicians to be mapped into the formalisms and standards that have been built up by the health informatics community. In particular, clinicians tend to underestimate the difficulties that computers may have in robustly interpreting what seems to them to be common sense understandings, and the informatics community has difficulty in being proportionate in the level of specificity and detailed formality that clinicians and patients could realistically provide when capturing data, and what extent of this is genuinely needed in order to deliver some near term benefits.”

3.1.6 Resources

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<th>[SHNDocs]</th>
<th>Download Site for the Public Deliverables of the SemanticHealthNet Project</th>
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<tbody>
<tr>
<td>Description:</td>
<td>SemanticHealthNet Deliverable 3.1 contains a guideline that specifies the principles and processes that should be followed when developing a record content model (i.e., clinical information model) intended for publication as a standard.</td>
</tr>
<tr>
<td>Availability:</td>
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<tr>
<th>[SHN3.1]</th>
<th>Design principles for record content models standards</th>
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<tr>
<td>Description:</td>
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</tr>
<tr>
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<td>Description:</td>
<td>SemanticHealthNet Deliverable 3.2 complements the guideline published in [SHN3.1] by adding further details about processes and people required for the development of clinical information models, and providing a checklist for the clinical information modelling process.</td>
</tr>
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<td>Availability:</td>
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### References and Further Information


3.2 Case Study #02: Semantic Mediation in ARTEMIS, RIDE and SALUS

- Author of case study within the eStandards project: Marco Eichelberg <eichelberg@offis.de>
- Project name: ARTEMIS, RIDE and SALUS
- Project type: limited deployment for experimental use
- Project status (in 10/2015): all completed
- Countries / Regions:
  o ARTEMIS: South-east Belfast Trust, UK (3 sites); Turkey (6 sites)
  o RIDE: not applicable (conceptual work only)
  o SALUS: LISPA (Lombardia Region, IT), Dresden University Hospital (DE)
- Project partners:
  o ARTEMIS: METU-SRDC (TR), OFFIS (DE), SEBT (UK), ALTEC (GR), Tepe Teknoloji (TR), IT Innovation Center (UK)
  o RIDE: METU-SRDC (TR), OFFIS (DE), IFOMIS (DE), EuroRec (FR), CNR (IT), NTUA-ICCS (GR), NUIG-DERI (IR), IHE-D (DE), OLE (BE)
  o SALUS: SRDC (TR), EuroRec (FR), WHO-UMC (SE), OFFIS (DE), AGFA (BE), ERS (NL), LISPA (IT), INSERM (FR), TU Dresden (DE), Hoffman-La Roche (CH)
- Scale of deployment: regional

3.2.1 Project Overview

This case study presents three different R&D projects funded by the European Commission in the 6th and 7th Framework Programme:


While these projects had different goals and consortia, they were all coordinated by the SRDC (Software Research and Development Centre) research team led by Prof. Asuman Dogac (Ankara, TR) and shared a common technological approach, the use of semantic mediation techniques to achieve semantic interoperability in the context of exchanging health information. Each project built and improved upon the results of the previous project. Therefore, from the perspective of this document it makes sense to combine them into a single case story.

In terms of their goals, the overall projects were quite different: ARTEMIS aimed at developing an infrastructure based on web-service and peer-to-peer technology for enabling the sharing of clinical information between healthcare professionals. RIDE was a classical “roadmapping” coordination and support project that developed a roadmap towards semantic interoperability in the eHealth sector, but also did some limited technical work. SALUS was a project that examined the challenge of “secondary use” of EHR data, i.e. the question of how clinical documentation created during the routine care processes can be used for research and public health questions, specifically, for the identification of yet unknown Adverse Drug Events (ADEs). In this context a tool was developed that uses data
mining techniques to identify probable cases of ADEs in a routine EHR database, presents the results to a human expert, and semi-automatically fills in the ADE Case Report Forms to notify the authorities about ADE incidents for those cases where the human expert decides that such reporting is appropriate. In all three projects, the question of concurrent use of, and conversion between, eHealth standards based on semantic mediation was addressed, in the first two projects in order to convert between competing standards (HL7v2 and HL7v3), in the last project in order to convert information from a format used for routine documentation (HL7 CDA) to the format required for ADE case reporting. The approaches developed by each project can be seen as refinements of the previous project. Details will be presented in the following sections.

3.2.2 Approach

When analysing the technical approach of the projects following the “Layers of Interoperability” defined by the ANTILOPE project [vPS14], it can be said that none of the projects addressed the legal/regulatory or policy layer, and there was no work on care process interoperability either. Various communication protocols (web-services, JXTA as peer-to-peer protocol) were used on the IT infrastructure layer, but this was also clearly not the focus of work. The following description, therefore, focuses on the information and application layers.

3.2.2.1 Information

3.2.2.1.1 The ARTEMIS Message Exchange Framework

One goal of the ARTEMIS project was to enable a fully automated conversion of messages exchanged between healthcare institutes from the format used by the sender to the format expected, and supported, by the recipient. Bicer et al. [BLD+05] describe the corresponding “engineering approach developed within the scope of the ARTEMIS project to provide the exchange of meaningful clinical information among healthcare institutes through semantic mediation.” The approach has two distinct phases, shown in Figure 4 and Figure 5.

The first phase, shown in Figure 4, the so-called “Message Schema Mapping Process”, starts with XML Schema Definitions (XSD) of both the source format in which messages will be available later on, and of the target format supported by the recipient. This means that the approach is only applicable to message formats that can be expressed in XML. However, for many non-XML based eHealth standards such as HL7v2 or DICOM, conversion rules to an equivalent XML representation exist, whereas other message formats like HL7v3 messages or EN 13606 extracts are usually defined in XML anyway, so this restriction seems acceptable. The following steps are applied during this phase:
1. The first step is a process called “conceptual normalization” that automatically converts the XSD schemas into equivalent OWL ontologies. [BLD+05] explain that “the [...] XML Schemas (XSDs) are converted to RDFS (Resource Description Framework Schema) by using the Conceptual Normalization (C-Normalization) engine of the HARMONISE project. This process uses a set of heuristics [...] and produces a “Normalization map” describing how a specific [...] message XSD is transformed into the corresponding RDFS schema and vice-versa. Then, by using the OWL Wrapper, which we developed using Jena API, RDFS Schemas are transformed to OWL.” The HARMONISE conceptual normalization engine is described by Fodor et al. in [FDR+02].

2. The second step is a manual process called “ontology mapping”, where a mapping from the source ontology to the target ontology must be defined by a human expert, with tool support. [BLD+05] explains: “The OWL message instances are then mediated through an ontology mapping tool that we developed, namely, OWLmt. OWLmt uses [the] OWL-QL engine which enables the mapping tool to reason over the source ontology instances while generating the target ontology instances according to the mapping patterns defined through a GUI. [...] In order to represent the matching between the classes of source and target ontologies, we have defined four mapping patterns: EquivalentTo, SimilarTo, IntersectionOf and UnionOf. [...] Furthermore, a class in a source ontology can be a more general (super class) of a class in the target ontology. In this case, which instances of the source ontology makes up the instances of the target ontology is defined through KIF (Knowledge Interchange Format) conditions to be executed by the OWLmt mapping engine.” The result of this step is a “mapping definition” that is used in the second phase. The OWLmt mapping tool has been published by the project as open source software, see [OWLmt].

The second phase, shown in Figure 5, is the “Automatic Message Instance Transformation Process”. Once the normalization maps and mapping definition have been developed, the system can convert messages from the source format into the recipient format without any manual interaction. First of all, the source message (in this case an HL7 v2 message in the classical HL7 “EDI” message encoding) is converted to an equivalent XML representation using a converter tool (the open source HAPI library was used for this purpose). Then the HARMONISE normalization engine together with the OWL wrapper are used to convert the XML message into an equivalent OWL instance. The mapping rules defined in the “mapping definition” are applied by the ARTEMIS mapping engine, producing an OWL instance in the format required for the recipient. Then again, OWL wrapper and HARMONISE normalization engine are used to convert the OWL instance back into an XML dataset. In this case, the desired target message format, HL7v3, is natively expressed in XML, so no further conversion is required.
It should be noted that this approach, which essentially performs the mapping between two messages on an XML schema level, is very coarse-grained. For example, in the XML schema defining the CDA document format, the same XSD element can represent a wide variety of different data that needs to be mapped to different parts of the target format. While the approach was sufficient for the limited set of HL7 messages used in the ARTEMIS project, it is not powerful enough for more complex mapping tasks. For this reason, more powerful approaches were developed by the same research group, as described in the following sections.

3.2.2.1.2 Semantic Mediation in ARTEMIS using Archetypes

Bicer et al. [BKD+05] present an extension of the ARTEMIS Message Exchange Framework for cases where the message content to be translated is defined in terms of Archetypes, i.e. constraint rules that are applied to a generic reference model. The approach assumes that different but equivalent archetypes have been defined both in the source format and in the target format for the various clinical statements in the message, and that these archetypes are expressed in the Archetype Definition Language (ADL) that is used in EN ISO 13606 and OpenEHR. However, [BKD+05] demonstrates that it is possible to also express HL7v3 templates using ADL.

In a first step, the ADL archetypes are converted into OWL ontologies following a methodology published by Kilic et al. in [KBD05]. Then a mapping between two corresponding archetypes is defined using the OWLmt mapping tool developed in ARTEMIS. [BKD+05] explains: “We need to transform archetypes of one standard into another through ontology mapping. For this purpose, we use the OWL representation of both the involved reference information models and the archetypes. Then, through an OWL ontology mapping tool that we developed, called OWLmt, we map the reference information models and the archetype schemas one into other. Once such a mapping is achieved, OWLmt automatically transforms a Web Service message annotated with an archetype in one standard into another.”

Once the mapping has been defined, the second phase, i.e. the Automatic Message Instance Transformation Process, works as described in the previous section. [BKD+05] explains: “The OWLmt mapping engine creates the target archetype instances in OWL, using the mapping patterns in the Mapping Definition and the instances of the source archetype. It uses OWL Query Language (OWL-QL) to retrieve required data from the source ontology instances. While executing the class and property mapping patterns, the query strings defined through the mapping GUI are sent to the OWL-QL engine with the URL of the source ontology instances. The query engine executes the query strings and returns the query results. During this process, OWL-QL uses the reasoning capabilities of Java Theorem Prover (JTP) to infer new facts from the source ontology and use them in order to construct the target ontology instance.”

3.2.2.1.3 R-MIM-based Transformation of EHR Structure and Content

A further development of the approach described in the previous section, i.e. semantic mediation based on archetypes, was developed in the context of the RIDE project and presented by Kilic and Dogac in [KD09]. The main difference of this approach is that it assumes that both the information model of the source EHR standard, and the information model of the target EHR standard are derived from, or can be expressed as a specialization of a common Reference Information Model, more specifically, the HL7v3 RIM. This applies not only to HL7v3 messages and HL7 CDA documents, but also to EN ISO 13606, because “the possibility to represent the constructs of the CEN reference model as
classes and attributes of the HL7 RIM is ensured. For this purpose, CEN has produced a D-MIM [Do-
main Message Information Model] correspondence of its reference model by deriving it from the HL7
RIM” [KD09]. So essentially the work demonstrates how a mapping between clinical statements for-
matted according to archetypes in HL7 CDA and EN 13606 can be achieved using semantic mediation
techniques.

![Diagram](image)

**Figure 6: R-MIM based mapping of EHR instances [KD09]**

The mapping approach is shown in Figure 6. Like described in the previous sections, there are two
phases, where in the first phase the mapping definitions are created and in the second phase EHR
instances are automatically transformed. The definition of the mapping, however, makes use of the
fact that both archetypes define constraint rules on a refined message information model (R-MIM)
derived from the same fundamental Reference Information Model (RIM). [KD09] explains:

“In the first phase, the “mapping definitions” are produced between two archetypes that are based
on different R-MIMs but express the same clinical concept. The classes of the source and the target
archetypes are compared in order to discover the origins of the classes in the RIM to find out matching
properties. Since this process involves reasoning, the OWL representations of the RIM, the R-
MIMs (the source and the target), and the archetypes (the source and the target) are used. The mapping
definitions produced in this phase are stored to be used later.” Kilic and Dogac further argue
that “the archetype concept proves to be a powerful mechanism in mapping different EHR content
semantics to each other for the following reason: ontology mapping, in fact, involves introducing
constraints when mapping the source ontology concepts to the target ontology concepts. For exam-
ple, when we want to map a “Person” concept in a source ontology to a “Female_person” concept in
the target ontology, we place a constraint on the gender attribute. On the other hand, such con-
straints used in the semantic mapping come prepackaged with the archetypes because archetypes
themselves define constraints to express semantics. […] The methodology provides semiautomatic
mapping of archetypes.”

“In the second phase, the “mapping definitions” are used to transform one EHR instance to another. [...] The inputs of the process are the source clinical statement instance in XML format and the “mapping definitions.” Since the clinical statement instance is in XML format, it is first converted to OWL through the “XML to OWL normalizer” component. In order to perform this conversion, the “XML to OWL normalizer” finds the archetype to which the source instance conforms to. This information is obtained from the instance that inherits the “templateId” attribute from “InfrastructureRoot” class in the HL7 RIM. [...] The OWL representation of a source instance is constructed from its archetype. The next step is finding the “mapping definitions” from the source archetype to the target archetype. When such a mapping is found, the “transformation engine” starts creating the target EHR instance in OWL using the property mappings available in the “mapping definitions.” After processing the property mappings, default values are assigned to the properties of the target instance. The next step is to transform the target OWL instance to XML format through the “OWL to XML normalizer.”

Kilic and Dogac conclude that “once the archetypes are mapped, clinical statement instances are transformed automatically given that they use a common terminology system.”

To summarize, the main differences of the improved mapping approach presented in [KD09] are that archetypes are used in the “conceptual normalization” of EHR content (i.e. in the conversion from XML to OWL), and that the mapping between two archetypes represented in OWL can be defined in a semi-automated manner because both are derived from the same RIM, which enables a reasoning engine to identify related concepts. The approach does not address the issue of mapping between different terminologies. Furthermore, the approach has – to the knowledge of the author of this case study – not been evaluated in a real-world setting, only in the context of academic “toy problems”.

### 3.2.2.1.4 The SALUS Semantic Framework

Laleci et al. [LDY12] describe the objective of the FP7 SALUS project (“Scalable, Standard based Interoperability Framework for Sustainable Proactive Post Market Safety Studies”) as follows: “We aim to create the necessary infrastructure to enable secondary use of EHRs in an efficient and effective way for reinforcing the post market safety studies so that patient safety can be ensured through early detection of rare adverse events, pharmaceutical industry can be fostered to enable faster medication innovation decreasing time to market new, safe and effective drugs, yet the load of overwhelmed medical practitioners can be reduced.” In another article, Laleci et al. [LYD13] explain that while there are various standards and standardisation activities both in the EHR domain and in the domain of public health and clinical research, there is a disconnect between these domains that often prevents interoperability: “When it comes to reusing the existing electronic health records (EHR) maintained at the investigator sites, these standard initiatives [CDISC and ICH-E2B] fall short and as a result, at present, the clinical research and the clinical care domains are quite disconnected. For example, the electronic data capture systems, which are widely used for the collection and submission of study data from investigators to sponsors, are usually not connected to the EHR systems that are being used by investigator sites (i.e., the health care providers) for managing clinical care. Currently, the clinicians have to manually copy the results of therapeutic procedures and examinations from an EHR system into the case report form which causes errors and work disruption as well as delays in reporting data. Similarly, the investigators have to manually select the eligible patients from the underlying EHR systems by examining the inclusion/exclusion criteria listed in the study design docu-
ments. These challenges basically stem from the fact that the clinical research and the clinical care domains each use different standards as “models of use.”

Krahn et al. [KEG+14] outline the approach implemented in SALUS as follows: “In order to facilitate access to the EHRs of distributed, heterogeneous clinical information systems, an interoperability platform is designed, supporting different interfaces based on widespread semantic technologies and “Integrating the Healthcare Enterprise” (IHE) integration profiles. In order to meet the SALUS requirements, the IHE profiles IHE "Query for existing data" (QED) and "Care Management" (CM) have been extended. On top of these components, which provide standardized access to EHR data, a semantic interoperability layer translates information between different clinical data representation standards and terminology systems according to our harmonized information model. The interoperability platform is used by a set of tools to detect and report cases of ADEs.”

Laleci et al. [LYD13] add: “Our Semantic Framework is based on semantic mediation, which is a process of matching schemas and mapping attributes and values using semantics. In achieving this, the mediator needs a shared conceptual reference model expressed as an ontology to serve as the common ground to correlate the concepts from different sources to reconcile their differences and to establish some well-defined relationships among them. In other words, there is a need for a common “model of meaning”. [...] Fortunately, this shared conceptual model exists for the clinical care and research domains thanks to the effort by the BRIDG Project: the BRIDG DAM (Domain Analysis Model) unifies various aspects of all the concepts in the clinical care and research domains and creates a shared generic representation for each concept. [...] For our Semantic Framework, we have developed the RDF representation of the BRIDG DAM to be used as the core ontology to make the common shared semantics available in a formal, machine processable form. [...] Once such a core ontology is established, there still remains the challenge of resolving heterogeneities among clinical care and research domains by making use of this machine processable shared conceptual reference model. For this, first, semantic models of the respective standards in clinical care and research should be built and aligned with the core ontology. [...] To facilitate this process, in our Semantic Framework, we have developed tools to: 1) import existing clinical care and research standards to a common knowledge base where the core ontology is hosted; 2) extract semantic models of these standards, and 3) align the extracted semantic models with the core ontology to create a harmonized ontology.”

The architecture of the SALUS Semantic Framework is shown in Figure 7. [LYD13] explains the components of this architecture as follows:

- **A: RDF Representation of the BRIDG DAM as the Basis of the SALUS Core Ontology:** “The BRIDG Project has developed a coherent clinical research vocabulary that integrates established domain knowledge from existing standards developed at CDISC, HL7, FDA, NCI, and others. [...] As a result, the latest BRIDG DAM (v3.0.3) is fully aligned with HL7 RIM. [...] UML was chosen as the representation language. In other words, the BRIDG DAM is an implementation independent UML model to represent common shared semantics of regulated clinical research studies which may have different implementations. [...] The first challenge of developing the Semantic Framework is to provide a machine processable semantic representation of the BRIDG DAM together with its mappings to the harmonized standards. [...] In this study, a complete RDF representation of the latest BRIDG DAM (v3.0.3) is created [...]. The created BRIDG DAM ontology in RDF is accessible from [SALUSres].”
B: Aligning the Standards Harmonized by BRIDG with the SALUS Core Ontology: “After having an ontological representation of the BRIDG DAM as the core of our Semantic Framework, called the SALUS core ontology, the next step is to semantically lift the standards harmonized within the scope of BRIDG initiative. This step involves making use of the schema-to-RDF tools to create RDF representation from the XML schemas of the standards. Then, the machine processable mapping definitions between these semantically lifted standards and the SALUS core ontology, which explicitly specify the relationships among them, are defined. Some of the standards harmonized by the BRIDG initiative are vocabularies termed as “datasets,” i.e., the variable definitions that can be used in clinical messages. […] The mapping between these datasets and the BRIDG domain is easy: an SPARQL query is defined to map each variable in the dataset to the SALUS core ontology. […] For those BRIDG harmonized standards that have a compositional nature enabling multidimensional representation of clinical data, such as HL7 RIM-based models, a more complex mapping is required where a target hierarchical object model should be created from a source hierarchical object model. […] To handle mediation among semantic hierarchical object models, ontology mapping tools are used that make it possible to represent mapping definitions declaratively so that the source objects can be automatically converted into target objects using these mapping definitions. The engines processing these mapping definitions also utilize reasoners to deduce implicit mappings between classes given the explicit mapping relationships. In the implementation of our Semantic Framework, for the ontology mapping definitions, the SPINMap formalism is used. SPINMap is an SPARQL-based language to represent mappings between RDF/OWL ontologies. In particular, SPIN facilitates to associate mapping rules with the ontology classes, and the SPIN templates and functions can be exploited to define reusable build-
ing blocks for typical modelling patterns. By associating mapping rules defined using the 
SPARQL CONSTRUCT clause, it is possible to define sophisticated rules that map one graph 
pattern in the WHERE clause to another graph pattern. Such mappings are used in our Se-
monic Framework to transform the source class instances to the target class instances.”

- **C: Exploiting Terminology Systems Within the Semantic Framework:** “When the terminolo-
  gy systems used by clinical care and clinical research centers differ, although the parties can 
  receive the clinical content in the expected standard such as CDISC or HL7, the exchanged 
  content may not be fully comprehensible. [...] There are a number of challenges to handle 
  this problem: First, the ontological representations of the terminology systems as well as the 
  mappings among them are needed to be hosted in the SALUS knowledge base, so that they 
  can readily be utilized by semantic mediation tools. An important resource enabling this ob-
jective is the BioPortal initiative. BioPortal is an open repository of biomedical ontologies 
hosted by the USA National Center for Biomedical Ontology. It gives the ability to browse, 
search and visualize more than 280 biomedical ontologies including major terminology sys-
tems both via Web browsers and REST services. It also serves the mapping definitions be-
tween these ontologies. BioPortal makes use of the available mappings in the UMLS and ex-
tends them with NLP-based methods. [...] To be able to automatically map the clinical data 
using different terminology systems to one another through the reasoners used by semantic 
mediation tools, there is a need to align SALUS core ontology instances with the respective 
terminality ontologies. In particular, it is necessary to link the coded terms in SALUS core 
tonology instances representing clinical data collected from participating sites with the SA-
LUS terminology ontology resources, and to utilize terminology reasoning while querying the 
collected clinical data. [...] In our Semantic Framework, terminology ontologies downloaded 
from the BioPortal are used where each terminology code is represented as a class in the 
corresponding ontology [...], which gives a part of SNOMED CT ontology. The mapping defin-
tions also imported from the Bioportal give the relationships established between matching 
classes of different ontologies.”

- **D/E/F: Semantic Mediation of Clinical Data Instances:** “Once the semantic models of clinical 
  research and clinical care standards together with their machine processable mapping defini-
tions are in the SALUS knowledge base, it becomes possible to use them for the semantic 
mediation of instances of the clinical documents and messages and also to semantically que-
ry the data gathered from clinical care and research systems. This is achieved in [the] follow-
ing [...] steps.
  - D: The Semantic Framework provides scripts to load the clinical data instances like a 
    patient’s medical summary to the knowledge base as the instances of the SALUS core 
    ontology. This is achieved through the XML-2-RDF scripts, which create an ontologi-
    cal representation of the data feeds in conformance with the semantic model of the re-
spective standards such as HL7 CDA. Then, by executing the previously defined 
SPINMap rules between the clinical content standard and the SALUS core ontology in 
an SPIN engine, the inferred triples representing the same clinical content as in the 
original document or message but compliant with the SALUS core ontology are au-
tomatically imported to the knowledge base.
  - E: Once the clinical data are transformed to the core ontology model and accumula-
ted in the knowledge base, it also becomes possible to semantically query them to re-
retrieve data annotated with dataset standards like, CDASH (Clinical Data Acquisition Standards Harmonization), SDTM (Study Data Tabulation Model), or CRFQ (HL7 Clinical Research Filtered Query). This is achieved through the library of SPARQL queries that have been defined for the respective dataset standard. […]”

- After having the clinical data instances represented in the core ontology model available in the knowledge base, again using the machine processable mapping definitions, it becomes possible to represent the same clinical data in the target clinical standard of interest. […]

Finally, Laleci et al. [LYD13] discuss the choice of Virtuoso as the reasoner used for the SALUS knowledge base: “All the semantic artifacts of our Semantic Framework, namely, the SALUS core ontology including the semantic models of clinical research and care standards, their mapping to the core semantic model, the terminology ontologies and the mappings between these terminology ontologies, are all hosted in a knowledge base. The main consideration for the choice of the SALUS knowledge base is its performance, which is related to the complexity of the reasoning process involved without sacrificing the needed computational power. In our Semantic Framework, we have the following reasoning requirements: 1) Subsumption reasoning […] 2) Reasoning on equivalence of classes […] 3) Reasoning on transitivity of properties […]. Clearly all the RDF and OWL-DL reasoners support all these features and much more. However, due to the very large number of triples (around 4.7 million) to be reasoned on in the SALUS knowledge base, we have chosen Virtuoso as the knowledge base tool. Virtuoso supports a limited reasoning capability when compared to other RDF and OWL-DL reasoners; however, the limited set of constructs […] fully address our reasoning requirements. In addition, with this limited but sufficient reasoning capability, Virtuoso outperformed many well-known reasoners with its performance in both time and space perspectives in our case. We tried to realize our scenario with Jena, OWLlim, Fact++, Pellet, and Hermit reasoners as well but either they were not able to load all the ontologies we have, or unable to complete the reasoning process.”

3.2.2.1.5 Terminology Mapping in the SALUS Semantic Framework

One of the challenges of semantic interoperability that was addressed in SALUS, but not in the earlier projects, was the mapping between different terminologies. Hussain et al. [HSS+14] explain: “Achieving a computable semantic interoperability among different healthcare applications is – at its core – deeply dependent on the use of “controlled terminologies” which enable the inter-machine exchange of clear and computationally unambiguous semantics. Aiming towards this goal, clinical experts go through a process of defining “terminology mappings” between “standard” terminologies developed by standards organizations (CDISC, IHTSDO, ICH, etc.), as well as local/legacy terminologies […]. Recent research projects focusing on computable semantic interoperability – such as SALUS, Open PHACTS, and EHR4CR — have published their experiences in defining and utilizing multiple mappings between various terminologies. Although, on the surface, it may appear to the uninitiated as a simple exercise like “this term in this terminology is the same as that term in that terminology”. However, it is often a considerably challenging task [1] due to: (i) availability of up-to-date information to assess the suitability of a given terminology for a particular use case; (ii) difficulty of correctly using complex, rapidly evolving terminologies; (iii) differences in granularity between the source and target terminologies; (iv) lack of semantic mappings in order to completely and unambiguously define computationally equivalent semantics; (v) lack of provenance information, i.e. how, when and for what purposes the mappings were created; and (vi) time and effort required to com-
Yuksel et al. [YDT+14] argue that “when different terminology systems are used in the same compositional structure, it is necessary to semantically mediate them for interoperability”. They explain this in the example shown in Figure 8, where two excerpts from HL7 CDA documents following the CCD template are shown. Both examples use exactly the same structure, and are thus compliant to the same entry-level template (archetype). Furthermore, both examples contain exactly the same information, that is, that the blood glucose status of the patient was tested, and the test result was normal. The problem here is that different terminologies can be combined to express the same meaning, and that complex terminologies such as SNOMED-CT often offer more than “one way” of expressing one statement.

Yuksel et al. [YDT+14] state that “this problem is well-known and to address it, terminology bindings have been proposed which specify the association between a data point (node) of an information or data model and the set of terms that can be used to populate that data point’s value. The set of permissible values for a data point can be expressed by a query or a rule.”

3.2.2.2 Applications

On this level, the import and export of medical information from and to the healthcare information systems is handled. In ARTEMIS (and RIDE), this was rather straightforward: An HL7v2 message feed with laboratory data was used as the input to the semantic mediation process, and converted to HL7v3 messages using the semantic mediation framework presented above.

For other medical data, an extended (decentralized) version of the IHE Retrieve Information for Display (RID) integration profile was developed. This Web-based integration profile only deals with sharing documents or structured data for presentation to a human reader in a Web browser, and does not care about semantic interoperability or integration of the information in a target information system.
system. This approach is presented in [AE05] and [EAT05].

In the SALUS project, two alternative approaches were implemented to access clinical information from the underlying clinical information system. Krahn et al. [KEM+14] explain: “Two different methods are being used to retrieve medical summaries from the underlying clinical information system (CIS). For semantically enabled EHRs systems, we use an interface to query the CIS through the native “SPARQL Protocol And RDF Query Language” (SPARQL) endpoint they expose. In such systems the medical summary is retrieved in a local “Resource Description Framework” (RDF) model of the underlying EHR database. As an alternative option, we implement IHE based standards to query and subscribe to the CIS to collect medical summaries; namely IHE “Query for Existing Data” (QED) and “Care Management” (CM) have been implemented. In this way, we communicate with the CIS through standard interfaces and are able to collect medical summaries in a format conforming to IHE PCC “Clinical Document Architecture” (CDA) based templates. [...]”.

It should be noted that the use of the profiles QED and CM to access EHR information significantly simplifies the process of semantic mediation, because data returned by these profiles already have a well-defined format and meaning.

### 3.2.3 Concurrent Use of Standards and Specifications (De-facto Standards)

The concurrent use of standards and specifications in the projects ARTEMIS, RIDE and SALUS has been outlined in the previous section. In brief, it can be summarized as follows:

- **Mapping between controlled terminologies (coding systems):** Addressed in SALUS, see section 3.2.2.1.5
- **Mapping between identifiers:** Not addressed.
- **Mapping between clinical concepts:** Addressed in the extensions of the ARTEMIS architecture that perform a mapping between EHR standards based on a semantically mediated mapping between archetypes, see sections 3.2.2.1.2 and 3.2.2.1.3.
- **Mapping between document formats:** A semantically mediated mapping between HL7 CDA R2 and EN ISO 1606 documents was designed in the extensions of the ARTEMIS architecture discussed in sections 3.2.2.1.2 and 3.2.2.1.3. A mapping from HL7 CDA R2 to a CDISC Study Design Document was implemented in SALUS, see section 3.2.2.1.4.
- **Mapping between messages (e.g. notifications, queries and responses):** A semantically mediated mapping between HL7v2 and HL7v3 messages was implemented in ARTEMIS, see section 3.2.2.1.1.
- **Mapping between different reference information models:** Addressed in the extensions of the ARTEMIS architecture that perform a mapping between EHR standards based on a semantically mediated mapping between archetypes, see sections 3.2.2.1.2 and 3.2.2.1.3.

Several tools – both existing third party tools and developments of the project teams – were used. The more important ones include the HARMONISE Conceptual Normalization Engine (which was an open-source implementation but seems to not be available anymore), the OWLmt mapping tool [OWLmt], the Java Theorem Prover [JTP05], the BRIDG DAM documentation [BRI12], BioPortal [NCB15] and Virtuoso [OL15].
3.2.4 Governance

The concepts and architectures described in this case study were developed in the context of R&D projects and academic research. There is no continuous maintenance or governance structure.

3.2.5 Lessons learned

3.2.5.1 Successes

3.2.5.1.1 Semantic Mediation works (under certain conditions)

The projects ARTEMIS, RIDE and SALUS have demonstrated that semantic mediation techniques can be successfully applied to convert messages or documents from one standard format to another format, and thus achieve semantic interoperability. This was shown for:

- A conversion of HL7v2 messages to HL7v3
- A conversion between HL7 CDA document and EN ISO 13606 EHR content
- A conversion from a HL7 CDA/CCD based patient summary to other document formats used in clinical research, such as the CDISC Study Design Document.

The primary challenge in applying semantic mediation techniques is the modelling of the information on the semantic level, and the definition of the mapping between ontologies. In the first approach implemented in ARTEMIS, the definition of the ontologies for source and target format in ARTEMIS was quite simple and directly derived from an XML Schema Definition, and the mapping between ontologies was completely manual. Later developments improved the ontologies by exploiting the information contained in archetypes/templates, and the information from common reference models such as the HL7 RIM (in RIDE) or the BRIDG DAM ontology (in SALUS), which allowed for a semi-automatic mapping processes supported by reasoning engines. In the SALUS project, the issue of terminology mapping was also addressed to some degree, based on BioPortal resources.

In all three projects, the conversion always took place on a very limited set of values. The typical problems of terminology mapping, such as the presence of similar, but not identical terms in different terminologies, or ontologies, or the absence of an appropriate term to map to, could be avoided or manually addressed in these cases. Furthermore, the scope of each project was small enough that the required ontologies could be developed by the project team. This may not translate well to projects that try, for example, to represent a patient summary in electronic form, where any body part, any family history, and diagnosis etc. may occur, which would require much more complex ontologies that are simply not available today. In summary, the approach works given that the scope of the semantic mediation can be kept sufficiently small, but it requires a development team with sufficient resources and expert knowledge in the underlying domain models, EHR standards, terminologies, and, quite importantly, semantic technologies (ontology modelling, semantic mediation), supported by state-of-the-art tools.

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2 To some degree, the semantic technologies used allow for complex mapping schemes such as splitting or merging of codes, and reasoning based on an “is-a” hierarchy of codes.
3.2.5.2 Pitfalls and Remedies

3.2.5.2.1 Limitations of the Approach
The authors cited in this case study paint a very positive picture of the possibilities of semantic mediation. However, one must keep in mind that, usually, mapping techniques work better the more the domain is limited (both in term of types of models mapped and kind of information); they usually work better with experts designed samples, than with real data. Sometimes the methodology applied assumes the availability of resources (such as ontologies, information model maps, terminology maps) that are often only partially (or not at all) available. These resources have to be developed and maintained and typically they require a huge investment in term of knowledge, time and resources. Models (e.g. HL7 V2 and V3 messaging) and terminologies (e.g. ICD-10 and SNOMED CT) are rarely iso-semantic, so mapping generally implies a loss of information. Maps are usually directional. If the representations of assertive data are complex, the problem could become even more complex for the representation of unknown / unavailable / uncertain data.

It should be stressed that the ideal solution is to work in the direction of harmonization. Mapping techniques (including semantic mediation) are, however, unavoidable for facing current coexistence issues. They should be applied only within well-defined, narrow scopes – this is where they work well. When selecting the technologies for an eHealth project, users need to carefully evaluate the balance between costs (knowledge, resources, time) and results to be achieved. For example, the most simple way to map terminologies is to use a directional tabular map; more complex mapping functions could be defined using non-linear maps, but sometime even the most complex techniques only provide very small improvements (i.e. a few additional mapped codes) over the simple ones.

Finally, it should be noted that any mapping needs to be done (implicitly or explicitly) on the conceptual level (i.e. on the level of the clinical information model or the “business logic”) – as the examples presented in this case study show, where the archetype, being the formal expression of a clinical information model, was quickly identified as the appropriate level on which a mapping should be based. This also means that the mapping is a task that cannot be done by IT experts alone – it requires medical domain experts, ontology experts, and IT experts who can finally implement the results.

3.2.5.2.2 Performance Considerations
One specific pitfall of the use of semantic mediation technology is that ontology-based reasoning is – possible very – computationally intensive, which may limit the usability or scalability of any such approach. Specific heuristics may be required to keep the performance of an implementation at an acceptable level. Laleci et al. [LYD13] report about the SALUS project: “Currently, the SALUS knowledge base contains about 4.7 million triples in total; around 4 million of these are from terminology ontologies; around 73K triples from the HL7 CDA ontology; approximately 19K from the BRIDG DAM; around 170K from the mapping between CCD model and the SALUS core ontology, and 450K comes from the mappings among terminology ontologies. [...] For the real life deployment of semantic interoperability systems, there are two critical challenges. The first is getting the harmonized domain specific information right because this affects the quality of the mediation. The second challenge is keeping the computational complexity of the reasoning process within reasonable bounds when the knowledge base contains real-life size data including more than 4.7 million triples. In order to efficiently handle this large—and still growing—knowledge base, several heuristic mecha-
nisms are developed within our Semantic Framework:

- “In the BioPortal terminology ontologies, terminology codes are represented through classes. While linking SALUS core ontology instances with BioPortal terminology ontologies, we have chosen to create instances of terminology ontology classes, and associating the coded terms in the SALUS core ontology instances through these instances rather than the terminology classes. In this way, we avoided the harmonized ontology to be OWL-Full, which would have made reasoning prohibitively expensive.

- “Rather than using a knowledge base system with full RDF and OWL-DL reasoning support, we use Virtuoso, which supports a limited reasoning capability, yet fully addresses reasoning requirements of our Semantic Framework with good performance.

“[…] On an average desktop computer with Intel Core 2 Duo—3 GHz CPU and 4 GB RAM, the semantic mediation of a medical history in CCD format to SALUS core ontology takes approximately 110 s. As for the query execution performance, an example SPARQL query to check the underlying conditions of patients can be executed on the knowledge base hosting more than 4.7 million triples under 7 s. These results are quite encouraging for a real-life deployment of our Semantic Framework.”

While 110s seconds processing time for the conversion of a single patient summary may be acceptable for a small-scale deployment, it may very well be a limiting factor for a large-scale nation-wide eHealth network.

3.2.6 Resources

<table>
<thead>
<tr>
<th>[OWLmt]</th>
<th>OWLmt</th>
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<tr>
<td>Description:</td>
<td>Graphical OWL Ontology Mapping Tool</td>
</tr>
<tr>
<td>Availability:</td>
<td>open source (Mozilla Public License, Version 1.1)</td>
</tr>
<tr>
<td>Link:</td>
<td><a href="http://sourceforge.net/projects/owlmt/">http://sourceforge.net/projects/owlmt/</a></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>[SALUSres]</th>
<th>SALUS Resources (ontologies, mappings, queries)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Description:</td>
<td>Various resources published by the SALUS project, including the mapping of BRIDG DAM to RDF, SPINmap mappings between ontologies, and SPARQL sample queries</td>
</tr>
<tr>
<td>Availability:</td>
<td>freely available</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>[SALUSmdr]</th>
<th>SemanticMDR</th>
</tr>
</thead>
<tbody>
<tr>
<td>Description:</td>
<td>A semantic implementation of an ISO/IEC 11179 based Metadata Registry/Repository.</td>
</tr>
<tr>
<td>Availability:</td>
<td>open source (GNU General Public License V3)</td>
</tr>
<tr>
<td>Link:</td>
<td><a href="https://github.com/srdc/semanticMDR">https://github.com/srdc/semanticMDR</a></td>
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<table>
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<tr>
<th>[SALUSont]</th>
<th>Ontmalizer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Description:</td>
<td>Ontmalizer is a tool for comprehensive transformations of XML Schemas (XSD) and XML data to RDF/OWL automatically.</td>
</tr>
<tr>
<td>Availability:</td>
<td>open source (Apache License 2.0)</td>
</tr>
<tr>
<td>Link:</td>
<td><a href="https://github.com/srdc/ontmalizer">https://github.com/srdc/ontmalizer</a></td>
</tr>
</tbody>
</table>

3.2.7 References and Further Information


3.3 Case Study #03: IHE Cross-Community Profiles

- Author of case study within the eStandards project: Marco Eichelberg <eichelberg@offis.de>
- Project name: IHE Cross-Community Profiles
- Project type: concept (but implemented in large-scale deployment for sustained routine use)
- Project status (in 10/2015): deployed for sustained routine use
- Countries / Regions: deployments primarily in the United States
- Project partners: Integrating the Healthcare Enterprise (IHE) International
- Scale of deployment: cross-border, cross-region, regional

3.3.1 Project Overview

This case study describes a number of specifications called “Integration Profiles”, which have been defined and are maintained by the Integrating the Healthcare Enterprise (IHE) initiative. IHE is described in [ITI-TF1, chapter 1] as follows: “IHE is an initiative designed to stimulate the integration of the information systems that support modern healthcare institutions. Its fundamental objective is to ensure that in the care of patients all required information for medical decisions is both correct and available to healthcare professionals. The IHE initiative is both a process and a forum for encouraging integration efforts. It defines a technical framework for the implementation of established messaging standards to achieve specific clinical goals. It includes a rigorous testing process for the implementation of this framework. IHE organizes educational sessions and exhibits at major meetings of medical professionals to demonstrate the benefits of this framework and encourage its adoption by industry and users. The approach employed in the IHE initiative is to support the use of existing standards, e.g., HL7, ASTM, DICOM, ISO, IETF, OASIS and others as appropriate, rather than to define new standards. IHE profiles further constrain configuration choices where necessary in these standards to ensure that they are used in their respective domains in an integrated manner between different actors. When clarifications or extensions to existing standards are necessary, IHE refers recommendations to the relevant standards bodies.”

IHE was founded in 1998, starting as a common initiative of the Radiological Society of North America (RSNA) and the Healthcare Information Management Systems Society (HIMSS), because medical users of IT systems complained that, despite being standards compliant, their IT systems often did not properly support their needs in an interoperable manner. Indeed, while the use of standards is a prerequisite for achieving interoperability, the use of standards in itself is not sufficient to guarantee interoperability, due to a number of reasons:

- **Incompatible options**: communication standards are often designed to support a wide range of possible use cases. For this reason, standards often contain a multitude of options, because not every bit of information that can be transmitted with the standard is known or needed in every use case, and because it is possible to use the same standard in quite different ways. That means that two products implementing the same standard may still be incompatible if they implement incompatible options.

- **Incompatible or incorrect implementations**: It is very difficult to write a standard so unambiguously that all implementers correctly understand all clauses as they were intended. Little ambiguities are often identified only later, when two implementations of the standard prove to be incompatible, and the reason is that the developers of the products interpreted the same standard...
differently. Furthermore, the implementation of any complex communication protocol may well contain errors (bugs), just like any other complex piece of software. Such bugs may also render devices incompatible.

- **Protocol stacks**: For each interface between devices, typically multiple standards need to be combined into a “protocol stack” to cover all layers of the communication link, from the physical layer (connector and cable or radio link), over the network and transport layers defining how packets and bit-streams are exchanged over the link, up to the application layer protocol defining messages, fields, and their meaning (semantics). In most cases it is necessary to combine several standards in order to define one protocol stack. Only if two products implement the same selection of standards, they will be interoperable without the use of an intermediate gateway (“translator”).

- **Mapping of data between standards**: In more complex application scenarios there will be more than one interface, and often one piece of information will be transmitted using one standard on the first interface, and using another standard on the second interface. A good example is the monitoring of vital parameters for patients with chronic diseases: The sensor itself may transmit its measurements like blood pressure or the patient’s weight using the ISO/IEEE 11073 standard to a gateway computer located in the patient’s home, for example a set-top box, tablet computer or smart phone. This device will then forward the information over a long-distance connection in encrypted form to a telemedicine service centre. However, this transmission will not be ISO/IEEE 11073, which is not intended for this purpose, but perhaps another standard like HL7. In this situation it needs to be defined which field of an 11073 message must be copied or translated to which field in the HL7 message. Such information cannot be found in either of these two standards, but still, it is a necessity in order to achieve interoperability for the overall use case.

The approach devised by IHE to deal with these issues consists of two central building blocks:

- **Integration profiles**: Many standards define so-called “application profiles” that reduce the complexity and optionality of the standard by defining more precise requirements for a specific use case (“application”). Here the goal is to ensure that two devices are interoperable if they implement the same application profile. Integration profiles go a step further by looking at complete use cases (application scenarios) and defining the complete protocol stack for each interface between systems or system components needed in that use case, plus a mapping between standards where needed.

- **Cross-vendor testing**: This term denotes tests where two or more products are connected, and tests are performed in order to validate whether or not the products are really interoperable. The advantage of cross-vendor testing is that complex use cases such as “integration profiles” can be tested, and that the test result is directly related to the customer’s expectation of user-perceived interoperability. IHE “Connect-a-thons”, organized annually in the United States, Europe, and various Asian countries, are large-scale cross-vendor testing events based on IHE integration profiles.

While the work of IHE historically started in the field of Radiology, the initiative has over time significantly widened its scope to include many other medical domains and, of prime importance for this case study, has one domain addressing the healthcare sector’s IT Infrastructure including the **cross-enterprise exchange and sharing of medical information**.
3.3.2 Approach

As described in the previous section, IHE follows a modular approach where different Integration Profiles can be combined in order to address different function requirements and different layers of interoperability of one network of eHealth systems. The following discussion follows the “layers of interoperability” as defined by the ANTILOPE project [vPS14].

The highest levels, “Legal and regulatory” and “Policy” are not directly addressed by IHE, although IHE has published a whitepaper entitled “Template for XDS Affinity Domain Deployment Planning” [ITI-XDSWP] that enumerates the planning requirements for the deployment of a cross-enterprise document sharing infrastructure, including legal and policy aspects. The lower levels are described in the following sections.

3.3.2.1 Care Process

The care process layer defines care pathways and workflows. In the context of cross-enterprise eHealth networks, this topic is addressed in the IHE Integration Profile “Cross-Enterprise Document Workflow” (XDW) [ITI-XDW] and the “Cross-Enterprise Document Workflow Extension for Cross-Community Environment” [ITI-XDWE], which covers the extensions required to manage workflows in a hierarchical “network of networks” environment. This layer is not further discussed in this case study.

3.3.2.2 Information

On the information layer, information models and document structures (e.g. templates) are defined. Obviously, such document structures are use-case specific. IHE defines a large number of integration profiles with document structures for different use-cases, many of them based on the HL7 CDA Release 2 document format and the Continuity of Care Document (CCD) document template for HL7 CDA. Final text Integration Profiles defining such document structures include:

- Sharing Laboratory Reports (XD-LAB)
- Cross-Enterprise Sharing of Scanned Documents (XDS-SD)
- Cross Enterprise Sharing of Medical Summaries Integration Profile (XDS-MS)
- Emergency Department Referral (EDR)
- Exchange of Personal Health Record Content (XPHR)
- Immunization Content (IC)
- Cross-Enterprise Document Sharing for Imaging (XDS-I.b)

Many more document template definitions are available as trial implementation drafts.

3.3.2.3 Applications

On this layer, “agreements are made about the way import and export of medical information are handled by the healthcare information systems. The technical specification of how information is transported is at this level (communication standards).” [vPS14] This is the layer addressed by the IHE Integration Profiles focused by this case study.

3.3.2.3.1 IHE XDS Family of Integration Profiles

Starting in 2003, IHE has developed a “family” of integration profiles, which together define a fully implementable specification of the core functionality of an Electronic Health Record (EHR). The speci-
fication consists of a number of integration profiles that can be combined in a modular way and address different aspects of an EHR architecture, such as the master patient index, security architecture, patient consent statements, document formats for clinical documents, etc. The central starting point, however, is the “Cross-Enterprise Document Sharing” (XDS) integration profile, which defines the most important actors (IT systems) and transactions (interfaces between these IT systems).

The XDS profile is defined in [ITI-TF1, section 2.2.10] as follows: “Cross-Enterprise Document Sharing enables a number of healthcare delivery organizations belonging to an XDS Affinity Domain (e.g., a community of care) to cooperate in the care of a patient by sharing clinical records in the form of documents as they proceed with their patients’ care delivery activities. Federated document repositories and a document registry create a longitudinal record of information about a patient within a given XDS Affinity Domain. This profile is based upon ebXML Registry standards and the Simple Object Access Protocol (SOAP). It describes the configuration of an ebXML Registry in sufficient detail to support Cross Enterprise Document Sharing.”

The actors and transaction of the XDS profile are shown in Figure 9. There are two central IT systems (actors) that will exist exactly once in any deployment of XDS (called an “XDS Affinity Domain”): The “Patient Identity Source”, which defines the Patient ID of all patients that may have records in the XDS affinity domain (this is typically a Master Patient Index system), and the “Document Registry”, which is a central database that stores index information (metadata) about all documents available in the XDS Affinity Domain. Furthermore, there will be one or more “Document Repositories”. These are the systems that store documents and make them available upon request, but do not maintain the metadata. Finally, there are the end-user systems called “Document Source” and “Document Consumer”: A “Document Source” is a system that submits one or more documents to the XDS affinity domain, which are then stored in a Document Repository and registered in the central Document Registry. A “Document Consumer” is a system that first searches documents pertaining to a specific patient by issuing queries to the Document Registry, and then downloads the desired documents.
from the Document Repositories based on the location information provided by the Document Registry.

It should be noted that IHE XDS is “content neutral”. From the perspective of the XDS architecture, the documents that are stored, registered, and downloaded, are only opaque byte-streams (files). XDS does not care about their content, format, or visualization (other than storing information about the file format as part of the metadata). XDS stores a document as a file and then primarily manages the metadata, which must be provided by the Document Source when submitting a new document. This means that for any deployment (XDS Affinity Domain) a number of decisions must be made, including the permitted file formats that all end-user systems need to support, and some tables for the metadata, including the following ones (all definitions quoted from [ITI-TF3, section 4.1.3.2]):

- **classCode**: “A high-level classification of documents that indicates the kind of document, e.g., report, summary, note, consent.
- **typeCode**: “A low-level classification of documents within a classCode that describes class, event, specialty, and setting.”
- **eventCodeList**: “This list of codes represents the main clinical acts, such as a colonoscopy or an appendectomy, being documented.”
- **formatCode**: “Code globally uniquely specifying the format of the document” “The formatCode shall be sufficiently specific to ensure processing/display by identifying a document encoding, structure and template (e.g., for a CDA Document, the fact that it complies with a CDA schema, possibly a template and the choice of a content-specific style sheet).”
- **healthcareFacilityTypeCode**: “This code represents the type of organizational setting of the clinical encounter during which the documented act occurred.”
- **practiceSettingCode**: “The code specifying the clinical specialty where the act that resulted in the document was performed (e.g., Family Practice, Laboratory, Radiology).”

One notable extension of the XDS integration profile compared to its initial version is the addition of the “On-Demand Document Source” actor, also shown in Figure 9. This optional extension, called On-Demand Documents Option, “offers a complementary service for document consumers to discover one or more document sources that have the capability to produce, for a specific patient, an on-demand document with content assembled at the time of processing the document consumer retrieve request” [ITI-TF1, section 10.2.7]. In practical terms this works by registering a special “on-demand document” in the document registry. Whenever a Document Consumer tries to retrieve this special document, an “on-demand document” is generated, assigned a new unique identifier, and returned to the Document Consumer. This is useful for situations where, for example, an EHR system has the ability to create a Patient Summary from the underlying patient database.

The high-level specification for IHE XDS is available in [ITI-TF1]. The detailed technical specifications of the transactions, which make use of SOAP-based Web Services with MTOM/XOP optimization for the transmission of large binary objects, the ebXML Registry standard, and HL7 (v2 or v3) for the connection between the Patient Identity Source and the Document Registry), are available in [ITI-TF2a], [ITI-TF2b] and [ITI-TF2x], with additional details on the metadata formats available in [ITI-TF3], and national specificities (currently only defined for the United States) documented in [ITI-TF4].
While the XDS integration profile addresses the need of repository-based cross-enterprise communication (i.e., undirected communication), there is also a need for a direct end-to-end transmission of medical documents (i.e., directed communication). There is a separate IHE integration profile for this use-case called Cross-Enterprise Document Reliable Interchange (XDR). The actors and transactions for this integration profile are shown in Figure 10. Note that the actors representing the sender and the recipient of the document have different names than the actors in the XDS profile, but the transaction, i.e. the specification of the communication protocol used to communicate between the actors, is “Provide and Register Document Set-b [ITI-41]”, which also appears in the XDS diagram (Figure 9), where the Document Source uses this transaction to submit a document to a Document Registry. So, essentially, IHE is re-using the same communication mechanism both for non-directed and for directed communication.

A common need of the cross-enterprise exchange of clinical documents is the authentication of users and roles, which are the basis for access rights and other security policies. IHE offers an Integration Profiles named “Cross-enterprise User Assertion” (XUA), which “provides a means to communicate claims about the identity of an authenticated principal (user, application, system...) in transactions that cross enterprise boundaries. To provide accountability in these cross-enterprise transactions there is a need to identify the requesting principal in a way that enables the receiver to make access decisions and generate the proper audit entries. The XUA Profile supports enterprises that have chosen to have their own user directory with their own unique method of authenticating the users, as well as others that may have chosen to use a third party to perform the authentication.” Essentially XUA enables the exchange of “certificates” issued by trusted servers that users in a distributed document sharing environment can use to prove their identity and role. This is based on the OASIS Security Assertion Mark-up Language (SAML) specification.

Further Integration Profiles related to the XDS “family”, which are not a topic of this case study, are the following ones:

- Patient Identifier Cross-Referencing (PIX)
- Patient Demographics Query (PDQ)
- Audit Trail and Node Authentication (ATNA)
- Basic Patient Privacy Consents (BPPC)

### 3.3.2.3.2 IHE Cross-Community Integration Profiles

The IHE XDS family of integration profiles, as described in the previous section, is primarily intended to support document sharing on a regional (or perhaps national) level. The primary limitation of XDS...
is the need to implement a single, central document registry where each document available in the overall system is registered. This limits the scalability of the approach, but was a deliberate design decision. Furthermore, a common master patient index (or other source of a common patient ID for all systems participating to the network) must be available.

In situations where different XDS affinity domains (deployments) or different non-XDS networks need to be connected, the so-called IHE Cross-Community Integration Profiles can be used:

- **Cross-Community Access (XCA)** “supports the means to query and retrieve patient relevant medical data held by other communities. A community is defined as a coupling of facilities/enterprises that have agreed to work together using a common set of policies for the purpose of sharing clinical information via an established mechanism.” [ITI-TF1, chapter 18]

- **Cross-Community Patient Discovery (XCPD)** “supports the means to locate communities that hold patient relevant health data and the translation of patient identifiers across communities holding the same patient’s data.” [ITI-TF1, chapter 27]

- **Cross-Community Document Reliable Interchange (XCDR)** “introduces the capability to send documents from a source Community with sufficient information to direct the documents through gateways to a designated target Community.” [ITI-XCDR, p. 5]

- **Cross-Community Fetch (XCF)** “defines a single transaction for accessing medical data between gateways that facilitate multiple dimensions of communication (trust, semantics, encoding, legislation, authority, etc.). The profile is highly inspired by the Cross Gateway Query/Cross Gateway Retrieve transactions and integrates these originally distinct transactions.” [ITI-XCF, p. 4]

The fundamental idea of the Cross-Community Access profile is that a “network of networks” (or “network of communities”) is established, where each participating network can be one XDS Affinity Domain or another eHealth network. The end-systems in both networks never directly communicate with each other. Instead, dedicated gateways are used that manage the exchange of queries and retrieve operations (document downloads) between networks. Figure 11 shows the actors and transactions of the XCA profile. There is one “Initiating Gateway” that sends “Cross Gateway Query” and “Cross Gateway Retrieve” requests from one community to a “Responding Gateway” in another community, which processes these requests.
The two new transactions defined for this Integration Profile, “Cross Gateway Query” and “Cross Gateway Retrieve”, are almost identical to the IHE XDS transactions “Registry Stored Query” and “Retrieve Document Set” – the major difference is that the identifier of the community (network) addressed by the query, the so-called “homeCommunityId”, must be sent as part of each transaction. The “homeCommunityId” is defined in [ITI-TF1, section 18.3.2] as “a globally unique identifier for a community and is used to obtain the Web Services endpoint of services that provide access to data in that community. Specifically, it is returned within the response to Cross Gateway Query and Registry Stored Query transactions to indicate the association of a response element with a community. [...] It is used by Initiating Gateways to direct requests to the community where the initial data originated.”

This makes it almost trivial for an XDS implementer to implement the XCA profile, as the transactions issued by the Document Consumer actor only require minimal modification before they can be forwarded to a Responding Gateway. IHE XCA does require, however that a common Patient ID is used across communities, which may require the use of an additional master patient index mapping identifiers between communities.

The Implementation of a “Responding Gateway” that actually communicates within an XDS affinity domain is similarly simple, since the gateway only needs to convert the incoming requests back into their XDS counterpart, and act as a policy enforcement point for any access control policy that might be in place for the exchange of information across communities.

In situations where the “Initiating Gateway” also operates within an XDS affinity domain, the gateway can furthermore be grouped with a Document Consumer actor that can forward incoming requests to the local Document Registry and Document Repository actors. In this case, other Document Consumers can issue all queries and retrieve requests to the Initiating Gateway, which may then forward these requests either within the affinity domain, or forward them to a responding community, and thus act as the central point of contact for Document Consumer actors in the affinity domain.

Figure 12 [ITI-TF1, section 18.3.3] shows a sequence diagram demonstrating a situation where an “Initiating Gateway” communicates both within its own XDS home community, and with two other
remote communities “B” and “C”, which are also both XDS affinity domains.

Figure 12: Cross-Community Access between XDS Communities [ITI-TF1]

It should be noted that while IHE XCA is easy to implement in a situation where the gateway actors connect XDS affinity domains, this is not a requirement. It is entirely possible to implement an initiating or responding gateway that within its own home community uses other standards, as long as the minimal set of meta-data required for the XCA transactions can be supported by the gateway. This enables, for example, the implementation of a gateway that connects an IHE XCA “network of communities” where one community uses IHE XDS, and the other one uses EN ISO 13606. However, no implementations of such gateways are known to the author of this case study.

While the XCA Integration Profile only addresses the “read-only” sharing of documents between
communities, the draft Cross-Community Document Reliable Interchange (XCDR) Integration Profile covers the submission of documents or document sets from one community to the other, either point-to-point or as a submission to a XDS Registry/Repository infrastructure in a different XDS affinity domain. Figure 13 shows the actors and transactions of this integration profile. It should be noted that the “Cross-Gateway Document Provide” transaction is again very similar to the “Provide and Register Document Set-b” transaction used in XDS and XDR, except for the provision “of the home-CommunityId” of the community to which the transaction is addressed.

![Figure 13: Cross-Community Document Reliable Interchange (XCDR) [ITI-XCDR]](image)

The third, and final, Integration Profile to be discussed in this section is the draft Cross-Community Fetch (XCF) Integration Profile [ITI-XCF]. This is essentially a simplified version of the XCA profile, where the two distinct transactions “Cross Gateway Query” and “Cross Gateway Retrieve” have been merged into a single transaction called “Cross Gateway Fetch” (see Figure 14).

![Figure 14: Cross-Community Fetch (XCF) Actors and Transactions [ITI-XCF]](image)

Essentially the Initiating Gateway issues a request containing a Patient ID, Home Community ID of the remote community, and a document type, plus various optional filter criteria such as date/time range, author, or healthcare facility type. The responding gateway identifies documents corresponding to this query (as it would do with a Cross Gateway Query, but instead of returning the meta-data of the documents found, it directly returns the documents found (as during a Cross Gateway Retrieve operation), depending on access rights (security policies). [ITI-XCF, section 29.4.1] describes a number of use cases for this simplified transaction:

- **Patient Summary Service with Translation/Transforming**: “A typical use case where data is processed on gateways is health data sharing among autonomous regions (states, countries) with distinct healthcare infrastructures and regulatory frameworks. As modifications on ex-
isting services and systems are typically not possible, gateways are used to encapsulate the specifics of the regional infrastructures and regulations. These gateways perform a transformation of data schema and coding from regional format to a canonical format and vice versa and implement means to broker trust among the regions by acting as guarantors for the enforcement of agreed security services (e.g., on originator authenticity and proper authentication). Health data sharing among autonomous regions is limited to an agreed set of documents because for example: a) many of the use cases of cross-regional care cover unscheduled care scenarios where a physician does not want to access the full EHR of a patient but is rather interested in aggregated health status information; b) reimbursement regulations only cover specific phases of a treatment (e.g., Dutch patients being allowed to go to Germany for certain surgeries) that require access to be restricted to a defined set of documents. The XCF Profile provides simple access to documents of limited number and volume within a gateway infrastructure, where the initiating regions have simple environments.

- **Highly Regulated Data Sharing Scenarios**: “Two states are enabling access for their citizen’s emergency data-sets. The contents of the data set are well-specified in advance, and only documents that are sanctioned will be accessed. A framework or community agreement needs to exist that governs, which documents, what contents and encoding are to be communicated under which conditions and environments. Both states reserve the right to enforce policies at their respective domain and may not be forced to adapt or change their existing IT systems due to the principle of sovereignty. Furthermore, only the most recent version of the emergency data-set is to be communicated at any time, potentially existing older version must not be communicated or made available for patient safety reasons: querying for just “any” document is disallowed.”

### 3.3.2.4 IT Infrastructure
The IT Infrastructure Layer covers generic interoperability standards and protocols. The IHE Integration Profiles use several of these standards to implement the application layer functionality described in the previous sections. These include:

- Transport Layer Security (TLS) as a reliable encrypted transport protocol
- SOAP-based Web Services compliant to the Web Service Interoperability (WSI) specifications
- ebRS, the ebXML Registry Services specification from OASIS
- Reliable Syslog for audit trails
- HL7 Minimal Lower Layer Protocol (MLLP) for HL7v2 messages
- Security Assertion Mark-up Language (SAML) for security assertions in the XUA Integration Profile

However, the protocols on this layer are not the focus of this case study and are thus not further discussed in this document.

### 3.3.3 Concurrent Use of Standards and Specifications (De-facto Standards)

The concurrent use of standards and specifications in the IHE Cross-Community Integration Profiles has been outlined in the previous section. In brief, it can be summarized as follows:

---

3 The canonical format is not specified by IHE, it must be agreed among the communities connected.
• Mapping between controlled terminologies (coding systems): Not addressed.
• Mapping between identifiers: The PIX profile addresses the mapping between different Patient ID namespaces, but is not further discussed in this case study.
• Mapping between clinical concepts: Not addressed.
• Mapping between document formats: Not addressed.
• Mapping between messages (e.g. notifications, queries and responses): The main value proposition of the IHE Cross-Community Integration Profiles is that they define interfaces that enable Electronic Health Record systems to be connected into a “network of communities”, even if the different communities internally use different EHR standards, as long as the minimal set of metadata required by the profiles can be supported.
• Mapping between different reference information models: Not addressed.

The architecture of the Cross-Community Integration Profiles assumes that health information is exchanged in the form of documents, which are either persistent or generated on-the-fly (such as patient summaries or EHR extracts), and where each document can be assigned to a single patient defined by a Patient Identifier known (or accessible) to all parties involved. The architecture further assumes that all parties involved have agreed on a set of mutually understandable document formats and value sets for describing documents. The profiles then cover the protocols required to locate documents, retrieve documents, or submit documents across communities.

3.3.4 Governance
The IHE Technical Frameworks are maintained by Integrating the Healthcare International under the Principles of Governance defined in [IHE-POG].

3.3.5 Lessons learned
3.3.5.1 Successes
3.3.5.1.1 Implementable Cross-Community EHR Specification
The IHE Cross-Community Integration Profiles are arguably the first fully implementable specification of a communication protocol for connecting different Electronic Health Record deployments (networks) into a “network of communities” that has seen large-scale implementation. The profiles have been designed to enable an interoperability between communities that internally use different EHR architectures.

3.3.5.1.2 Real-World Deployment
In 2010, Keith W. Boone, one of the authors of the IHE XDS and HL7 CDA specifications, started to maintain a website listing real-world deployment projects of the IHE XDS family of integration profiles, and HL7 CDA. This list, available at [Boo10], also mentions several projects that have implemented the IHE Cross-Community Integration Profiles (XCA and supplementary profiles). These implementations include:

• The U.S. Nationwide Health Information Network (NwHIN) [ONC15], where the XCA and XCPD profiles are part of the official interface specifications. There have been more than 20 trial implementation sites based on these specifications.
• The Austrian ELGA project (“Elektronische Gesundheitsakte”) [ELG15], which is based on HL7
CDA documents using IHE content templates, XDS for regional deployment, and XCA for the federation of 7 Austrian regions.

- The HEALTH OPTIMUM (HEALTHcare delivery OPTIMisation throUgh teleMedicine) project was “a European project that aims the development of telemedicine services. In Veneto Region HEALTH OPTIMUM has built an IHE-XDS network that allows to share CDA documents (according to NAV and XDS.b profiles) and images (XDS-I) between 23 different local health authorities. The 7 XDS Document Registries that have been developed are federated together throughout the IHE-XCA Profile.” [Boo10]

- The Swiss National Interoperability Specifications “have been established and agreed among Swiss Canton and Federal Health Ministry. Based on the following IHE profiles: XDS and XCA, ATNA, BPPC, PIX, PDQ, and XCPD, PCC CDA R2 based document content profiles.” [Boo10]

It should be noted that the NwHIN project in the United States has developed a comprehensive implementation of the IHE XDS family of integration profiles including the cross-community profiles and published the resulting software, which is continuously being maintained, under a permissive Open Source licence, see [CONNECT].

### 3.3.5.2 Pitfalls and Remedies

#### 3.3.5.2.1 Usability with non-XDS Communities not Proven

The IHE XCA specification claims that the gateways that are at the core of the specification can be implemented even if the EHR system to be connected to the XCA network of communities is not based on the IHE XDS family of integration profiles. However, no such implementations are known to the author of this case study, so at this time the usability of the XCA profile for “communities” that are not internally using IHE XDS is not proven.

#### 3.3.5.2.2 No Mapping of Content or Identifiers

The IHE Cross-Community profiles assume that all communities to be connected agree on a set of document formats and metadata that will be understood by all communities involved. While the profile explicitly supports the case where a document is generated “on the fly” during a retrieve operation, IHE XCA does not explain how a conversion or mapping can be implemented. This is a significant limitation that implementers need to be aware of. As a remedy, the approach described in this case studies may be combined with the approaches of converting between document formats described in other case studies, such as the SemanticHealthNet approach, or the approach implemented in the ARTEMIS, RIDE and SALUS projects.

### 3.3.6 Resources

<table>
<thead>
<tr>
<th>IHE-TF</th>
<th>IHE Technical Frameworks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Description</td>
<td>All Technical Frameworks (Integration Profile specifications) defined by IHE are freely available for download from the IHE website.</td>
</tr>
<tr>
<td>Availability</td>
<td>freely available</td>
</tr>
</tbody>
</table>

| IHE-CRD      | IHE Connectathon Results Database |
### 3.3.7 References and Further Information

<table>
<thead>
<tr>
<th>Description</th>
<th>NIST Document Sharing Test Facility</th>
</tr>
</thead>
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<tr>
<td><strong>IHE</strong></td>
<td>The National Institute of Standards and Technology (NIST) maintains a reference implementation of the IHE XDS family of integration profiles, which is free available under open source license and also used as a test tool during the IHE cross-vendor testing events (connectathons). This implementation currently supports the Cross-Community Integration Profiles XCA and XCPD.</td>
</tr>
<tr>
<td><strong>Availability</strong>:</td>
<td>open source (public domain)</td>
</tr>
<tr>
<td><strong>Link</strong>:</td>
<td><a href="http://ihexds.nist.gov/">http://ihexds.nist.gov/</a></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Description</th>
<th>CONNECT</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>IHE</strong></td>
<td>An open-source implementation of the technical specifications for the U.S. Nationwide Health Information Network (NwHN), which include the IHE XDS and XCA family of integration profiles.</td>
</tr>
<tr>
<td><strong>Availability</strong>:</td>
<td>open source (BSD license)</td>
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</tr>
</tbody>
</table>


3.4 Case Study #04: X-Paradigm

- Author of case study within the eStandards project: Giorgio Cangioli (giorgio.cangioli@gmail.com)
- Project name: HL7 Implementation Guide: Immunization; Cross-Paradigm Interoperability Implementations, Release 1 [X-Paradigm]
- Project type: concept
- Project status (in 10/2015): Planning
- Countries / Regions: Not applicable
- Project partners: HL7 International and OMG [INVITALIA/HL7 Italy; Model Driven Solutions – USA; Deontik – Australia; Semantix – USA; NHS Wales – UK; The Informatics Applications Group – TIAG –USA]
- Scale of deployment: Not applicable. Only test cases.

HL7 Implementation Guide – Cross-Paradigm Interoperability Implementations (X Paradigm): Immunization, Release 1 January 2015 is a Health Level Seven International Standard. Copyright © 2015 Health Level Seven International® ALL RIGHTS RESERVED. Thanks to Stefano Lotti, HL7 SOA WG Co-Chair for the material provided.

3.4.1 Project Overview

The X Paradigm project is an OMG and HL7 joint project that aims to provide organizations with a concrete and practical standardization solution in achieving interoperability in an environment comprising multiple different data exchange paradigms – messages, documents and services; normalizing, managing and automating the integration among the various standard and non-standard paradigms and their different versions, with a concrete set of methods and tools for integrating the different standards effectively in place at a point in time.

The keywords of this approach are Model Driven and Service Oriented Architectures: the HL7’s Services-Aware Interoperability Framework (SAIF) has been chosen as reference framework and the OMG’s Model Driven Message Interoperability (MDMI) standard has been selected to address the cross-referencing of the data models of the multiple standards and/or profiles that are potentially used in a specific setting.

The expected benefits include easier implementation, reduced complexity, long-term system sustainability, and enhanced standards compliance. Moreover, this approach should empower the domain experts role, through the development of the semantic mappings, leaving to the machine runtime processes the actual technical message transformation.

For supporting this approach an MDMI based open source tool [OHT-MDMI] has been built to facilitate the development of MDMI maps.
The project is focused on the immunizations domain. In the first stage, different implementations based on a set of relevant standards have been compared and a table cross-referencing the fields used for those information models has been created and used in the initial analysis. Then, based on the experience gained with this first analysis, a Proof of Concept implementation using the MDMI tool have been developed for HL7 v2, CCDA, and FHIR for the patient demographic and immunization data (see the example below).

The experience gained so far, shows how the use of MDMI appears to greatly improve the mapping methodology (“Information Dimension”), and to provide more rigorous traceability among the SAIF perspectives (Conceptual, Logical, and Implementable). The promise of MDMI is in translating the data elements of one message, document or service to another; and it helps in connecting requirements, models, and implementable standards in a rigorous way according to SAIF, ultimately producing machine-readable artefacts that can be used in implementation.

### 3.4.2 Approach

The X-Paradigm follows a model driven approach based on HL7’s Services-Aware Interoperability Framework (SAIF): the SAIF Specification Interoperability Matrix (ISM) has been used as framework for identifying, normalizing and organizing the necessary artefacts in a meaningful way. The Enterprise, Informational, Computational/Behavioural RM-ODP dimensions have been considered in this analysis for all the three Conceptual, Logical and Implementation perspectives roughly related to the Model Driven Architecture (MDA) viewpoints.

SAIF is crucial in permitting to clearly distinguish the business and logical aspects from the implementation ones. It forces in fact to correctly identify and classify what needs to be distinguished and that often is mixed-up in specifications: business from architectural aspects; logical perspectives from implementation viewpoints.

The following table – extracted from the X-Paradigm document – indicates how different kinds of artefacts used in the X-Paradigm analysis are mapped into the ISM matrix and how a meet-in-the-middle approach has been applied.

---

4 HL7 Version 2, HL7 Version 3, the Continuity of Care Documents (CCD), and the Immunization Content as profiled by Integrating the Healthcare Enterprise (IHE)


6 OMG MDA (http://www.omg.org/mda/). MDA defines three viewpoints: CIM (Computation-Independent Model), PIM (Platform-independent Model), PSM (Platform-Specific Model)
The project covers both informational and behavioural aspects: at this stage, however, methodologies and tools to support the automatic transformation among different paradigms have not been yet identified by the project for the behavioural dimension.

For the informational dimension, the OMG’s Model Driven Message Interoperability (MDMI) standard has been used.

Standard modelling languages as the BPMN\(^7\) (Business Process Model and Notation) for the process design and analysis and SoaML\(^8\) (Soa Modelling Language) for the services modelling – have been used for the behavioural dimension in order to achieve a fast and affordable identification of required functions and appropriate mapping with the service interfaces and operations.

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\(^7\) OMG, *Business Process Model and Notation (BPMN)*, Version 2.02, formal/2013-12-09

\(^8\) OMG, *Service oriented architecture Modeling Language (SoaML) Specification*, Version 1.0.1, formal/2012-05-10
The OMG’s Model Driven Message Interoperability (MDMI) standard has been used to address cross-referencing of the data models of the multiple standards that are in play in the environment, allowing one to support natively the MDA approach (distinguishing among the Computation-Independent, Platform-Independent and Platform-Specific Models).

MDMI provides a formal specification that defines “machine readable” maps against a commonly defined business dictionary (the MDMI Referent Index), so that syntactical (and semantic) transformations among different paradigms can be handled developing a library of distinct maps, separately created by each entity involved. In other words, each message format is decomposed into its syntactic and semantic elements; these semantic message elements are remapped with uniquely identified business elements of a common domain dictionary; using the specified maps, all the implemented elements that are linked to the same business element can be extracted and processed at runtime, independently on the paradigm used.

The MDMI Referent Index leverages and is compatible with Reference Information Models and thus enables separation of the semantics from the syntax for each paradigm.

Because the MDMI model can produce a machine executable file, this model-driven approach can then provide computable semantic interoperability between different models. As long as any two MDMI models use the same referent index, interoperability can be achieved in the HL7 SAIF Information Dimension.

In MDMI, there are moreover two distinct processes. The “Design Time Process” is creating and maintaining a MDMI Map for a specific format and covers all the three MDA perspectives (conceptual, logical and implementation). The “Run Time Process” devoted to the actual transformation of the source message into the target message, refers mainly to the implementation perspective.

A Proof of concept using the MDMI tool has been therefore developed for HL7 v2, CCDA, and FHIR for the patient demographic and immunization data.

As described above, the X-Paradigm uses the SAIF ISM as reference framework. It can, however, easily be remapped into the Antilope layers as follows:

- Care Process is substantially covered by the Enterprise Dimension
- Information is equivalent to the Informational Dimension
- Applications is substantially covered by Computational/Behavioural Dimension
- IT Infrastructure is substantially covered by the Engineering Dimension

3.4.2.1 Care Process (Enterprise Dimension)

For this dimension only the conceptual perspective has been considered.

A meet-in-a-middle approach has been followed to identify the use cases characterizing the immunisation domain: the storyboards and use cases specified in the HL7 Immunization DAM (Domain Analysis Model) have been used as primary reference (UC01: Manage Patient Information; UC02 Manage Immunization History Use Case; UC03 Clinical Decision Support; UC04 Manage Adverse Event Reporting; UC05 Manage Vaccine (inventory); UC06: Manage Reports; UC07: Manage CDS Rules) and use cases / storyboard implicitly or explicitly by several other projects have been re-
mapped to them. From that analysis, a sub set of 5 core Use Cases among those above mentioned, have been selected to be considered for the mapping towards the service stack: UC01; UC02; UC03; UC05; UC06.

3.4.2.2 Information (Informational Dimension)

A general description of the MDMI based approach for the information dimension has been provided in the parent section 3.4.2. More in detail we can assert that MDMI is based on two core concepts:

- The MDMI Meta-Model specifies the syntax of a modelling language and concretely allows any organization to create models for any message or data format. The MDMI Meta-Model contains three distinct sub-meta-models:
  - Syntax Meta-Model: used to define the data format and can be used for any data format,
  - Semantic Meta-Model: used to define necessary relationships among the Semantic Elements of the data format. e.g. the actual meaning of a field may depend on the value of another field in that record,
  - Mapping Meta-Model: used to relate the Semantic Elements in the data format to the Business Elements in the MDMI Referent Index.
- The MDMI Referent Index: is a list of very precise, unique terms that represent all the vocabulary (meaning of the data elements needed when transferring data in one format to another format).

MDMI Maps are machine-readable and are used for the transformation, on the fly, of any specific message/document instance. MDMI maps can be shared and reused. Any organization can create a model for any message or data format using the MDMI Standard.

3.4.2.2.1 Conceptual perspective

The first step of the MDMI design process is the identification of the MDMI semantic elements and of the MDMI Referent Index. This is related to the conceptual perspective and can be realized using a pure bottom-up or a meet–in-the-middle approach.

3.4.2.2.2 Logical Perspective

As the MDMI Referent Index has been fully specified, the semantic and the mapping meta-models for each considered paradigm can be determined. Those meta-models act as the bridge between the common business elements and the specific syntax used for expressing them.

3.4.2.2.3 Implementation Perspective

The Syntax Meta-Model, defined for each specific paradigm, closes the loop linking the business elements to a specific implementation. The set of meta-models allows for the creation of a computable file (the MDMI map) used in the Runtime Process for the message conversion.

In the X-paradigm project proof of concept, MDMI Models for HL7 V2 format, for the Consolidated Continuity of Care Document (CCDA) format, and for Fast Healthcare Interoperability Resources (FHIR) format using the OHT MDMI Meta-Model tool have been created (see figure below).
3.4.2.3 Applications (Computational Dimension)

The Behavioural Dimension has a lower maturity level respect to the Informational one, since methodologies and tools to support the automatic transformation among different paradigms have not been yet identified by the X-Paradigm project. Standard modelling languages (BPMN2 and SoaML) have been used to achieve a fast and affordable identification of required functions, and to map them with the service interfaces and operations used by a set of commonly used paradigms (e.g. HSSP, IHE-ITI, FHIR). The analysis done by X-Paradigm follows the same MDA approach adopted for the Informational Dimension, applied to a Service Oriented Architecture considering:

- The Service Functional Models (SFM), that defines the characteristic and feature of candidate services
- The PIM (Platform-independent Model), computationally complete without any reference to a specific implementable platform
- The PSM (Platform Specific Model), that represents a specific implementable specification (e.g. WS*, REST).

3.4.2.3.1 Conceptual Perspective

The scope of this is to transform the storyboard and use cases identified in the Enterprise Dimension into process models (specifying also participants) and service business capabilities. In the case of the Record Immunization History a set of capabilities have been identified and remapped –where existing– into standardized SFM operations. This is an example:

- Patient Identification:
  a. Create Identity()
  b. Record Management()
  c. Immunization History Request().

- Record Immunization History:
a. Record Vaccination Event().

   • Evaluation:
      a. Request Evaluation and Forecast().

3.4.2.3.2 Logical Perspective

The identified business services are mapped onto Platform-Independent Model (PIM) operations that are detailed with all the necessary parameters in a computable model, even if abstracted from any implementation platform\(^9\). In the Immunization example, the following interfaces have been used at the PIM level:

   • IXSManagementAndQuery from OMG Identity Cross-Reference Service (IXS)\(^{10}\)
   • RLUSManagementAndQuery from OMG Retrieve, Locate, and Update Service (RLUS)\(^{11}\)
   • CDSSEvaluation from OMG Clinical Decision Support Service (CDSS)\(^{12}\)

3.4.2.3.3 Implementable Perspective

The PIM operations have been used conceptually as a sort of Referent Index\(^{13}\) to map the different paradigms (e.g. OMG WS* or REST, IHE-ITI, FHIR, etc.) in a highly reusable way. To do that the preselected platforms have been retro-modelled in a set of common PSMs represented with SoaML. As described above, for the time being, no automatic methodologies have been identified. As a result, manual code development has to be performed. At this stage of the project, this has been applied to the IHE-ITI and OMG services.

The operation mapping is not always 1 to 1, so that different orchestrations have to be implemented depending on the paradigm applied. The formalization using formal languages can help putting in evidences those differences. Moreover it is not assured that all the capabilities required are supported by all the specific platforms. Implementers shall in this case to choose how to technically cover this gap, e.g. adopting for this purpose an alternative paradigm. For exemplification purposes is hereafter reported the Service Architecture associated to the IHE-ITI platform.

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\(^9\) WS*, REST, Messaging in the specific standard flavor as OMG services, IHE-ITI, FHIR.
\(^13\) See information about previous discussion on MDMI standard.
Figure 17: IHE – ITI Immunization Services architecture
Figure 18: IHE – ITI Immunization Services architecture (Service Choreography Diagram detail)

3.4.2.4 IT Infrastructure
X-Paradigm doesn’t address the generic communication and network protocols and standards.

From a deployment point of view the solution has been conceived in order to support several deployment architectures (see figure) that will be more in details specified in the future version of this project.
The approach described by the X-Paradigm project provides a generic methodology based on existing messages mapping standards for supporting multi-paradigms environments.

The way the coexistence of standard is handled is described in detail in the previous section.

In synthesis this methodology:

- addresses the mapping between implemented information models (e.g. messages, documents, ...) fostering the tracing towards a common model;
- provides a formal foundation for supporting the coexistence of different behavioural models.

It doesn’t consider the vocabulary bindings and therefore the value sets mapping.

In this phase this methodology has been proved in the Immunization domain analysing:

- OMG WS* or REST, IHE-ITI, FHIR for the behavioural aspects
- HL7 v2, CCDA, and FHIR for the patient demographic and immunization data.

**Figure 19: Supported deployment solutions in X-Paradigm**

### 3.4.3 Concurrent Use of Standards and Specifications (De-facto Standards)

The approach described by the X-Paradigm project provides a generic methodology based on existing messages mapping standards for supporting multi-paradigms environments.

The way the coexistence of standard is handled is described in detail in the previous section.

In synthesis this methodology:

- addresses the mapping between implemented information models (e.g. messages, documents, ...) fostering the tracing towards a common model;
- provides a formal foundation for supporting the coexistence of different behavioural models.

It doesn’t consider the vocabulary bindings and therefore the value sets mapping.

In this phase this methodology has been proved in the Immunization domain analysing:

- OMG WS* or REST, IHE-ITI, FHIR for the behavioural aspects
- HL7 v2, CCDA, and FHIR for the patient demographic and immunization data.
3.4.4 Governance

X-Paradigm doesn’t specify any concrete governance for the development and the distribution of the MDMI maps. However being strongly inspired to Enterprise Architecture frameworks it presumes the existence of governance and management boards that drive the full process.

3.4.5 Lessons learned

3.4.5.1 Successes

So far, use of MDMI appears to both greatly improve the mapping methodology (“Information Dimension”), and to provide more rigorous traceability among the SAIF perspectives (Conceptual, Logical, and Implementable). The promise of MDMI is in translating the data elements of one message, document or service to another; and it helps in connecting requirements, models, and implementable standards in a rigorous way according to SAIF, ultimately producing machine-readable artefacts that can be used in an implementation as well.

3.4.5.2 Pitfalls and Remedies

3.4.5.2.1 Entry Level Investment

The adoption of this Model Driven Architecture approach requires a not negligible entry level investment in term of

1. Basic Knowledge of the SAIF framework, BPMN, SoaML and MDMI standards
2. Develop of the MDMI Referent Index and paradigm specific Meta-Models
3. Consolidation of tools for the editing of those metamodel and the run-time processing of the MDMI Maps.

This challenge is probably even more critical in the case of the behavioural dimension.

3.4.5.2.2 Semantic Mapping

When semantic mapping is applied to real-world samples, it is not always guaranteed that a one to one mapping between elements is applicable, or that the represented concepts would be iso-semantic. In that case it needs to be better understood how the approach proposed by X-Paradigm support those conditions.

3.4.5.2.3 Terminology Mapping

Even supposing that the implemented elements could be mapped correctly (e.g. that the XML element foo/too/x used in paradigm A can be mapped into the XYZ|||^b| used in paradigm B), this do not address the fact that different terminologies could be used.

3.4.6 Resources

<table>
<thead>
<tr>
<th>[HL7_IG_IZ_XPARADIGM_R1_I2]</th>
<th>HL7 Implementation Guide: Immunization; Cross-Paradigm Interoperability Implementations, Release 1 January 2015</th>
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<tr>
<td>Description:</td>
<td>It is an implementation guide based upon HL7’s Services-Aware Interoperability Framework (SAIF) to assist organizations in achieving interoperability in an environment comprising multiple different data exchange paradigms –messages, documents and services.</td>
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<tr>
<td>Availability:</td>
<td>HL7’s IP Compliance Policy</td>
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</tbody>
</table>
3.4.7 References and Further Information

[BPMN2] OMG, Business Process Model and Notation (BPMN), Version 2.02, formal/2013-12-09
http://www.omg.org/spec/BPMN/2.0/

[CDSS] OMG, Clinical Decision Support Service (CDSS), PIM and PSM formal/2011-07-01,
http://www.omg.org/spec/CDSS/


[HL7_IMM_DAM] HL7 Domain Analysis Model: Immunization, Release 1

[HL7_SAIF] HL7 Service-Aware Interoperability Framework (SAIF): Canonical Definition Specification,
Release 2
http://www.hl7.org/documentcenter/private/standards/ARB/SAIF_CANON_R2_N1_2014SEP.zip


[IXS] HL7 Version 3 Standard: Identification Service (IS), Release 1 SFM


[OHT-MDMI] Open Health Tools Model Driven Health Tools / MDMI Project,
https://www.projects.openhealthtools.org/sf/projects/mdht/

[RLUS] HL7 Version 3 Standard: Retrieve, Locate, and Update Service (RLUS) Release 1
OMG Retrieve, Locate, and Update Service (RLUS) PIM and PSM
http://www.omg.org/spec/RLUS/

[RM-ODP] ISO/IEC 10746 http://www.rm-odp.net/publications.html (see also

http://www.omg.org/spec/SoaML/
3.5 Case Study #05: DICOM SR to HL7 CDA Imaging Report Transformation Guide

- Author of case study within the eStandards project: Jan Schlamelcher <schlamelcher@offis.de>
- Project name: DICOM SR to HL7 CDA Imaging Report Transformation Guide
- Project type: Published Standard (DICOM parts 16 and 20); DICOM Supplement 155
- Project status (in 10/2015): Completed
- Countries / Regions: Not applicable
- Project partners: DICOM Standards Committee, Working Groups 8 and 20
- Scale of deployment: Not applicable

3.5.1 Project Overview

Digital Imaging and Communications in Medicine (DICOM) is a world-wide established standard for archiving and interchanging medical images and related data. Clinical documentation, for example within patient summaries, is on the other hand mostly realized employing the Health Level 7 (HL7) Clinical Document Architecture (CDA). The main goal of the project described in this study was to realize a translation between both standards, for transferring the gathered image related data into a format sufficient for clinical documentation.

Special care was taken with regard to existing national requirements. The created reports shall, for example, be usable as Consolidated CDA documents under the Meaningful Use of Electronic Health Record Systems program in the United States.

Different types of CDA documents are described by so-called CDA document templates, so the first requirement was the creation of CDA templates that reflect the requirements of an imaging report. CDA templates are defined as part of a so-called “implementation guideline”. Although there are “official”, balloted implementation guides in HL7, anyone is allowed to write and publish an implementation guideline. DICOM on the other hand, has its own definition of structured documents called Structured Reporting (DICOM SR). As opposed to HL7 CDA, DICOM SR templates must be part of the DICOM standard. Although it is called Structured Reporting, other types of documents are possible. The term “Structured Reporting document” is, therefore, used in the following sections instead of “Structured Report”.

The DICOM standard is developed through a consensus driven process in Working Groups that create and discuss so called Supplements. This means there are no different “versions” of the standard, but instead each supplement immediately becomes incorporated into the standard the moment it is accepted. The resulting DICOM standard is separated into different parts that address different topics. DICOM SR document templates for example are defined within part 16, the content mapping resource [DCM16].

DICOM Working Group 20 and the HL7 Imaging Integration Work Group together created Supplement 135 “SR Diagnostic Imaging Report Transformation Guide” [SUP135], which introduced the new part 20 “Transformation of DICOM to and from HL7 Standards” [DCM20]. Several HL7 CDA templates were defined within part 20 as a CDA implementation guideline. Furthermore, the mapping between appropriate SR templates, either existing or newly introduced into DICOM part 16, was described.
However, practical experience with the created templates and mappings led to the discovery of several problems. These were resolved in Supplement 155 “Imaging Reports using HL7 Clinical Document Architecture” [SUP155], which was created by Working Groups 20 and 8 together. Supplement 155 made several modifications to the existing templates in part 16 and completely replaced the existing part 20 based on the collected experiences.

Details about the created templates and mappings, as they are currently defined in parts 20 and 16 of the DICOM standard, will be explained in the following sections.

3.5.2 Approach

The conversion approach is centred on the information layer, that is, it focuses on the associated templates and mapping instructions required for the translation. The Application Layer is addressed indirectly by using the transmission / message exchange standards DICOM and HL7, therefore allowing the resulted documents to be transferred employing the existing DICOM and / or HL7 transmission / message exchange protocols.

3.5.2.1 Information Layer

Structured documents are generally unrestricted in regard to potential contents and described relations of these contents. Restricting such documents to reflect specific kinds of reports, as in this case an imaging report, can be realized by employing so-called document templates and codes.

Codes are unique identifiers in regard to a specific coding scheme, for example the nomenclature Logical Observation Identifiers Names and Codes (LOINC). A code refers to one specific entity in such coding scheme and can therefore be unambiguously interpreted, as long as the recipient has access to the employed coding scheme. This makes coding a good way to represent information when semantic interoperability is sought to enable automatic translation between two standards.

### CID 4030 CT, MR and PET Anatomy Imaged

<table>
<thead>
<tr>
<th>Coding Scheme Designator</th>
<th>Code Value</th>
<th>Code Meaning</th>
<th>SNOMED-CT Concept ID</th>
<th>UMLS Concept Unique ID</th>
</tr>
</thead>
<tbody>
<tr>
<td>SRT</td>
<td>T-42500</td>
<td>Abdominal aorta</td>
<td>7832008</td>
<td>C0003484</td>
</tr>
<tr>
<td>SRT</td>
<td>T-41070</td>
<td>Abdominal aorta and its branches</td>
<td>360524005</td>
<td>C1283352</td>
</tr>
<tr>
<td>SRT</td>
<td>T-B3000</td>
<td>Adrenal gland</td>
<td>23451007</td>
<td>C0001625</td>
</tr>
<tr>
<td>SRT</td>
<td>T-42300</td>
<td>Aortic arch</td>
<td>57034009</td>
<td>C0003489</td>
</tr>
</tbody>
</table>

Include CID 4031 “Common Anatomic Regions”

<table>
<thead>
<tr>
<th>Coding Scheme Designator</th>
<th>Code Value</th>
<th>Code Meaning</th>
</tr>
</thead>
<tbody>
<tr>
<td>SRT</td>
<td>T-83000</td>
<td>Uterus</td>
</tr>
</tbody>
</table>

![Figure 20: Context Group Definition Table (DCM16)]

Templates constrain the structure of a document or certain parts of a document. Templates can require certain entities at a specific position within the document and enforce certain relations between them. This may be realized by limiting certain entities to be selected from a specific set of codes. DICOM defines the concepts of context groups, defined terms (DT) and enumerated values (EV) for this purpose. Context groups are reusable definitions of such sets, whereas defined terms and enumerated values are local “inline” definitions at the very position they are used (for example by referring to a context group). Whereas both EVs and DTs define sets of codes, EVs strictly enforce the use of one of the listed codes as opposite to DTs that may be extended with application specific
codes if necessary.

### TID 1005 Procedure Context

<table>
<thead>
<tr>
<th>NL</th>
<th>Rel with Parent</th>
<th>VT</th>
<th>Concept Name</th>
<th>VM</th>
<th>Req Type</th>
<th>Condition</th>
<th>Value Set Constraint</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td></td>
<td>UIDREF</td>
<td>EV (121018, DCM, &quot;Procedure Study Instance UID&quot;)</td>
<td>1</td>
<td>U</td>
<td>Defaults to Study Instance UID (0020, 000D) of General Study Module</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td></td>
<td>UIDREF</td>
<td>EV (121019, DCM, &quot;Procedure Study Component UID&quot;)</td>
<td>1-n</td>
<td>U</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td></td>
<td>TEXT</td>
<td>EV (121020, DCM, &quot;Placer Number&quot;)</td>
<td>1</td>
<td>U</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>&gt; HAS CONCEPT MOD</td>
<td>TEXT</td>
<td>EV (110190, DCM, &quot;Issuer of Identifier&quot;)</td>
<td>1</td>
<td>U</td>
<td>See note</td>
<td></td>
</tr>
<tr>
<td>5</td>
<td></td>
<td>TEXT</td>
<td>EV (121021, DCM, &quot;Filler Number&quot;)</td>
<td>1</td>
<td>U</td>
<td></td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>&gt; HAS CONCEPT MOD</td>
<td>TEXT</td>
<td>EV (110190, DCM, &quot;Issuer of Identifier&quot;)</td>
<td>1</td>
<td>U</td>
<td>See note</td>
<td></td>
</tr>
<tr>
<td>7</td>
<td></td>
<td>TEXT</td>
<td>EV (121022, DCM, &quot;Accession Number&quot;)</td>
<td>1</td>
<td>U</td>
<td>Defaults to (0008,0050)</td>
<td></td>
</tr>
<tr>
<td>8</td>
<td>&gt; HAS CONCEPT MOD</td>
<td>TEXT</td>
<td>EV (110190, DCM, &quot;Issuer of Identifier&quot;)</td>
<td>1</td>
<td>U</td>
<td>See note</td>
<td></td>
</tr>
<tr>
<td>9</td>
<td></td>
<td>CODE</td>
<td>EV (121023, DCM, &quot;Procedure Code&quot;)</td>
<td>1-n</td>
<td>U</td>
<td>Defaults to Procedure Code Sequence (0008,1032) of General Study Module</td>
<td></td>
</tr>
</tbody>
</table>

**Figure 21: DICOM SR Template Definition Table [DCM16]**

CDA templates describe similar constraints for CDA documents in whole or in part. They also limit or enforce the occurrence of certain information entities at certain positions within the document. The main differences to SR templates are of syntactic nature, based on the different syntaxes used in the DICOM and HL7 standards. This applies for example to the Value Type (VT) definition of ST templates, which is called Data Type in the CDA context. Also, different value types and data types exist, so each value type has to be mapped to at least one corresponding data type.

One important aspect of CDA templates is that their contents can often be referred to employing specifically created Business Names. DICOM SR lacks such a concept, however, in DICOM SR each template row may be referred to by the row number (the number given in the first column of its definition table), which is not available for CDA templates.
To realize the automatic conversion of a DICOM Structured Reporting document to a semantically equivalent HL7 CDA document, three different requirements need to be addressed:

1. The expressive power and semantics of all utilized templates and codes (coding schemes) need to be equivalent. This means it won’t work if, for example, the DICOM templates only addressed top-level document contents while the CDA templates also addressed nested ones.

2. The template and coding scheme contents need to be equivalent. This means if, for example, the DICOM template were describing various image properties, equivalent descriptions must exist in the related CDA template definition.

3. A mapping between the related templates and coding schemes must be defined, such that for each piece of information potentially contained in a conforming document the conversion to an equivalent piece of information can be realized.

Requirements 1 and 2 address the definition of templates and Codes and may be summarized under the term data model unification. Requirement 3 may be called data model mapping. How these requirements were addressed will be described in the following sections.

### 3.5.2.1.1 Data Model Unification

DICOM utilizes an own code dictionary that refers to several different external coding schemes and incorporates the codes from these schemes into the DICOM standard. DICOM uses codes from existing coding schemes as appropriate, but adds additional, DICOM specific codes if no suitable code is available e. g.in SNOMED-CT, LOINC, etc. For the definition of the imaging report, several such codes were defined for use in DICOM SR. These codes are also used in the equivalent CDA representation (the result of transforming an SR document to the CDA format), thereby unifying the code base of both document representation formats.
Regarding templates, it was first analysed, which templates are required in both standards. Some new templates were added to the DICOM standard and some existing templates were modified to address some information entities that are required or at least meaningful in the context of the related CDA template. Furthermore, some restrictions were lifted that prevented the existing DICOM templates from being used to reflect the respective CDA document structure.

### 3.5.2.1.2 Data Model Mapping

The data model mapping addresses several portions of both document formats (CDA and SR). Both formats contain data within a header and within the actual document tree. Data from the DICOM header is not necessarily mapped to the CDA header and may be mapped to the CDA body instead. The opposite may also apply, some pieces of information from the DICOM SR document tree are best represented as part of the CDA header.

DICOM SR documents are structured by containers, which may be related to document sections to create a CDA representation. However, multiple containers might be merged into one and the same section and vice versa. Furthermore, containers are mostly identified by a unique code, which has to be translated into a CDA section heading by an appropriate mapping table.

In general, the mapping is achieved by creating a mapping table that “feeds” appropriate information from a SR document instance to the fitting entity defined in the related CDA template. The mapping table is therefore created with regard to one specific CDA template definition table, while the information might be extracted from various entities in the SR document, not necessarily defined by a single SR template – or, if information is extracted from the DICOM header, not related to any SR template at all.

<table>
<thead>
<tr>
<th>CDA Business Name</th>
<th>DICOM SR</th>
</tr>
</thead>
<tbody>
<tr>
<td>ComparisonStudy: ProcedureTechnique:</td>
<td></td>
</tr>
<tr>
<td>ProcedureCode</td>
<td>(121023, DCM, &quot;Procedure Code&quot;)</td>
</tr>
<tr>
<td>ComparisonStudy: ProcedureTechnique:</td>
<td></td>
</tr>
<tr>
<td>EffectiveTime</td>
<td>(111060, DCM, &quot;Study Date&quot;) + (111061, DCM, &quot;Study Time&quot;)</td>
</tr>
<tr>
<td>ComparisonStudy: ProcedureTechnique:</td>
<td></td>
</tr>
<tr>
<td>Modality</td>
<td>(122142, DCM, &quot;Acquisition Device Type&quot;)</td>
</tr>
<tr>
<td>ComparisonStudy: ProcedureTechnique:</td>
<td></td>
</tr>
<tr>
<td>MethodCode</td>
<td></td>
</tr>
<tr>
<td>ComparisonStudy: ProcedureTechnique:</td>
<td></td>
</tr>
<tr>
<td>TargetSite</td>
<td>(123014, DCM,&quot;Target Region&quot;)</td>
</tr>
<tr>
<td>ComparisonStudy: ProcedureTechnique:</td>
<td></td>
</tr>
<tr>
<td>Laterality</td>
<td></td>
</tr>
<tr>
<td>ComparisonStudy: ProcedureTechnique:</td>
<td></td>
</tr>
<tr>
<td>Ref:</td>
<td></td>
</tr>
<tr>
<td>ComparisonStudy: ProcedureTechnique:</td>
<td></td>
</tr>
<tr>
<td>ProviderOrganization</td>
<td></td>
</tr>
<tr>
<td>ComparisonStudy: Study[*]: StudyUID</td>
<td>(121018, DCM, &quot;Procedure Study Instance UID&quot;)</td>
</tr>
<tr>
<td>ComparisonStudy: Study[*]: Description</td>
<td>(121065, DCM, &quot;Procedure Description&quot;), if present, or (121023, DCM, &quot;Procedure Code&quot;) &gt; Code Meaning (0008,0104)</td>
</tr>
<tr>
<td>ComparisonStudy: Study[*]: Time</td>
<td>(111060, DCM, &quot;Study Date&quot;) + (111061, DCM, &quot;Study Time&quot;)</td>
</tr>
</tbody>
</table>

**Figure 23: DICOM SR / HL7 CDA Template Mapping Table [DCM20]**

The mapping tables connect the information from the SR document to the CDA template using the CDA Business Name. The DICOM part of the mapping is a realized employing some kind of selector syntax, roughly defined in the standard. Information from the SR document is often addressed em-
ploying the concept name of a content item or by referring to a DICOM attribute from the header employing its tag. In some cases constants are given instead for information that is not contained in the SR document but has to be present in the CDA representation. Some definition are even described in free text, e.g. “Thumbnail constructed from referenced image”.

References to SR content might be combined by several operators, for example referring to a content item nested below a certain other content item employing the “>” operator. In some cases conditional mappings are defined, employing keywords like “if”. However, the used “language” seems to be some kind of “pseudo-code” that, while being mostly intuitive, is not defined anywhere in the standard prior to use.

### 3.5.3 Concurrent Use of Standards and Specifications (De-facto Standards)

The described approach creates a harmonized representation of DICOM SR imaging reports as HL7 CDA documents and describes a mapping for automatically translating existing SR imaging reports to this new representation.

The approach effectively unifies the information representation in both standards while considering both standards’ peculiarities. This is achieved by creating several CDA document templates and by mapping the information entities from DICOM SR imaging reports to the definitions of these templates in carefully designed mapping tables.

### 3.5.4 Governance

The created templates and mappings are maintained by DICOM Working Groups 8 and 20 and the HL7 Imaging Integration Work Group. Adjustments based on user feedback may be incorporated by creating additional supplements to the DICOM standard, which has already happened with Supplement 155 as mentioned above.

### 3.5.5 Lessons learned

This section summarizes the “lessons learned” from the project in terms of successes as well as pitfalls and remedies, i.e. problems the project has identified that the architects of future projects need to keep in mind when designing their solution, and remedies the project has developed or proposed.

#### 3.5.5.1 Successes

The translation of a valid DICOM SR imaging report to a valid CDA document is possible, which is even shown by the example contained in the DICOM standard (part 20) [DCM20].

#### 3.5.5.2 Pitfalls and Remedies

One of the already experienced problems was that such a mapping may force an application to implement both standards, although it is meant to work with only one of them. This has been the case with the definitions in DICOM supplement 135 [SUP135]: the defined CDA templates only made sense to an application with knowledge of the DICOM standard. This was resolved by changing the definitions within supplement 155 [SUP155].

Further evaluation is not available so far, since no known practical implementation of the described approach exists. However, it may already be noted that the lack of a formal definition of the employed mapping language complicates the creation of such an implementation. At least automated
code generation based on the standard becomes very difficult without such a formal definition.

3.5.6 References and Further Information


3.6 Case Study #06: Trillium Bridge – Bridging Patient Summaries across the Atlantic

- **Author of case study:** Catherine Chronaki <euoffice@HL7.org>
- **Project or Initiative name:** Trillium Bridge – Bridging Patient Summaries across the Atlantic
- **Project type:** concept | limited deployment for experimental use
- **Status (in 10/2015):** Successfully concluded. Deployed for experimental use (demonstrator)
- **Countries / Regions:** Italy, Spain, Portugal, Luxemburg
- **Partners:** HL7 Foundation (Be, EU), IHE Europe (Be, EU), EuroRec (Fr, EU), Phast (Fr, EU), LISPA (It, EU), NEN (for CEN/TC251, EU), MoH Spain (ES, EU), MoH Portugal (PT, EU), Lantana (US), ProSocial (US), Atrius Health (US), Mayo Clinic (US)
- **Scale of deployment:** cross-border, transatlantic (if at all applicable – as it is a proof of concept)

3.6.1 Project Overview

The Trillium Bridge project “Bridging Patient Summaries across the Atlantic”, the operational arm of the EU/US Memorandum of Understanding on eHealth/Health Information Technology Cooperation Roadmap, compared patient summaries in Europe and the US to support interoperability for health and healthcare delivery, economic growth and innovation.

Recognising that there is value in transatlantic cooperation to support emergency or unplanned care scenarios when European patients travel to the US and vice versa, Trillium Bridge assembled a broad transatlantic community of collaboration and knowledge sharing, for eHealth stakeholders including key standards bodies to compare specifications and samples, to create bridging transformations, and to establish the common baseline for an international patient summary.

Trillium Bridge compared patient summary samples and specifications from the European Union (EU) Patient Summary Guidelines (epSOS patient summary implementation guide) and the United States (US) Meaningful Use Stage II Program Clinical Summary for Transitions of Care (HL7 Consolidated Clinical Document Architecture, Continuity of Care Record) and delivered a gap analysis.

Starting from concrete patient stories of unplanned care events affecting people traveling across the Atlantic, the project captured the relevant patient summaries in Europe and clinical summaries in the US. Two main use cases, situations of using patient summaries in an unplanned care setting were identified in collaboration with the US Office of the National Coordinator S&I Framework, EHR Workgroup. The first was a patient mediated scenario where a patient carries his/her own summary, transforms it into a format fit for the purpose of use on the other side of the Atlantic, shares it with a physician in an unplanned care setting, and receives an encounter report in the same format to take back home. The second is a provider mediated scenario where with the consent of the patient, the physician connects with the home health system of the patient, requests and receives the patient’s patient summary.

Trillium Bridge identified a clear baseline of clinically aligned content in the EU and US comprising demographics, problems, medications, and allergies. In a proof of concept endeavour assembling interoperability assets to align structure and terminology, the Transformer software created by Mayo Clinic [MC15], employs the Phast Common Terminology Service [CTS-2] to convert patient summaries.
created in the EU context, to patient summaries that can potentially be useful in the US context and vice versa. The Trillium Bridge Gateway [IHIC2015], developed in cooperation with Gnomon Informatics/IUZ, proves the technical feasibility of the provider mediated scenario demonstrating the connection of Portugal, Spain, Lombardy (Italy), and Luxembourg with Kaiser Permanente in the US.

Trillium Bridge, building on pragmatic evidence and an intense reflection process on concrete steps towards policy convergence, delivered twenty recommendations [TB5.2] and a draft action plan to endorse, refine and implement for advancement of eHealth innovation to achieve the triple win: quality care, health system sustainability and economic growth. As of September 2015, the recommendations of Trillium Bridge have been endorsed by the Joint Initiative Council on SDO Global Health Informatics Standardization in their work on standard sets, GS1, IHTSDO, CEN TC251, the National program of Luxemburg, and representatives of Ministries of Health in member states of European Union.

### 3.6.2 Approach

Trillium Bridge investigated extending the epSOS National Contact Point (NCP) infrastructure in the transatlantic setting for the patient summary query/retrieval and the encounter report use cases of epSOS [epSOS, epS1.4.3]. Eventually, the encounter report was not demonstrated as none of the participating Member States have developed or tested the functionality across member states. Trillium Bridge proved the technical feasibility of exchanging patient summaries across the Atlantic. It also created interoperability assets (i.e. trillium gateway, transformer, and PHAST terminology mapping service) and identified discrepancies in the implementation of IHE profiles in Europe (epSOS) and United States (HealthWay). The open source components of the Trillium Bridge gateway have been delivered to the openNCP community. All these are described in detail in the relevant deliverables for Trillium Bridge available at [www.trilliumbridge.eu](http://www.trilliumbridge.eu).
3.6.2.1 Care Process

Building on the trust cycle of a network of national contact points that mediated patient summary requests, the fundamental idea was to expand the trust cycle with one or more contact points in the US. One such contact point had been US/Kaiser Permanente that would later appear in the list of available contact points in Lombardy (Italy), Portugal, Spain and Luxemburg.

Two distinct care processes were envisioned: the patient mediated scenario and the provider mediated scenario. In the patient mediated scenario, the citizen is able to log on into the national portal and view his/her patient summary in one of the supported languages. This is shown in Figure 26,
where the red sequence walks us through the process of Martha’s story, an American visiting Europe, while the black sequence follows Paolo’s story, an Italian visiting the United States. With Trillium Bridge, the functionality on the European side was extended with the ability to download the patient summary in the selected language and format (i.e. epSOS pivot document). Then, using the transformer service the patient was able to translate it to the HL7 Consolidated Clinical Document Architecture, Continuity of Care Document format. On the US side, BlueButton and Meaningful Use II [MOU] specify that patients should be able to receive their clinical summary after an appointment. Once again the transformer can help converting a US patient summary to the epSOS format that is close to the European Patient Summary Guideline [eHN13] endorsed by the voluntary eHeath Network of Member State representatives established under Article 14 of the European Directive on Patient’s Rights to Cross-Border Care [EPC11]. The patient can hand in the transformed patient summary to a physician in Europe who can import it to the national portal and display it in his/her preferred language.

![Figure 27: Trillium Bridge Technical Architecture Overview [TB4.1]](image)

In the provider mediated scenario case, the GP in Europe logs into the national portal and performs are patient summary query for Martha to US/KP as they would from any other any national contact point in Europe: (1) The list of matching patients is retrieved and displayed, (2) the appropriate patient is selected, (3) the list of documents for that patient is queried and retrieved, (4) the patient summary document is selected, requested, retrieved and displayed. Under the hood, the transformer software created by Mayo [MC15] processes the patient summary with the help of terminology mapping service developed by Phast.

On the US side, following the use case developed and demonstrated at HIMSS, the Electronic Health Record System of KP is able to query the national contact points of Italy (Lombardy), Spain, Portugal, and Luxemburg for Paolo using the identification traits applicable to that Member State. All requests are mediated through the Trillium Bridge gateway, a special contact point using the openNCP technology [TB2.2, OpenNCP]. Again the transformer is involved transparently as a converter to HL7 CCDA-CCD. The process is graphically depicted in the figure below, from [TB4.2].
3.6.2.2 Information

The information model of the patient summary is presented in the relevant implementation guides of epSOS and HL7 CCDA. Trillium Bridge performed a detailed gap analysis and review of structures and terminology data sets used in the relevant specifications [TB2.2, TB3.1].

<table>
<thead>
<tr>
<th>epSOS/EU Directive</th>
<th>EU Patient Guidelines</th>
<th>epSOS PS</th>
<th>CCD</th>
<th>Optionality</th>
</tr>
</thead>
<tbody>
<tr>
<td>Section</td>
<td>Optionality</td>
<td>Optionality</td>
<td>Section</td>
<td>Optionality</td>
</tr>
<tr>
<td>Allergy</td>
<td>R</td>
<td>R</td>
<td>Allergies</td>
<td>R</td>
</tr>
<tr>
<td>List of current medicines</td>
<td>R</td>
<td>R</td>
<td>Medications</td>
<td>R</td>
</tr>
<tr>
<td>List of current problems / diagnoses</td>
<td>R</td>
<td>R</td>
<td>Problem</td>
<td>R</td>
</tr>
<tr>
<td>*List of resolved, closed or inactive problems</td>
<td>O</td>
<td>O</td>
<td>Problem</td>
<td>R</td>
</tr>
<tr>
<td>Surgical Procedures prior to the past six months</td>
<td>R</td>
<td>O</td>
<td>Procedures</td>
<td>O (R only for inpatients)</td>
</tr>
</tbody>
</table>
Major Surgical Procedures in the past six months

<table>
<thead>
<tr>
<th></th>
<th>R</th>
<th>R</th>
<th>Procedures</th>
<th>O (R only for inpatients)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medical Devices and implants</td>
<td>R</td>
<td>R</td>
<td>Medical Equipment</td>
<td>O</td>
</tr>
</tbody>
</table>

*Treatment Recommendations

|                         | R | O | Plan of Care | O |

*Autonomy / Invalidity

|                         | R | O | Functional Status | O |

Vaccinations

|                         | O | O | Immunizations | O |

Social History Observations

|                         | O | O | Social History | O |

Pregnancy history (Expected date of delivery)

|                         | O | O | Social History (Pregnancy Observation) | O |

Physical findings (Vital Signs Observations)

|                         | O | O | Vital Signs | O |

Diagnostic tests (Blood group)

|                         | O | O | Results Section | R |

Advance Directives

|                         | O |

Family History

|                         | O |

Payer

|                         | O |

Encounters

|                         | O |

### 3.6.2.3 Applications

The communication standards involved are IHE profiles IHE PCD, PIX, PDQ, and XCPD, and they are used just as in epSOS. Workarounds had to be developed to address differences between the EU and US implementations. These are graphically shown as part of the logical architecture in the figure below, cited from [TB4.1].

![Diagram](image_url)

**Figure 30: Communication standards and components for the TB Patient Summary exchange**

### 3.6.2.4 IT Infrastructure

The Trillium Bridge gateway serves as the central part of the architecture since it mediates all the
patient summary exchanges between Europe and the United States serving as a trusted third party. The logical structure of the gateway appears in the figure below [IHIC2015]:

Figure 31: Trillium Gateway: transformation, terminology, and translation components.[IHIC2015]

3.6.3 Concurrent Use of Standards and Specifications (De-facto Standards)

With respect to mapping between controlled terminologies, an analysis of the terminologies used in epSOS and Meaningful use was carried out. Then, for the shared value sets a mapping exercise followed. The corresponding mapping is offered as part of the Phast terminology service [CTS-2]. The coverage of the value sets (concepts with correspondence / concepts present) appears in Table 3 below.

Table 3 – The Trillium value set mappings with % covered [IHIC2015]

<table>
<thead>
<tr>
<th>epSOS Value Set</th>
<th>epSOS Code System</th>
<th>concepts with correspondence/ concepts present/ (%) covered</th>
<th>CCD Value Set</th>
<th>CCD Code System</th>
<th>concepts with correspondence/ concepts present/ (%) covered</th>
</tr>
</thead>
<tbody>
<tr>
<td>epSOSActiveIngredient</td>
<td>ATC</td>
<td>606/5592 (6%)</td>
<td>Medication Drug Class</td>
<td>NDF-RT</td>
<td>1365/10699 (13%)</td>
</tr>
</tbody>
</table>
### 3.6.4 Governance

Trillium Bridge relied on the Joint initiative Council SDO global health informatics standardization as the method to sustain and continue its results. There were no project derived specifications per se. Assets developed in the project have been handed off to other projects and the OpenNCP community [OpenNCP].

### 3.6.5 Lessons learned

The main lesson can be closed in the phrase “the devil is in the details” In Trillium Bridge, we underestimated the amount of effort required to compare patient summary specifications in Europe and US and map between them. The fact that the same baseline standard i.e. HL7 CDA is used, leaves a lot to wish for in terms alignment and consistent deployment of the implementation guides.

One particular remedy we hope to pursue in Trillium Bridge, hoping to set it as the norm, is the use of tools for the implementation and deployment of standards or solutions based on standards to eliminate as far as possible redundancy and human error.

### 3.6.6 Resources

The resources and interoperability assets created by Trillium Bridge will be submitted to the EXPAND asset

<table>
<thead>
<tr>
<th>epSOSActiveIngredient</th>
<th>ATC</th>
<th>Medication Brand Name</th>
<th>RxNorm</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>epSOSActiveIngredient</td>
<td>ATC</td>
<td>2836/5592 (51%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>epSOSAllergenNoDrugs</td>
<td>SNOMED CT</td>
<td>79/112 (71%)</td>
<td>Ingredient Name</td>
<td>UNII</td>
</tr>
<tr>
<td>epSOSRoutesofAdministration</td>
<td>EDQM Standard Terms</td>
<td>55/73 (75%)</td>
<td>Medication Route FDA</td>
<td>NCI Thesaurus</td>
</tr>
<tr>
<td>epSOSDoseForm</td>
<td>EDQM Standard Terms</td>
<td>28/457 (6%)</td>
<td>Medication Product Form</td>
<td>NCI Thesaurus</td>
</tr>
<tr>
<td>epSOSIllnessesandDisorders</td>
<td>ICD-10</td>
<td>1775/9525 (19%) IHTSDO maps</td>
<td>Problem</td>
<td>SNOMED CT</td>
</tr>
<tr>
<td>epSOSIllnessesandDisorders</td>
<td>ICD-10</td>
<td>1147/9525 (12%) NLM maps</td>
<td>Problem</td>
<td>SNOMED CT</td>
</tr>
<tr>
<td>epSOSVaccine</td>
<td>SNOMED CT</td>
<td>27/31 (87%) Vaccine Administered</td>
<td>CVX</td>
<td>87/163 (53%)</td>
</tr>
</tbody>
</table>
repository.

**[EXP-AR]** EXPAND Asset Repository

**Description:** A repository created in the frame of the EXPAND Project

**Availability:** Beta

**Link:** To be available at [http://www.expandproject.eu/](http://www.expandproject.eu/)

**[MC15]** Mayo Clinic: Trillium Bridge Transformer.

**Description:** The Trillium Bridge Transformer is a Java API, Command Line Interface, and Web-based Application to translate between epSOS Patient Summary documents and HL7 C-CDA Continuity of Care Documents (CCD). Further information at [TB3.2]

**Availability:** Open Source, Apache Licence

**Link:** [http://informatics.mayo.edu/trillium-bridge](http://informatics.mayo.edu/trillium-bridge) (Binaries and Documentation)  
[https://github.com/trillium-bridge/trillium-bridge-transformer.git](https://github.com/trillium-bridge/trillium-bridge-transformer.git) (Source Code)

**[OpenNCP]** epSOS Open Source NCP Software

**Description:** A set of Open Source Components (OpenNCP) that can be adopted by Participating Nation, to build their local implementation of the epSOS NCP (National Contact Point).

**Availability:** Open Source, GPLv3 and ASLv2

**Link:** [https://openncp.atlassian.net/wiki/display/ncp/OpenNCP+Releases](https://openncp.atlassian.net/wiki/display/ncp/OpenNCP+Releases)

**[CTS-2]** Phast Standard Terminology Services

**Description:** Terminology services based on the HL7 Common Terminology Services Release 2 Service Functional Model Specification (HL7 CTS-2 SFM)

**Availability:** Online Service

**Link:** [http://extension.phast.fr/STS_UI](http://extension.phast.fr/STS_UI)

### 3.6.7 References and Further Information


- **[epS1.4.3]** epSOS Deliverable D1.4.3: EED SERVICES including specifications for all services. Online: [http://www.epsoos.eu/uploads/tx_epsoosfileshare/D1.4.3_EED_Services_including_specifications_for_all_services_01.pdf](http://www.epsoos.eu/uploads/tx_epsoosfileshare/D1.4.3_EED_Services_including_specifications_for_all_services_01.pdf) (accessed 2015-10-12)


- **[MOU]** United States, Department of Health and Human Services, Office of the National Coordinator for Health Information Technology. Meaningful Use Regulations. Online: [https://www.healthit.gov/policy-researchers-implementers/meaningful-use-regulations](https://www.healthit.gov/policy-researchers-implementers/meaningful-use-regulations) (accessed 2015-10-12)


Trillium Bridge Deliverable D4.1: Interoperability test plans, tools, data sets, available at [www.trilliumbridge.eu](http://www.trilliumbridge.eu)

Trillium Bridge Deliverable D5.2: Final versions of strategy briefs as outputs from multi-stakeholder workshops held in collaboration with other initiatives: Feasibility Analysis for EU/US patient summary exchange, available at [www.trilliumbridge.eu](http://www.trilliumbridge.eu)
4 Solutions for a Coexistence of Standards in eHealth Deployment Projects

4.1 Case Study #07: Cross-Border Patient Summary and ePrescription Services

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This case study covers three EU projects focusing on cross-border eHealth Patient Summary and ePrescription / eDispensation services: epSOS, EXPAND, and e-SENS.

epSOS
- Project name: epSOS: Smart Open Services for European Patients and related projects
- Project type: large-scale deployment for experimental use
- Project status (in 10/2015): deployed for experimental use. Project ended on 30/06/2014, deployment continued in following projects.
- Countries / Regions: Austria, Belgium, Croatia, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Italy, Luxembourg, Malta, Norway, Poland, Slovenia, Slovakia, Spain, Sweden, Switzerland, The Netherlands, Turkey, United Kingdom.
- Project partners: See www.epsos.eu
- Scale of deployment: cross-border

e-SENS
- Project name: e-SENS (Electronic Simple European Networked Services)
- Project type: large-scale deployment for experimental use
- Project status (in 10/2015): deployed for experimental use
- Countries / Regions (in the eHealth Domain): Greece, Austria, Italy, Luxembourg, Portugal, Spain, Switzerland.
- Project partners: see www.esens.eu
- Scale of deployment: cross-border

EXPAND
- Project name: EXPAND (Expanding Health Data Interoperability Services)
- Project type: CIP Thematic Network
- Project status (in 10/2015): handing over assets to EC DG Santé – Connecting Europe Facility
- Countries / Regions: Portugal, Austria, Belgium, Bulgaria, Germany, Spain, Finland, France, Greece, Italy, Netherlands, Slovenia, United Kingdom, Sweden.
- Project partners: see www.expandproject.eu
- Scale of deployment: cross-border
4.1.1 Project Overview

This case study is multifolded. Starting from epSOS activities it includes further achievements in e-SENS, Stork, Trillium Bridge, e-SENS, EXAND and their evolution on the one hand into new H2020 projects, like eStandards, openMedicine, ASSSESS-CT, VALUeHEALTH, on the other hand towards the hand over to CEF / DG Santé and to the eHealth Network through the Joint Action to support the eHealth Network (JAseHN).

The epSOS project aimed at designing, building and evaluating a service infrastructure that demonstrates cross-border interoperability between electronic health record systems in Europe. epSOS attempted to offer seamless healthcare to European citizens. Key goals were to improve the quality and safety of healthcare for citizens when travelling to another European country. Moreover, it concentrated on developing a practical eHealth framework and ICT infrastructure that enables secure access to patient health information among different European healthcare systems. epSOS can make a significant contribution to patient safety by reducing the frequency of medical errors and by providing quick access to documentation as well as by increasing accessibility of a person’s prescribed medicine also abroad. In emergency situations, this documentation provides the medical personnel with life-saving information and reduces the (sometimes needless) repetition of diagnostic procedures.

The technical, legal and organizational concepts developed within the framework of the project were subject to an extensive practical testing phase. epSOS tested cross-border services in the following areas:

- Patient Summary: access to important medical data for unplanned patient treatment
- Cross-border use of electronic prescriptions ("ePrescription" – or "eMedication" systems)

In the extended project phase – which started 2011- the epSOS project team consolidated, scaled up and operationalized the epSOS Services, moving from 12 Member States to 27 participating nations. Additional epSOS Services like the Patients ACcess to their data (PAC), Health Care Encounter Report (HCER) or the Medication Related Overview (MRO) were analyzed and tested. For the first time, patients in Europe had the opportunity to use cross-border eHealth services when seeking healthcare in participating epSOS pilot countries – whether as tourists, business travelers, commuters or exchange students.

With the end of the epSOS project in June 2014 the many outputs of the project can be summarized now. The intention of epSOS has been to deliver and test building blocks to implement cross-border eHealth services in the future. epSOS has achieved this in different ways:

- by defining and setting up the necessary infrastructure based on National Contact Points (NCP) that exchange patient information with other countries on a piloting basis (epSOS pilot start in April 2012), jointly developed by Member States and Vendors and
- by defining, testing and evaluating the services from a user’s – health professional’s and patient’s – perspective.

Both a methodological process and durable implementations (termed building blocks) that form the basis for a longer term, pan-European approach to building interoperable solutions were delivered during the course of the project. The re-use / continuation of use is dependent on the commitment
of the Member States.

To facilitate the realization of a National Contact Point (NCP), in January 2013 epSOS created a second Open Source reference implementation of the technical infrastructure that connects the national eHealth system of a Participating Nation to the epSOS network. Since the first reference implementation (called NCP-in-a-Box), which has been used successfully by many participating nations, contained some proprietary software, the new reference implementation, commonly referred to as OpenNCP, is available, since 2013 under the open source GPLv3 and Apache Software License.

Furthermore, epSOS has introduced a Framework Agreement (FWA) that articulates the legal conditions under which an exchange of electronic medical information on a pilot basis was made possible. For operation beyond the project, another more sustainable legal framework needs to be in place in order to enable the exchange of patient information across borders. The recommendations of the project will, hopefully, support the process towards a sustainable legal framework.

epSOS also supported the convergence of the eHealth services in the EU by encouraging cooperation, by providing the eHealth network (eHN) with the epSOS data set of the Patient Summary, and by working on the topic of semantic sustainability especially in the context of ePrescriptions. Thus, epSOS helped the process towards interoperable healthcare in Europe.

During the Simulated Consultations carried out by the Evaluation Work Package, the patients testified positively towards using the epSOS service and thought it was a useful tool for health professionals. The health professionals attested good service aspects too (understandable information, usability and response time) and declared that it was a valuable service because language barriers were lowered. These results were also confirmed in the health professional interviews where technological aspects, personal skills (ability to handle computer applications), and context variables (different drug legislations among countries) were identified, among others. Moreover, the ease of use, user manuals or integrated systems, were some of the stated facilitating elements.

Trillium Bridge (see section 3.6 for details) extended the epSOS services geographically (EU/US Patient Summary exchange) and functionally, introducing the new paradigm of “Patient Mediated Access”. In epSOS the “Provider Mediated” approach, also adopted in Trillium Bridge, consists in setting up a Business-to-Business architecture, in which a Health Professional requests a clinical document through the National Contacts Points (or Gateway for EU/US interoperability) to Country of Affiliation. In the case of Patient Mediated Access, it is the Patients who retrieve and translate their clinical document in a (electronic) format understood by the Health Professionals and hand it over to them, bypassing most of the legal and technical connectivity constraints.

In e-SENS (see section 4.9 for details), Building Blocks derived from diverse domains (e-Procurement, e-Justice, e-Business and eHealth) are consolidated and partially adopted among the domains, with the objective of building an as shareable as possible “Connecting Europe Facility” (CEF) infrastructure. The e-SENS Pilot should be operational both in a testing environment (similar to epSOS Pre-Production Testing infrastructure) and real environment with real patients. The former has no legal constraints, only technical readiness is required. The latter implies the building of a circle of trust similar to the epSOS Framework Agreement. In this case, the eHN Temporary Legal Agreement should be required. In the eHealth e-SENS domain, no clinical Use Cases were added. Actions were
mainly directed to overcome some of the limitations encountered in epSOS, such as to overcome some of the security relaxation criteria, adopt eIdentification and eSignature, and the refactoring of the Central Configuration Services, exploiting some of the components of the e-Delivery provided by the EC DG DIGIT.

The EXPAND Project played the role of a keeper, consolidator, and integrator of eHealth assets (mainly from epSOS), in order to hand the OpenNCP implementation platform over to CEF, enriched by the components derived from other projects. EXPAND established the seven so called “Maintenance Shops” to manage the Legal & Organizational, Semantic, Specification, Technical Implementation, Testing, Deployment, and Operation Assets. The co-operation with the H2020 eHealth projects, mainly those falling under the topic PHC-34 eHealth (eStandards for the harmonization of specifications, openMedicine aiming to solve the issue of identifying medicinal products, ASSESS-CT to evaluate the suitability of SNOMED-CT or other terminologies for clinical use, and VALUeHEALTH addressing the definition of business plans and business model for the eHealth service sustainability beyond 2020) allowed to create bridges to keep and expand assets after the end of EXPAND, helping to create the mechanism to consolidate and submit a proposal for procedures and guidelines to the eHealth Network (eHN) for adoption through JAseHN, the Joint Action to Support the eHN. In 2015, strict co-operation with EC DG Santé was established, including in the OpenNCP Community and governance structure members of EC DG Santé, who started learning by practicing (and installing, in Bruxelles, an OpenNCP). The hand-over to DG Santé covered all assets managed by the Maintenance Shops. Support was also provided in the preparation of CEF eHealth call both to the EC and to the Member States, mainly through the Deployment Shop with guidelines and checklist to set up legal, organizational, technical infrastructure for eHealth Cross-Border services. During the EXPAND Final Event, an ad hoc IHE Connect-a-thon testing event, called EXPAND-a-thon, was organized to allow to member states to show their readiness for CEF.

4.1.2 Approach

According to [epSOS D3.4.2], “the overarching goal of epSOS (Smart Open Services for European Patients) is to develop a practical eHealth framework and ICT infrastructure that will enable secure access to patient health information [...] between European healthcare systems. [...] The methodology will strive to build a common architecture and core services for the identification of users and institutions, security, confidentiality and privacy aspects, and aim to enhance various semantic aspects of the systems. “The core principle of epSOS is to bridge existing national eHealth infrastructures instead of setting up a new, centralised European healthcare service network from scratch. To make this approach work technical, semantic and legal interoperability among European eHealth infrastructures must be achieved. This includes identity as well as security matters and information management issues within heterogeneous, distributed environments. None of the problems faced by epSOS is new or extremely challenging: cross-border data exchange is common practice in many domains. Nearly every European country has use cases and processes for cross-enterprise health data exchange defined and decoupled security services spanning federated domains are well-covered by international standards. Therefore, the challenge for the development of technical specifications for the epSOS building blocks is not to find a solution that works for the defined use cases. The challenge is to find a solution that

1) can evolve over the next years and lay ground for a seamless, secure and privacy-aware ex-
change of any kind of medical data across Europe,
2) can easily connect to the existing infrastructures without imposing unreasonable new risks on the privacy and integrity of existing data managing systems,
3) is flexible enough to be used in conjunction with different means of identification, authentication, and authorization to allow for any citizen and country to participate based on existing legal regulations and technical actualities, and
4) is widely accepted, and has the potential for reuse of software components and test tools.

Those 4 criteria were at the basis for the process to select the Architecture and the Technical Specifications to be followed, to define the clinical documents to be exchange and to select the Code Systems and Value Sets for the document terminologies. Reference to these procedures will be provided in the following sections.

4.1.2.1 Care Process
The technical, legal as well as organizational concepts developed in the project were subject to the extensive practical testing phase that lasted until the project end. epSOS tested its two core eHealth services in the following areas:

- **Patient Summary**: Access to important medical data for the further treatment of patients
- **Cross-border use of electronic prescription services (“ePrescription” or “eMedication”): Access to an individual’s ePrescription from the home country

In the extended project phase, which started in 2011, the epSOS project team consolidated, scaled up and operationalized the services for ID management, security, semantics and standards. Additionally to the two core epSOS services Patient Summary and ePrescription, services like the **patient access to their data (PAC)**, the **Medication Related Overview (MRO)**, the **Healthcare Encounter Report (HCER)**, the integration of the **112 emergency services** and the integration of the **European Health Insurance Card (EHIC)** processes were analysed and tested if feasible:

- **Patient Access to their data (PAC)**: It was planned to provide patients with access to their existing Patient Summaries generated and kept in other countries (different from the home country) with or without the presence of a health professional at the point of care or elsewhere. The patient access use case was found feasible for testing and included in the epSOS piloting phase.
- **Medication Related Overview (MRO)**: The MRO is a document for informational purposes only that supports all possible information that might be needed in the process of prescribing, dispensing (and possibly even administering) medication to the patient in a foreign country. The absolute minimum set of medical information in the MRO consists of all the coded prescriptions and medication dispenses available in country A. Other useful information for the medication process, such as allergies and intolerances, are in the extended data set of the MRO. The MRO use case was found feasible for testing and included in the epSOS piloting phase.
- **Healthcare Encounter Report (HCER)**: The HCER service aims at informing the Country of Affiliation after a Patient Summary has been requested for a healthcare event that took place abroad. Informing the Country of Affiliation about a healthcare encounter in the Country of Treatment is done only with the consent of the patient. The patient access use case was
found feasible for testing and included in the epSOS piloting phase.

- **European Health Insurance Card (EHIC):** epSOS analyzed and assessed whether, and how to use the EHIC identification data not only for submitting reimbursement requests, but also for identifying the patient, thus, benefiting the users by simplifying the administrative process. The EHIC use case was not found feasible for testing and was therefore excluded from the epSOS piloting phase.

### 4.1.2.2 Information

The patient must give her/his consent before any of her/his data is made available to the epSOS network. The health professional’s permission to access the patient’s medical data is verified through the data-controlling country (with respect to the consent given in that country), the national security policy of the specific country, and, if available, through a patient privacy policy. It is assumed that this step is piggybacked with each data access operation and solely implemented behind the capsule of the national eHealth infrastructures. The consent is realized through the IHE Basic Patient Privacy Consent (BPCC) profile. The file is a Clinical Document Architecture (CDA) Level 1 or Level 3 document as specified in the IHE XDS-SD (“scanned document”) profile, based on the HL7 CDA Standard. The HL7 CDA Standard Version 2.0 is based on XML and describes the following three levels:

- **CDA Level 1:** Uniform document title and header
- **CDA Level 2:** Standardized structure of the document (chapter titles) for e.g. anamneses, diagnoses, medications and so on.
- **CDA Level 3:** Completely structured document in which individual data fields can be addressed directly (e.g. presentation of laboratory data, blood pressure, etc.)

The health professional sends a query for medical data of the identified patient and retrieves the information she/he needs. Medical data is solely accessible in the common epSOS format. The required encoding and decoding functionality is provided by the sending and receiving Participating Nation, respectively. This is realized using the IHE Profile XCA Cross Gateway Query and Cross Gateway Retrieve. These transactions employ OASIS/ebXML Registry standards and are transmitted using Web Services Exchange.

The documents exchanged are epSOS-specific CDA Level 1 and Level 3 documents called “ePrescription” and “Patient Summary”, which are based on the HL7 CDA Release 2.0 standard and the HL7 Implementation Guide: CDA Release 2 – Continuity of Care Document (CCD). The documents are also harmonized with the IHE Patient Care Coordination CDA Content Modules.

Some operations performed on patients’ data could result in a change of the state of the available data (e.g. dispensation of an ePrescription). It is therefore mandatory that the Participating Nation is notified about this change, as it maintains the state of the affected object. The result of this step is a modification of the state of the affected object (which may include a data update). The modification is carried out with the IHE XDS profile transaction “Provide and Register Document”. This transaction uses MTOM/XOP to convey both metadata and attached documents from the Document Source actor to the Document Repository actor as well as ebRIM version 3.0 to code the metadata. The document exchanged is an epSOS-specific CDA 3 document named “eDispensation”, which in turn is based on the HL7 CDA Release 2.0 standard and the HL7 Implementation Guide: CDA Release 2 – Continuity of Care Document (CCD). The document is also harmonized with the IHE Patient Care Co-
ordination CDA Content Modules.

All attempts to access a patient’s data through epSOS are recorded in audit trails. By regular evaluation of audit trails unauthorised disclosure of medical data can be detected and prosecuted. Auditing and Authentication are achieved using the IHE Profile “Audit Trail & Node Authentication”. This profile contributes to access control by limiting network access between nodes and limiting access to each node to authorized users. Network communications between secure nodes in a secure domain are restricted to other secure nodes in that domain. Secure nodes limit access to authorized users as specified by the local authentication and access control policy.

- **User Authentication:** The Audit Trail and Node Authentication Integration Profile requires local user authentication. The profile allows each secure node to use the access control technology of its choice to authenticate users. The use of IHE “Enterprise User Authentication” is one such choice, but it is not mandatory to use this profile.
- **Connection Authentication:** The Audit Trail and Node Authentication Integration Profile requires the use of bi-directional certificate-based node authentication for connections to and from each node. The DICOM, HL7, and HTML protocols all have certificate-based authentication mechanisms defined. These mechanisms authenticate the nodes, rather than the user. Connections to machines that are not bi-directionally node-authenticated are either prohibited, or designed and verified to prevent access to PHI.
- **Audit Trails:** User Accountability is provided through Audit Trail. The Audit Trail permits a security officer in an institution to audit activities, to assess compliance with a secure domain’s policies, to detect instances of non-compliant behavior, and to facilitate detection of improper creation, access, modification and deletion of Protected Health Information (PHI).

Profile secure communication is realized with RFC 2246 Transport Layer Security (TLS) 1.0 and WS-I Basic Security Profile 1.1. Audit Log transport is executed using RFC 5424/5425/5426 Syslog Protocol. Audit Log messages are performed using RFC 3881 Security Audit and Access Accountability Message XML Data Definitions for Healthcare Applications

### 4.1.2.3 Applications

The epSOS service interface defines the semantics of identification and data sharing operations for European eHealth services. “On the wire”, the service operations are implemented by SOAP messages that are exchanged between an initiating gateway (operated by NCP-B) and a providing gateway (operated by NCP-A). [epSOS D3.4.2] specifies the mapping of epSOS service operations onto standardised messages and as such is the normative implementation guideline for the epSOS-facing NCP interface.

**4.1.2.3.1 NCP: A Standards based Implementation**

The epSOS NCP-to-NCP interface is based on the IHE X* family of Interoperability Profiles and utilises a set of supporting profiles. The decision of adopting the IHE X* profiles was the result of the assessment of these profiles and of the competing OMG “Retrieve, Locate, and Update Service” (RLUS) specifications. Although RLUS seemed at that time more easily implementable, a strong pressure of the Industry Team within epSOS induced the Member States to vote in favor of the IHE X* profiles, which were at that time more consolidated and widely used.
The IHE profiles that are implemented for epSOS NCP-to-NCP data exchange are:

- Cross Community Fetch (XCF)
- Cross-Community Access (XCA) incorporating a modified getAll() transaction
- Cross-Enterprise Document Reliable Interchange (XDR)
- Cross-Community Patient Discovery (XCPD)

The epSOS service specifications that build on these IHE profiles introduce various extensions and restrictions on IHE actor and transaction definitions in order to properly cover the epSOS use cases and to align with the epSOS security framework:

- Registry query and repository retrieve transactions are conflated to a single list() operation.
- Additional error messages are defined that cover specific failure conditions of the epSOS use cases on patient summary and ePrescription.
- Warning messages are introduced to allow for notifications on specific environmental conditions that apply to a member state and that may affect the interpretation of data in another member state.
- The optionality of data fields is aligned to European privacy regulations.
- The application of security measures and the contents of the SOAP security header are specified normatively.

### 4.1.2.3.2 epSOS Identification Service

The epSOS Identification Service is used to discover a valid patient identifier from an ID assigning authority by providing identifiers and/or demographic data that is sufficient for patient identification. The implementation of the epSOS Identification Service is based on the HL7 V3 Identification Service standard (HL7 IS) and is an extension to the IHE profile XCPD “Cross-Community Patient Discovery”
4.1.2.3.3 epSOS Patient Service

The epSOS Patient Service is used to share an identified patient’s medical summary between the patient’s country of affiliation and the country of care. Both countries are represented by their respective NCPs. The implementation of the epSOS Patient Service is based on the IHE Cross-Community Fetch [IHE XCF] profile, which in turn is based on the following standards:

- ebRIM: OASIS/ebXML Registry Information Model v3.0 [OASIS ebRIM 3.0]
- ebRS: OASIS/ebXML Registry Services Specifications v3.013 [OASIS ebRS 3.0]
- MTOM: SOAP Message Transmission Optimization Mechanism [W3C MTOM]
- XOP: XML-binary Optimized Packaging [W3C XOP]

4.1.2.3.4 epSOS Order Service

The epSOS Order Service is used to share an identified patient’s ePrescriptions between the patient’s country of affiliation and the country of care. Both countries are represented by their respective NCPs. The implementation of the epSOS Order Service is also based on the IHE Cross-Community Fetch [IHE XCF] profile.

4.1.2.3.5 epSOS Dispensation Service

The epSOS Dispensation Service is used to share an identified patient’s eDispensation data between the patient’s country of affiliation and the country of care. Both countries are represented by their respective NCPs. The implementation of the epSOS Dispensation Service is based on the IHE Cross-Enterprise Reliable Exchange (XDR) profile [IHE ITI TF-1] [IHE ITI TF-2b], which in turn is based on the same standards as XCF: ebRIM, ebRS, MTOM, and XOP.

4.1.2.3.6 epSOS Consent Service

The epSOS Consent Service is used to send an identified patient’s eConsent data from the country of care (Country B) to the patient’s country of affiliation (Country A). Both countries are represented by their respective NCPs. The implementation of the epSOS Consent Service is based on the IHE Cross-Enterprise Reliable Exchange (XDR) and Basic Patient Privacy Consent [IHE ITI TF-3] profiles.

4.1.2.4 IT Infrastructure

epSOS service providers and consumers use the epSOS messaging infrastructure to Exchange request and response messages. The message infrastructure builds upon the epSOS communication infrastructure that interconnects the epSOS network of trusted nodes.

![Figure 33: epSOS Trusted Nodes and Messaging Infrastructure.](image)

The epSOS trusted node infrastructure implements the core epSOS security services that ensure con-
fidentiality of medical data transmission and availability and authenticity of epSOS services:

- virtual private network (VPN) on top of the public internet,
- message encryption (TLS) and integrity protection, and
- mutual NCP authentication.

The epSOS messaging infrastructure provides mechanisms for the implementation of the derived epSOS security services (e.g. non-repudiation and access control) and for the standardized enveloping of data and documents:

- transmission of authenticated HCP attributes,
- common message format, and
- signature of message elements for auditing and brokering of document authenticity claims.

It must be noted that only NCPs acting as epSOS service providers and consumers are part of the epSOS trusted node infrastructure. Points of Care within country B or national data registries/repositories in country A have to be connected to the epSOS trusted nodes by means that respect the epSOS end-to-end privacy, security and data protection requirements. See [epSOS Security Policy] and [epSOS D3.7.2] for details.

### 4.1.2.4.1 Trusted Node Infrastructure

The mutual trust between a service consumer and a service provider is based on a mutually trusted, secure channel between the underlying network nodes. The establishment of mutual trust between nodes is performed by:

- IPSec [RFC 4301]
- Transport Layer Security v1.021 [RFC 2246]
- IHE Audit Trail and Node Authentication [IHE ITI TF-2a]

#### IPSec Configuration

A gateway-to-gateway VPN must be set up between all epSOS nodes. IPSec ESP transport modus must be used. Perfect Forwarding Secrecy must be activated. Security Association (SA) Lifetime should be based on the number of exchanged packets and should not exceed 4GB. Algorithms and key lengths must be used according to [epSOS D3.7.2]. Gateway certificates must comply with the certificate profiles defined in the same document. The issuing Certificate Authorities (CAs) and all components and services for managing the lifecycle of the certificates must comply with the respective epSOS security policies.

#### TLS configuration

All network nodes running epSOS service consumers or service providers must be implemented as IHE Secure Node actors according to the IHE ATNA profile. The establishment of mutual trust and the setup of the secure transport layer channel between two epSOS nodes are always initiated by a service consumer that connects to a service provider. The messages for the establishment of the basic transport layer secure channel correspond to the TLS handshake protocol as profiled in the IHE ATNA Integration profile (transaction ITI-19 as specified in [IHE ITI TF-2a]).
With respect to the ITI-19 transaction specification the following constraints and extensions apply:

- Algorithms and key lengths must be used according to [epSOS D3.7.2].
- The node certificates must comply with the epSOS Node Authentication Certificate Profile also specified in [epSOS D3.7.2]
- The issuing CA and all components and services for managing the lifecycle of the epSOS Node Authentication Certificates must comply with the respective epSOS security policies.

**Time Synchronisation**

Time synchronization within the network of epSOS gateways is performed by using the Network Time Protocol (Version3) [RFC 1305] as described in the IHE Consistent Time Integration Profile [IHE ITI TF-2a]. Stratum 2 time servers (Consistent Time Mediators) should be operated by NCPs. All services that rely on consistent time within the epSOS Circle of Trust must be operated on a node that acts as a stratum 3 time server (Consistent Time Consumer). This in particular holds for services that apply or verify digital signatures on messages, medical data or assertions, and services that contribute to the security audit trail. epSOS time synchronisation for Consistent Time Consumers is handled by respective mechanisms of the underlying operating systems. The messages exchanged correspond to the NTP transactions described in detail in RFC 1305 and http://www.ntp.org/. The underlying network protocol is UDP (port 123). Authentication may be enabled with the ntp authenticate command. Consistent Time servers that represent a Stratum n+1 server should have a configuration with a default polling interval of 4096 seconds at a minimum in order to synchronize the epSOS reference time to all nodes. Following time servers should only configure a polling interval of 65536 seconds. Each Consistent Time Mediator should accept a maximum clock skew of 256 seconds. With respect to lower the system resources (due to incoming requests) of the Consistent Time Source, Consistent Time Mediators should peer themselves.

**Audit Trail**

All epSOS service consumers and service providers must write audit trails for all message Exchange operations, as well as for exceptions encountered. The main objective of the audit trail written at the country of the patient’s affiliation is to protect the patient’s privacy. The main objective of the audit trail written at the country of care is to protect the acting health professional’s reputation and to protect him from false accusations. epSOS only defines the schema for exporting audit trails and by this makes sure that audit data can be assessed for post-mortem security and privacy issues in a uniform manner. The transport of audit trail data to the audit repository is national concern and only governed by the epSOS security concept. Exchange of audit data among countries is a sole organizational issue and not covered by this specification. The epSOS Audit Trail specification builds upon RFC3881: “Security Audit and Access Accountability Message XML Data Definitions for Healthcare Applications” [RFC 3881]. Regarding the concrete use of RFC 3881, epSOS borrows coded values and extension mechanisms from DICOM Supplement 95: Audit Trail Messages [DICOM Sup95], and IHE ATNA: IHE IT Infrastructure Technical Framework – Audit Trail and Node Authentication Profile [IHE ITI TF-2a].

**4.1.3 Concurrent Use of Standards and Specifications (De-facto Standards)**

The paradigm adopted by epSOS and maintained in the subsequent projects was to consider the NCP
as an interface between the European world and the National specificities, at legal, organisational, technical and semantic level. On the European side, the same selected standards were adopted by all the NCPs to establish the cross-border interoperability. On the National side, semi-standardised National Connectors allow for the creation of a seamless interface with the specific National Infrastructures.

### 4.1.3.1 Document formats

The documents exchanged are: Patient Summary, eDispensation, ePrescription, Consent (Privacy Policy Acknowledgement Document). HL7 CDA V2 Level 3, structured and fully coded is coupled with the original document in CDA V2 Level 1 PDF format, for safety reasons.

The data elements included in the exchanged document have been defined by member state clinical experts, approved by the Project Steering Board of the Member States Ministries of Health and subsequently included in the EC Guidelines for Patient Summary and ePrescription / eDispensation.

The process applied follows the HL7 RIM process (see the following picture), from Conceptual Model, to Logical Model to the Implementation Model, supported and thoroughly described in the Implementation Guide.

![Figure 34: epSOS Trusted Nodes and Messaging Infrastructure.](image)

The criteria, described in detail in [epSOS D2.2.7, chapter 5], can be summarized as follows:

- Relevance to the scope
- Information sufficient for clinical decision
- Information systems in use
- Frequency of use
- Severity (Consequences)
- Content evaluation and acceptance
- Reconcilability
• Non-ambiguity
• Clinical acceptability
• Consistency and systematic order

The process to transform a document from Country of Affiliation (Country A) structure and language, to the Country of Treatment (Country B) structure and language is depicted in the Figure 35 below.

![Figure 35: epSOS Semantic Services](image)

The original document is first transformed within the National Connector A, into the “epSOS Friendly” CDA V2 L3 format, which is structured according to the epSOS specification, but still keeps the Country A codes and language.

Within the NCP-A, the transformation services transcode the terms into the epSOS Standard Code Systems and Value Sets, expressed in English, The Master Value Set Catalogue (MVC) and the corresponding Master Translation/Transcoding Catalogue (MTC) contains the Value Sets of the selected code systems and the mapping among the Country A code systems and the epSOS ones.

The obtained “epSOS Pivot CDA” is transferred together with the original PDF through the epSOS document sharing platform.

In Country B, the epSOS Pivot is translated into the Country B language using the translation of the selected Value Sets contained in the MTC. The obtained epSOS Friendly document is transferred to the National Infrastructure B and displayed to the Health Professional by the appropriate portal.

4.1.3.2 Terminologies

In the epSOS project different coding systems have been used. The selection of the Code Systems and the Value Sets associated to each data element was performed by the clinical/semantics experts and approved by Project Steering Board as described in the previous section.

The criteria, described in detail in [epSOS D2.2.7, chapter 5], can be summarized as follows:

• Internationally Used
- In Use
- Existence of translation in Different Languages
- Has a Maintenance Process
- Existence of Transcoding Systems / Services
- Cost of licenses, implementation and maintenance
- The code system must be easily implementable.

The application of those criteria led to the selection of the following code systems:

- **ActCode**: de facto standard in epSOS. General category of medical service provided to the patient during their encounter
- **ATC Code**: Anatomical Therapeutic Chemical
- **LOINC**: the Value Set is used for the observations of Blood Pressure recorded in the section for Vital Signs Observations in the Patient Summary. It codes what type of pressure (diastolic, systolic) is measured. Defines to which category the document belongs to: summary, prescription, or dispensation. The Value Set is used to determine the patient’s delivery date estimation. The Value Set is used for naming the sections used by the three CDA-documents.
- **Confidentiality**: de facto standard in epSOS. Encoding the confidentiality level of the entire CDA
- **ISO 3166-1**: identifies the nationality
- **EDQM**: pharmaceutical dose form, Medicinal product package, Route of Administration
- **EntityNamePartQualifier**: de facto standard in epSOS. Used to define the type of prefixes or suffixes to be added (if any) to the patient’s name
- **SubstanceAdminSubstitution**: de facto standard in epSOS. Indicates if the replacement of a prescribed medication is allowed if it is not available in country where the dispensation is carried out. It is also used to indicate if the patient needs care in a specific healthcare facility
- **epSOS codes (error codes)**: de facto standard in epSOS. Error code messages specific to the epSOS project
- **AdministrativeGender**: de facto standard in epSOS. The gender of a person used for administrative purposes (as opposed to clinical gender)
- **ISCO**: to code the health care professional’s profession (functional code). It is mandatory for each Prescriber (author) in the prescription message and optional for all other Health Care Professionals
- **IHEActCode**: information (immunization, intolerance, instructions) are related to the entry
- **IHERoleCode**: technical codes defined by IHE to represent certain roles that entities play or are scoped by
- **ICD-10**: codes illness, allergies, syndromes or symptoms the patient suffered in the past or is currently suffering. This is mapped to ICD-9
- **ISO 639-1**: identifies the language the document will be written with, as well as the patient’s preferred language
- **NullFlavor**: de facto standard in epSOS
- **RoleCode**: de facto standard in epSOS. Code the type of contact relationship between a person and the patient
- **RoleClass**: de facto standard in epSOS. Make the distinction between an emergency contact
and the next of kin for a patient

- **AddressUse**
- **TimingEvent**: de facto standard in epSOS. Encode the frequency of intake of medications in the Medication Summary as well as the Prescription
- **UCUM Unified Code for Units of Measure**: used to provide values with an international unit codification to quantify it
- **URLScheme**: de facto standard in epSOS. To make the distinction between telephone numbers and e-mails in contact information for all roles involved. Also for coding any other forms of communication
- **ObservationInterpretation**: de facto standard in epSOS. Classify the result of an observation or a measurement
- **ActSite**
- **epSOS Display Labels**: de facto standard in epSOS, identifying the labels and messages used for the epSOS CDA display
- **SNOMED-CT**:
  - code the patient’s kind of adverse reactions against substance, food or drugs
  - code the allergenic agents (apart from drugs) against which the patient has developed an adverse reaction
  - code the value of patient’s blood group + Rh
  - indicate, when a patient has no medication, if it is because the treatment is unknown, or if no medication was prescribed, or if the patient doesn’t take medication on his own (self-medication)
  - optional description of a problem in the patient Summary. It gives an information on the circumstances under which the problem was defined/discovered
  - describing the patient’s medical devices and implants in the Patient Summary
  - encode procedures in the section “Surgical Procedures prior past six months” in the patient Summary
  - code the clinical manifestations of allergy developed by patient in the "Allergies and Other Adverse Reactions" section of the patient Summary (along with epSOS ActiveIngredient)
  - describe the clinical status of a problem outcome
  - used for all Problems and Allergies in the Patient Summary to indicate the severity of the problem (or Allergy)
  - code the different elements of the patient’s social history
  - encode the clinical status of both problems and concerns within the Patient Summary document
  - used when information about a problem or allergy is unknown or where there are no problems or allergies. This element is actually used to confirm explicitly the absence of information
  - identify the patient's vaccinations in the Patient Summary
  - identify the medical equipment used in various observations or procedures.

### 4.1.4 Governance

The governance process evolved from the epSOS Process, in which the specific work packages made
research activities and proposals, technically harmonised among the work packages by the Technical Management Board (TMB) and submitted to the epSOS Project Steering Board (PSB, composed by the representatives of the Ministries of Health of the 26 involved Member States), to the second phase in which PSB proposals were submitted for adoption to the EC DG Santé eHealth Network (eHN), the permanent board created by the Member States to implement Article 14 of EC Dir. 2011/24 on patients right on cross border health services), which, for example, adopted the EC Guidelines for Patient Summary and ePrescription / eDispensation.

The adoption process by eHN sometimes introduces indications on developments expected by eHN, e.g. the adoption of ISO Identification of Medicinal Product (ISO IDMP) for the ePrescription / eDispensation and Medication Summary of the Patient Summary, in line with the roadmap under definition among the European Medication Agency (EMA) and the National Agencies.

In EXPAND, the same process was adopted, with the creation of the already described Maintenance Shops.

The Joint Action to Support eHealth Network (JAseHN) project started in 2015 and now has the role of assessing the contributions, the processes and the procedures to be submitted to eHN for approval. Correspondences among the EC project outcomes (in 2015 it was mainly EXPAND) were identified and applied.

In December 2015, the EC “Connecting Europe Facility” (CEF) Call for eHealth services has been published. Connected to that, the Governance Process to maintain the CEF Core Services and provide reference solutions to the Country Specific Generic Services was proposed by EC DG Santé and approved by the eHealth Network [eHDSI]. The following high level picture provides a view on such Governance Process.

**Figure 36: Governance of the eHealth Digital Service Infrastructure Proposal [eHDSI]**

### 4.1.5 Lessons learned

It is hard to summarize in a few lines the lessons learned within epSOS and the subsequent projects. It is recommended to refer to [epSOS D2.2.7] for a complete analysis of lessons learned, encountered issues and proposed recommendation to Governance Structures, Standardization Bodies, Member
States and Vendors. In the following sections we try to summarize some of the key elements.

4.1.5.1 Successes
When epSOS started in 2008, the level of readiness of Member States was not sufficient to assure a full deployment of eHealth cross-border services. However the political willingness of the Member States to come to the practical adoption the EC Directive 2011/24 on cross-border health services was the real engine to move eHealth in Europe. The pillars of this process were:

- Provide services base on standards, in a seamless way
- avoid safety and security risks for patients
- avoid interfering (as much as possible) with national clinical / organisational and legal process.

These pillars brought to define the National Contact Point for eHealth as an element to decouple National and European realities. The decision of specifying the European interface based on standards has brought the possibility of defining standardized validation processes, based on the IHE Connect-a-thon procedures. The decision taken twice by the epSOS Project Steering Board to go toward the “NCP-in-a-Box” common implementation and the following decision to jointly develop the “OpenNCP”, and create the OpenNCP Community, allowed for a quick ramp-up of most of the participating Member States, including the ones who entered only in epSOS phase 2. The OpenNCP platform is now available through the EC Join-Up portal14.

The same process has recently enabled the EXPAND project to include new components and services originated in other EC projects, like Trillium Bridge and e-SENS/Stork, into the main OpenNCP implementation and release process.

4.1.5.2 Pitfalls and Remedies
A problem known in epSOS was the sustainability / survivability of the assets. In terms of making them evolve and keeping alive the centralized services (Central Configuration Services, Terminology Services, OpenNCP Community, and code system licenses). The coexistence of Open Source under Apache ASL V2 License and GNU GSL V3 license presented a potential limitation for vendors to freely enter into the market.

Some of the epSOS recommendations in that direction were taken over by the EXPAND project. Others, more politically strategic, were endorsed by the eHealth Network, also through the Joint Action to support eHN and, more recently, by the CEF eHDSI Governance.

Some encountered issues (trust enforcement, central service refactoring, eldentitycation) were addressed in e-SENS, by adopting building blocks adapted from other business domains and integrated into the main implementation stream in EXPAND. Other issues lead to the creation of four H2020 projects, under PHC-34 eHealth topic, eStandards, openMedicine, ASSESS-CT and VALUeHEALTH, as described in section 4.1.1.

4.1.6 Resources

<table>
<thead>
<tr>
<th>Resource</th>
<th>Description</th>
<th>Availability</th>
<th>Link</th>
</tr>
</thead>
<tbody>
<tr>
<td>epSOS</td>
<td>eSOS specifications and Deliverable</td>
<td>Freely available</td>
<td><a href="http://www.epsos.eu/home/download-area/deliverables.html">http://www.epsos.eu/home/download-area/deliverables.html</a></td>
</tr>
<tr>
<td>OpenNCP</td>
<td>OpenNCP platform and Community</td>
<td>open source (ASL V2 / GPL V3)</td>
<td><a href="https://openncp.atlassian.net/wiki/display/ncp/OpenNCP+Community+Home">https://openncp.atlassian.net/wiki/display/ncp/OpenNCP+Community+Home</a></td>
</tr>
<tr>
<td>EXPAND</td>
<td>EXPAND consolidated assets and deliverable</td>
<td>Freely available</td>
<td><a href="http://www.expandproject.eu">http://www.expandproject.eu</a></td>
</tr>
</tbody>
</table>

4.1.7 References and Further Information


4.2 Case Study #08: Nation-wide EHR System in Romania

- Author of case study within the eStandards project: Dan Oprea <dan.oprea@uti.eu.com> and Nicolae Goga <n.goga@rug.nl>
- Project name: Electronic Healthcare Record System (EHR)
- Project type: Large-scale deployment for sustained routine use
- Project status (in 10/2015): Completed
- Countries / Regions: deployments primarily in the United States
- Project partners: UTI GRUP – integrator / IBM, Oracle and Cisco – technology providers
- Scale of deployment: Nationwide in Romania

4.2.1 Project Overview

An Electronic Health Record represents a medical data collection about the patient, consolidated nationally, gathered from all the providers of medical services with whom the patient came into contact. Benefits of such a national EHR system are:

- **Gathers, administers and organizes** medical data from health service providers.
- **Allows for safe and protected access** to medical information from any location, via an Internet connection.
- Provides **private and secured access** to medical data registered in the system.
- **Facilitates** tracking the health evolution and ensures continuity of the medical process.
- Provides **transparency** of medical acts.
- **Significantly reduces** the access time to medical information necessary in emergency situations.
- **Increases** the promptness and efficiency of the health services received.

The Romanian EHR is interconnected with the platforms of the IT systems within the National Health Insurance House (NHIH/CNAS), implemented within the same financing line:

- **SIPE** – Electronic prescription that refers directly to the method of settlement and management of prescriptions
- **CEAS** – National Health Card providing a unique identification of the insured persons
- **SIUI** – Integrated IT system provides uniform reporting system and data processing of health at national and county level

As compared to the abovementioned platforms, which are focused on the settlement/management of judicious fund use, the EHR system targets both the patient and the physician, being an essential tool in improving the quality of the health services. The Romanian EHR is the first national health system of EHR (Electronic Health Records) and PHR (Patient Health Records) type developed on the basis of the HL7 standard. From this point of view, EHR is a premiere in the Balkan area.

4.2.2 Approach

An EHR (Electronic Health Records) system is an evolving concept defined as a systematic collection of medical information about individual patients or populations. It is a record in digital format that is theoretically capable of being shared between different institutions that offer medical services. An EHR system manages a set of data including demographics, medical history, medication and allergies, immunization history, the results of laboratory investigations, radiological imaging, vital signs and
personal data such as age or weight or reimbursement information services. EHR systems require communication with health care providers’ protocols, and standard vocabularies known. The following standards were chosen for the Romanian EHR:

- HL7 V3 CDA revision 2.0
- LOINC
- ICD-10
- CIM10 (the national equivalent to ICD-10 in Romania)
- SNOMED
- ATC: Medicines, active substances, pharmaceutical concentrations

The EHR system uses an encrypted data communication channel between the EHR system and external systems like the National Health Insurance House (CNAS). Data encryption is performed on several levels: database, storage equipment, archiving equipment. Authorization mechanisms are implemented on all levels of the system.

### 4.2.2.1 Care Process

#### 4.2.2.1.1 Actors

The actors are the types of users who interact with the system. Actors can be human users or other external systems.

<table>
<thead>
<tr>
<th>Crt. Nr.</th>
<th>Actor Name</th>
<th>Description interaction with the system (actual use)</th>
</tr>
</thead>
</table>
| 1.      | Administrator         | Central EHR User Module, which has access to:  
  - Internal User Administration  
  - External Users Administration (doctors)  
  - Internal Users Administration Roles  
  - Parameters Administration  
  - View log OCSP (on line certificate status protocol)  
  - View security log |
| 2.      | Analyst               | Central EHR User Module, which has access to:  
  - View reports |
| 3.      | Primary care GP application | A type of medical service providers’ application used only by family physicians (primary care). |
| 4.      | Application healthcare providers | External System, which interacts with the EHR Central System in the following cases:  
  - Query and receipt of relevant medical data (DMR)  
  - Query and receive electronic medical documents  
  - Authentication  
  - Initialization file from applications providers  
  - Get DMR data from the EHR for GP  
  - DMR data transmission for GP  
  - Medical document correction for GP |
| 5.      | Auditor               | Central EHR User Module, which has access to:  
  - View log of DMR transmission by WS (web service)  
  - View log data DMR request by WS  
  - Loading chronic disease registry data  
  - Managing files |
<p>| | | |</p>
<table>
<thead>
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<th></th>
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</thead>
</table>
| 6.  | CEAS (National Healthcare Card) | External system, which interacts with the central system (EHR) in the following case of use:  
- Login patient in portal  
- Checking existing card |
| 7.  | Doctor (physician) | User that interacts with EHR system for:  
- Login physician in portal  
- Registration patients as users with security matrix  
- Setup patient folder in EHR portal  
- Completion information in the portal as a result of hospitalization  
- Completion information in the portal as a result of discharge  
- Completion information in the portal after day visit  
- Completion information in the portal as a result of consultation  
- Completion information in the portal regarding doctor’s letter and recommendations  
- Management of Own medical records  
- The consultation summary and information for emergency  
- View the file in front of patient or patient contact |
| 8.  | Family physician (GP) | It is a specialization of the physician, interacts specifically with EHR for:  
- Consultation of patient file registered on GP’s list |
| 9.  | Consultant (specialist physician) | It is a specialization of the physician, interacts specifically with EHR for:  
- View chronically under care (sick dependent) patient’s file |
| 10.  | Patient or patient contact | Patient or patient contact interact with EHR for:  
- Login patient in portal  
- Patient Management User Account Type  
- Access rights  
- View log visits  
- Consultation electronic health records within the EHR’s portal |
| 11.  | Registry chronic disease | External system, which interacts with the central system EHR in the following case of use:  
- Transmission data register of chronic diseases |
| 12.  | Maternity Information System | It is a specialization of "Application healthcare providers (medical services)" that interact specifically with HER for:  
- New born file initialization |
| 13.  | Hospital Information System (HIS) | It is a specialization of "Application healthcare providers (medical services)" that interact specifically with EHR for:  
- Transmission – admission of patient record  
- Transmission – release of patient record  
- Data transmission visit  
- Transmission – day care patient record  
- Transmission – data doctor’s letter and recommendations |
| 14.  | SIPE (electronic prescription) | External System, which interacts with the Central System (EHR) in the next case of use:  
- Get DMR from SIPE for initialization  
- Get DMR from SIPE |
| 15.  | SIUI (unique integrated IT system) | External System, which interacts with the Central System (EHR) in the following cases of use:  
- Get DMR from SIUI for initialization  
- Sync of classifications (lists)  
- Sync of users CJAS/CNAS(County Health Insurance House/National Health Insurance House) |
### 4.2.2.1.2 Use cases

Use cases show how the EHR system’s users will use it to perform the tasks for which it was created. A use case shows how an actor uses a system to meet an objective that has value to him. The most important elements of a use case are:

- **Usual Flow**: describes the usual interaction (most common) between actor and system to achieve the objective
- **Alternative Flow**: describe what others interactions may exist between the user and the system to achieve the same objective
- **Exceptions**: describe how the system reacts at exceptional situations
- **Scenarios**: Shows actual use of the system by chaining flows to achieve the objective or the failure to achieve goal
- **Special requirements**: are requirements that apply to use case but are not included in the description flows not to lose their coherence.

Use case relations:

- **Initiates** (represented by arrow) – indicates the actor who initiates the use case. A use case may be initiated by a single actor
- **Includes**: relationship indicating that a use case includes another case entirely. Every time when is executed a use case is executed included case too.
- **Expand**: indicates that in certain situations the user case is extended by another use case. It runs only when the conditions are accomplished.
- **Generalization**: indicates a relationship of generalization / customization of an application or an actor

Use cases are briefly described below.
Figure 37: Authentication Package (in portal)

Figure 38: Management accounts patient Package
Figure 39: File Management Package
Figure 40: Data transmission from EHR and Hospitals Package
Figure 41: Consultation data from EHR in portal and in medical information system Package
Figure 42: EHR System Management Package
4.2.2.2 Information
The objective of this section is to specify requirements for relevant medical data in the EHR system.
By „relevant medical data” we understand organizing patient data collected in the EHR system on the basis of medical relevance so that it can be used most effectively within the health system.

In this respect, organization based on medical relevance will bring to the forefront summary data, which the doctor must see immediately. From this most relevant summary, the doctor will be able to access data from increasingly detailed, reaching to actually consult electronically form of the medical document underlying these data.

The information transmitted within EHR system are organized in two ways due to different objectives to be fulfilled:

- Objective 1 supply data – refers to the receipt of data in EHR from other information systems or to the introduction of this data by doctors in EHR portal
- Objective 2 – exploitation, use of such data by physicians in diagnosing specific activity.

To achieve the first objective, data is organized so as to be optimally transmitted and received. Thus, referrals to the EHR are related to events which involving, in general, a complete interaction between the patient and doctor – such as consultation completed, a discharge etc. Following these completed interactions result a series of documents, usually on paper. For these reasons, an electronic form of receiving data in EHR link it to the concept of "medical electronic Document".

The structure of the electronic medical document shall be based on the documents that are currently used in hard copy form. For example, the electronic document "Continues Hospitalization Sheet – Medical Letter to Discharge" will contain information from the "Observation sheet" and "Ticket out of the hospital" forms.

To achieve the second objective, however, it requires that doctor access information received by EHR system in an organized form on the principle of medical relevance and linked to the patient treated. The organized information in this form is called "relevant medical data", for short: DMR.

DMR organization facilitates a synthetic presentation of the information stored in the EHR: on top of the pyramid is the most relevant information but with less detail. From this information the doctors will be able to access increasingly detailed info for the sections they are more interested in. The maximum level of detail is offered by the electronic documents underlying this pyramid.

Thus, consolidation means the technical mechanism by which information received in the EHR system like medical electronic documents (the pyramid’s base) are rearranged into different structures based on the principle of medical relevance.
4.2.2.2.1 Electronic Medical Documents

Documents taken within the EHR from other systems or introduced by users are described in the document: "Specifications electronic document templates". Electronic documents will be referenced in the present document, using the following code:

Table 5 – Document Codes (see [http://ehr.certificare.des-cnas.ro/validator/](http://ehr.certificare.des-cnas.ro/validator/) for details)

<table>
<thead>
<tr>
<th>Document Code</th>
<th>Document Title</th>
</tr>
</thead>
<tbody>
<tr>
<td>OtherSectionCodes</td>
<td>ClinicalReferralDocument</td>
</tr>
<tr>
<td>LOINC</td>
<td>ConsultationDocument</td>
</tr>
<tr>
<td>OtherSectionCodes</td>
<td>HomeCareReferralDocument</td>
</tr>
<tr>
<td>LOINC</td>
<td>HospitalAdmissionDocument</td>
</tr>
<tr>
<td>OtherSectionCodes</td>
<td>InpatientDischargeDocument</td>
</tr>
<tr>
<td>OtherSectionCodes</td>
<td>LaboratoryReferralDocument</td>
</tr>
<tr>
<td>OtherSectionCodes</td>
<td>MedicalDevicesReferralDocument</td>
</tr>
<tr>
<td>LOINC</td>
<td>MedicationPrescriptionDocument</td>
</tr>
<tr>
<td>OtherSectionCodes</td>
<td>OutpatientDischargeDocument</td>
</tr>
<tr>
<td>LOINC</td>
<td>PrimaryCareConsultationDocument</td>
</tr>
</tbody>
</table>

4.2.2.2 Relevant medical data

4.2.2.2.1 EHR Summary – Emergency Summary

Summary of EHR are those medical data with the highest relevance. They will be displayed with priority over other data. The information in EHR summary can also be found in other sections. In the EHR’s summary will show data for the users about:
Patient identification data

Warnings

Patient notes

Emergency Information

All physicians regardless of previously set viewing rights by the patient will have access to the data summary.

4.2.2.2.2 Patient identification data

Patient identification data come both from the SIUI system and the "patient identification information" section within electronic documents received in EHR. In the DMR will gather SIUI data if they are available even if the data are received in electronic documents as well.

4.2.2.2.3 Case history

Section "Case History" will gather the medical information collected from the patient in the anamnesis process. Each set of information received in EHR regarding history enrich already existing information in the sense that they are added. Where is possible, the system can decide whether or not to add new information. For instance in respect to the age of death of the mother / father the system will ignore new information if they are identical.

- Heredo-colateral Data (genetic / relatives data)
- Physiological personal history
- Pathological personal history
- Lifestyle

4.2.2.2.4 Medical history

Section "Medical History" will gather medical data — associated with the patient by the physician in medical acts, throughout the existence of the health file.

- History diseases / Diagnostics
- Interventions and procedures performed
- Clinical and paraclinical services
- Immunizations
- Chronic diseases
- Allergies
- Treatments in the clinical studies

4.2.2.2.5 Medical Events history

The history of medical events is gathered based on electronic medical documents received in the EHR system. For each medical event, from DMR can be accessed and viewed data from electronic medical document received on that occasion and the other documents associated with that event.

- Consultation history from GP
- Consultation history by specialties
- Admissions history
- Prescriptions history
- Doctor’s letter history
4.2.2.3 Applications

4.2.2.3.1 The interaction of EHR system with PIAS (informatics platform of health insurance) system

The EHR system will communicate with existing PIAS systems (SIUI, SIPE, CEAS) via Web services. The following technologies are used to achieve and expose Web services, inherent requirements for SOA architecture (service oriented architecture):

- W3C recommendations regarding SOAP – 1.2 version;
- W3C specifications regarding XML;
- W3C specifications and recommendations and XML Security Working Group related XML Encryption and XML Signature;
- W3C specifications and recommendations regarding WSDL (Web Services Description Language) and WSDL extensibility with the aid of SOAP.
- UDDI (Universal Description, Discovery and Integration).

In the existing systems, SIUI, SIPE and CEAS, there will be one user for the EHR system. This user will be used by the EHR for authentication and authorization in these three existing systems. Communication between the systems will be achieved through the HTTPS protocol.

4.2.2.3.2 The interaction of EHR system with Medical Services Providers System

The applications send medical data of patients as medical records (Electronic Medical Documents – see above) at the time of admission, discharge, consultation and prescription.

Furthermore the applications extract relevant medical data about a patient from the EHR system. Extracted data are described in section 4.2.2.2.2. Both transmission of data and query of data are made by calling the exposed web services of the EHR system. The form of this data are exchanged is HL7 CDA Release 2.

4.2.2.4 IT Infrastructure

Technological challenge – high complexity: the technical solution involved the implementation of more than 20 complex software products, over 125 virtual servers. In the data storage area, a 0.5 Petabyte solution was installed, using complex technologies such as storage virtualization, replication, and tiering.

4.2.3 Concurrent Use of Standards and Specifications (De-facto Standards)

The EHR integrates at HL7 level with the other hospital applications, family physicians, CEAS, SIPE, SIUI. All classifications (medicines, doctors, etc./ ICD 10, SNOMED) are kept and updated in SIUI system. From here they are taken into the EHR. The EHR central system will communicate with the SIUI system for obtaining relevant medical data to initialize the patient file.

Vocabularies used are of the following types: vocabularies specific to the EHR, vocabularies specific to the SIUI, and international mapped vocabularies. The table below lists the vocabularies used and their origin.
### Table 6 – Vocabularies used in the Nation-wide EHR system in Romania

<table>
<thead>
<tr>
<th>Name</th>
<th>Description</th>
<th>Origin – OID</th>
</tr>
</thead>
<tbody>
<tr>
<td>ActiveSubstances</td>
<td>Active substances used for medical prescription</td>
<td>SIUI – 2.16.840.1.113883.3.3368.6.11</td>
</tr>
<tr>
<td>AdmissionTypes</td>
<td>Hospitalization Cases</td>
<td>EHR via DRG (Diagnostic Related Groups – Romanian Standard). Diagnosis related groups (DRGs) are a way to categorize and characterize episodes care received by patients admitted to hospitals. - 2.16.840.1.113883.3.3368.6.20</td>
</tr>
<tr>
<td>ClinicalServices</td>
<td>Types of medical services</td>
<td>SIUI - 2.16.840.1.113883.3.3368.6.7</td>
</tr>
<tr>
<td>CIM10 (ICD10)</td>
<td>Accident cases</td>
<td>International Statistical Classification of Diseases and Related Health Problems, Australian modifications (ICD10) – CIM10 SIUI – 2.16.840.1.113883.3.3368.6.18.1</td>
</tr>
<tr>
<td>Cities</td>
<td>Romanian cities</td>
<td>SIUI – 2.16.840.1.113883.3.3368.6.4</td>
</tr>
<tr>
<td>ClinicalServicesMF</td>
<td>GP – Vaccine testing, examination children, pregnant women</td>
<td>SIUI – 2.16.840.1.113883.3.3368.6.43</td>
</tr>
<tr>
<td>ConfidentialityCode</td>
<td>Types of access code – Privacy Level</td>
<td>HL7 – 2.16.840.1.113883.3.3368.6.44.1</td>
</tr>
<tr>
<td>Concentrations</td>
<td>Concentrations of substances in drugs</td>
<td>SIUI – 2.16.840.1.113883.3.3368.6.13</td>
</tr>
<tr>
<td>Diag999</td>
<td>999 types of diagnoses</td>
<td>SIUI – 2.16.840.1.113883.3.3368.6.1</td>
</tr>
<tr>
<td>DischargeStatus</td>
<td>Status of discharges</td>
<td>EHR – 2.16.840.1.113883.3.3368.6.16</td>
</tr>
<tr>
<td>DischargeType</td>
<td>Type of discharges</td>
<td>EHR – 2.16.840.1.113883.3.3368.6.19</td>
</tr>
<tr>
<td>Districts</td>
<td>Counties catalog</td>
<td>SIUI – 2.16.840.1.113883.3.3368.6.3</td>
</tr>
<tr>
<td>Drugs</td>
<td>Types of drugs</td>
<td>SIUI – 2.16.840.1.113883.3.3368.6.5</td>
</tr>
<tr>
<td>FamilyMemberRelationType</td>
<td>Relative’s members</td>
<td>HL7 – 2.16.840.1.113883.3.3368.6.25</td>
</tr>
<tr>
<td>HomeCareServices</td>
<td>Types of services for homecare</td>
<td>SIUI – 2.16.840.1.113883.3.3368.6.45</td>
</tr>
<tr>
<td>HospitalServices</td>
<td>Types of services made in Hospital</td>
<td>SIUI – 2.16.840.1.113883.3.3368.6.42</td>
</tr>
<tr>
<td>LaboratoryServices</td>
<td>Types of paraclinically services</td>
<td>SIUI – 2.16.840.1.113883.3.3368.6.8</td>
</tr>
<tr>
<td>LocationType</td>
<td>Location type for consultation (Home/Surgery)</td>
<td>EHR – 2.16.840.1.113883.3.3368.6.21</td>
</tr>
<tr>
<td>MedicalDeviceLaterality</td>
<td>Left/Right</td>
<td>SIUI – 2.16.840.1.113883.3.3368.6.14</td>
</tr>
<tr>
<td>MedicalDevices</td>
<td>Orthotics/Prosthetics</td>
<td>SIUI – 2.16.840.1.113883.3.3368.6.2</td>
</tr>
<tr>
<td>MedicalProcedureTypes</td>
<td>Surgical procedures or other types</td>
<td>EHR – 2.16.840.1.113883.3.3368.6.41</td>
</tr>
<tr>
<td>MedicalProcedures</td>
<td>All Types of surgical procedures</td>
<td>SIUI – 2.16.840.1.113883.3.3368.6.17</td>
</tr>
<tr>
<td>Nation Health Programmes</td>
<td>Types of programs run by the Ministry of Health</td>
<td>SIUI – 2.16.840.1.113883.3.3368.6.6</td>
</tr>
<tr>
<td>OtherSectionCodes</td>
<td>EHR own codes – LOINC extension</td>
<td>EHR – 2.16.840.1.113883.3.3368.6.26</td>
</tr>
<tr>
<td>PharmaceuticalForms</td>
<td>Types of medication forms (spray, solution, powder ond so on.)</td>
<td>SIUI – 2.16.840.1.113883.3.3368.6.12</td>
</tr>
<tr>
<td>PrescriptionTypes</td>
<td>Electronic Prescription</td>
<td>SIUI – 2.16.840.1.113883.3.3368.6.10</td>
</tr>
<tr>
<td>ProsthesisTypes</td>
<td>Type: Temporary / Final</td>
<td>EHR – 2.16.840.1.113883.3.3368.6.15</td>
</tr>
</tbody>
</table>

### 4.2.4 Governance

There is still a project team assigned by the beneficiary (CNAS), this team will be allocated throughout the life of the project because they administer the system. Also there is a project team from the supplier, for 5 years. If legislative changes occur that may involve vocabularies / standards
as well, the two teams determine the changes that will be made in the EHR System. Organization teams:

- Beneficiary: Project manager, medical consultants and technical consultants (IT, legal etc.)
- Provider: Project manager, business analysts

4.2.5 Lessons learned

The EHR system is a scalable solution, built on standards existent in the IT and medical field, allowing for an easy, continuous, extensive and qualitative development, using a convergent and integrated approach through:

- Addition of new actors and features, such as:
  - Integration of IT systems for clinical/visual diagnosis, specific to laboratories, for clinical and imagery results
  - Integration of IT systems from other Health Service Providers (dental, medical devices and ambulances, dialysis centers, rehabilitation, home care, etc.)
- Adjustment for real time use on mobile devices, tablets and smartphones, providing the same high level of security.
- Integration with similar European IT systems (based on the HL7 standard)
- Development of new complex reporting capabilities and features and Big Data Analytics that will contribute to the continuous improvement of health policies at national level.

4.2.5.1 Successes

The Romanian EHR is the first national health system of EHR (Electronic Health Records) and PHR (Patient Health Records) type developed on the HL7 standard (an interoperability standard in the IT medical field). From this point of view, EHR is a premiere in the Balkan area. UTI GRUP has become member of the HL7 association in Romania and one of the promoters of this standard.

EHR is the first health system dedicated both to the patient and the physician. Personal and medical data can be viewed only by the patient. Full health information can be viewed by the physician only with the patient’s permission.

Using CDA allowed the project to register their own vocabularies for EHR and SIUI at the HL7 OID REGISTRY, and their effective use along with international standardized vocabularies (ICD10, SNOMED).

4.2.5.2 Pitfalls and Remedies

It is difficult to find equivalent terms in vocabularies used (LOINC, ICD 10, SNOMED). Even when they are found, meanings can be slightly different from local ones. The fact that we could not easily identify terms has necessitated the creation of specific Romanian EHR vocabularies, without being sure that those terms not already exist. For instance,

- ClinicalReferralDocument – we have not found an equivalent in LOINC. It is possible that an equivalent exists and we could not identify it, or it doesn’t exist.
- ConsultationDocument – LOINC 11488-4 = consult note. An analysis has been performed to see if the term acceptably reflects the Romanian “sheet of consultation”. The identification process is difficult.
• HomeCareReferralDocument – we have not found an equivalent in LOINC. It is possible that an equivalent exists and we could not identify it, or it doesn’t exist.
• HospitalAdmissionDocument – LOINC 67852-4= Hospital Admission Evaluation Note. An analysis has been performed to see if the term acceptably reflects the Romanian “sheet of consultation”. The identification process is difficult.

4.2.6 Resources

<table>
<thead>
<tr>
<th>[EHRPortal]</th>
<th>Romanian EHR Portal</th>
</tr>
</thead>
<tbody>
<tr>
<td>Description:</td>
<td>Various resources for the Romanian EHR System: An HL7 Implementation Guide for the Romanian EHR, the Romanian specific vocabulary for EHR, examples (CDA documents exchanged with other systems), and an online validator for CDA documents exchanged with other systems.</td>
</tr>
<tr>
<td>Availability:</td>
<td>Freely available</td>
</tr>
<tr>
<td>Link:</td>
<td><a href="http://ehr.certificare.des-cnas.ro/validator/">http://ehr.certificare.des-cnas.ro/validator/</a></td>
</tr>
</tbody>
</table>

4.2.7 References and Further Information


4.3 Case Study #09: National eHealth network in Denmark

- Author of case study within the eStandards project: Morten Bruun-Rasmussen <mbr@mediq.dk>
- Project name: National eHealth network in Denmark
- Project type: Large-scale deployment for sustained routine use
- Project status (in 10/2015): Deployed for sustained routine use
- Countries / Regions: Denmark
- Project partners: Ministry of Finance, Ministry of Health, Regions, Municipalities, Hospitals, GPs, Health specialist, Vendor of eHealth systems, Consultants
- Scale of deployment: National, cross-sector

4.3.1 Project Overview

The vision for the health care system in Denmark is to provide coherent clinical pathways through the various parts of the health care system, focusing on the needs of patients and the provision of high quality treatment. One of the main prerequisites for a coherent integrated health care system is to ensure that all health care professionals have easy access to relevant patient information where and when it is needed.

Since 1995, IT strategies have been an important instrument in Denmark to agree about which systems and services were going to be developed and implemented on a large scale, on a national basis. Below is a list with years and titles of the strategies:

- 1995-1999: IT political action plan
- 2000-2002: IT for the hospitals
- 2003-2007: IT for the health services
- 2008-2012: Digitizing the health sector
- 2013-2017: Digitize with effect

The use of those strategies has been important for the rather satisfactory results achieved for citizens, patients, and professionals in Denmark.

Because of the specialisation and division of labour, there is a need for extensive communication between the participants involved in the health care sector, i.e. communication of everyday routine messages such as prescriptions, referrals, discharge letters and laboratory results. The communication, sharing, and access to data has been a general topic in all the strategies.

Today, eHealth is very commonly used throughout the whole Danish health care system and supports many work processes, including processes that reach across organisations and sectors, which is also a major result of the national strategies. The IT landscape (October 2015) is shown below:
4.3.2 Approach

It is important to mention that, as the development has been use-case driven, there have not been a lot of efforts as regards the coordination and selection of the standards used. The development and use of national standards is a history of approximately 20 years of work. Throughout this time, the technology has changed and the solutions can be grouped into the following three technologies:

- Messaging
- Repositories
- Indexing

Each of the technologies and the standards used are described below.

4.3.2.1 Messaging

Messaging is peer to peer communication which includes a sender and a receiver. In some cases a copy can be sent to additional receivers.

MedCom ([www.medcom.dk](http://www.medcom.dk)) was established in 1994 with the purpose of developing nationwide communication standards for the most common messages between public hospitals and general practitioners as well as private companies linked to the health care sector, e.g. pharmacies.

The messages cover the most frequent clinical messages in the Danish health care system, e.g. discharge letters, referrals, lab test orders, e-prescriptions and reimbursement from public health insurance. In the past years, focus has been placed on new messages between hospitals and nursing homes in municipalities, including discharge letters and nursing homes plans. In 2015, more than 6 million messages were sent every month.
The primary users of messaging are hospitals, municipalities, specialists, general practitioners. The messages are also used for internal communication within the hospitals.

The messages are based on EU EDIFACT standards. For each message, MedCom has developed a Danish profile, which only includes the core and needed content for the implementation. All the profiles are also found in an XML-version and it is up to the vendor to use the EDIFACT or XML-version. Today, more than 100 profiles are used and new profiles are still developed. The timeframe for a new profile, including implementation in the vendor and end-user system can be as low as 6 month.

MedCom is doing testing and certification of all vendor systems. The result of the test and certification is published at MedCom’s web-page for each profile and vendor system. This information has been very useful for the adoption of the standards as all end-users can easily follow what systems have implemented the national agreed standards. To support the vendor implementation of the profiles, MedCom organises annual test-camps, where the vendor can get advice, talk to colleagues and get its systems tested.

### 4.3.2.2 Repositories

Repositories are national databases, which can be physically placed and maintained by a health care organisation, e.g. a hospital. A quite large number of repositories (>100) are clinical databases, which are used for monitoring and improving the quality of care for selected diseases (cancer, cardiovascular, diabetes etc.).

Some repositories are an improvement and add-on to the messaging communication, where the messaging data are stored in a central database and can be accessed by all health care organisations and the patients. For example, all laboratory results are communicated to the ordering system as a message and a copy of the result is stored in a central database. The advantage is that all other health care professionals and the patients can access all the laboratory results, which have been per-
Figure 48: A copy of all laboratory messages is stored in a national repository

The shared medication card is another example of national repository. The shared medication card holds the current active medication for all patients. It is mandatory (by law) that all systems have integration to the shared medication card and that all health care professionals update the information.

A last group of repositories is called “Hotels” for example Hotels for ePrescriptions and eReferrals. The first generation of ePrescription was implemented as messages, where the patients had to choose the pharmacy where the drug was to be delivered. The ePrescription Hotel makes it possible for the patients to travel around in the whole country and select a pharmacy on his route and buy the prescribed drug. Based on the patient’s personal identification number, the pharmacy can retrieve information on all the patient’s prescriptions and handout the drug to the patient.

The eReferrals are useful as the patient is able to freely choose the location for the treatment. The patient’s GP can store the referral in the national referral Hotel and the patient can then select a Hospital based on the distance and published quality of the treatment offered.

The typical main users of the repositories are the health professionals. Some repositories (lab-results, shared medication card) can also be viewed by the patients via the public health portal (www.sundhed.dk).

The exchange of data with the repositories is based on proprietary formats. Repositories which are add-on to messaging are based on messaging standards extended to access via web-services. The test and certification of systems is only mandatory for few of the national repositories.

4.3.2.3 Indexing

Indexing is a technology where data are stored by the owner and a central index (pointers to data) is maintained and can be used to search for specific information by using filters to focus and limit the data to be retrieved. Indexing is under development in Denmark for the exchange of radiology imag-
es and for the establishment of a national infrastructure for Telemedicine services.

The indexing standard is based on IHE XDS and the content information to be used for the Telemedicine infrastructure is HL7 CDA. Until now 3 Danish CDA profiles have been developed (in English):

- Personal Health Monitoring Record (DK CDA PHMR)
- Questionnaire Form Definition Document (DK CDA QFDD)
- Questionnaire Response Document (DK CDA QRD)

The infrastructure and the CDA profiles have been validated in 2014-2015. A new project to mature the use is planned.

4.3.3 Concurrent Use of Standards and Specifications (De-facto Standards)

As described above the implementation has been use case oriented and includes only one standard (e. g. exchange of discharge letters, lab-results). However, an exception is the use-case for Home-monitoring, which are based on Continua Health Alliance and involves several content and infrastructure standards (XDS, HL7 v2 and HL7 CDA).

The National Board of Health maintain a national coding system Sundhedsvæsenets Klassifikations System (SKS = Health Care Classification System). SKS is based on ICD10 and includes diagnosis and procedures which are used in all hospitals and the related eHealth systems.

All laboratories in Denmark are using national codes from the Committee on Nomenclature, Properties and Units in Laboratory Medicine (C-NPU).

General Practitioner (GP) is using International Classification for Primary Care (ICPC) codes. A mapping table is used to translate ICPC codes to ICD10 diagnoses, when a GP sends a referral to a hospital. The mapping table is also used when a GP receive a discharge letter.

The municipalities are using the International Classification of Functioning (ICF) codes, but only internal in the care systems and not for cross sector communication.

The above mentioned codes are the most important and are “probably” the glue for ensuring that clinical content in the many different standards can be exchanged and used for other purposes than for the specific use case. However, this has not been analysed in depth.

The National Board of Health developed a common reference model in 2005. The objective was that clinical data should only be entered once for a patient and all data should be structured. The model was very similar to the OpenEHR model and was tested in a number of full scale pilot projects. Several years of testing and assessment lead to political discussions on governmental level and the model was closed down.

4.3.4 Governance

The National eHealth Authority is a government authority, responsible for setting national standards for eHealth with powers stipulated in legislation. The National eHealth Authority has established an online catalogue containing a list of the standards applying to each individual area as well as how strongly these are recommended. As part of its work of setting standards for the healthcare services,
the National eHealth Authority also draw up reference architectures which together create a coherent data and ICT architecture for the Danish healthcare sector. The National eHealth Authority is also responsible for the National Service Platform (NSP), which is a central communication platform making it possible to cost-effectively and uniformly couple a large number of local/decentral health applications with national health services, registers and reporting solutions. The National Service Platform has been in operation since 2010 and it is regularly developed in step with digitalisation of the healthcare system and consolidation of government ICT systems. The NSP does not store any clinical data for the individual patient.

MedCom was established in 1994 as a public funded, non-profit cooperation. MedCom facilitates the cooperation between authorities, organisations and private firms linked to the Danish healthcare sector. In the 1999 financial agreement between the counties and central government, it was decided that MedCom would be made permanent, with the following objective: "MedCom will contribute to the development, testing, dissemination and quality assurance of electronic communication and information in the healthcare sector with a view to supporting good patient progression". MedCom’s profile was intensified further in connection with the financial agreement between the regions and the government for 2011 which states that “MedCom is continued based on the politically established goals and milestones concerning cross-sectorial communication and with a precise role as operating organisation. MedCom solves problems with a focus to support efficient performance and a gradual expansion of the national eHealth infrastructure, which is necessary for a safe and coherent access to relevant data and communication across regions, municipalities, and general practitioners”. MedCom is financed and owned by:

- The Ministry of Health
- Danish Regions
- Local Government Denmark

MedCom’s steering committee is furthermore composed by the partners in MedCom.

MedCom has, since its establishment, worked in time-constricted project periods of 2 – 4 years. MedCom9 takes place in 2014 – 2015. Based on the national eHealth strategy, three project lines will be implemented during the MedCom9 period:

- Realisation of the national telemedicine action plan, where MedCom is responsible for Clinically Integrated Home Monitoring, deployment of telepsychiatry and the deployment of telemedical ulcer assessment
- Full dissemination and implementation of the Shared Medication Record (FMK), with MedCom involved in adoption by general practitioners and municipalities
- Full dissemination and implementation of message-based communication in regions and municipalities, in addition to an ongoing focus on full dissemination and implementation of MedCom standards between hospitals, municipalities and general practitioners. Initiatives are also set in motion in the fields of psychiatry and social services.

Furthermore MedCom is responsible for permanent basic tasks within four main areas:

- Cross-sectoral dissemination and expertise
• Standards, testing and certification
• Operation and further development of the Danish Healthcare Data Network and national data sources
• International activities

4.3.5 Lessons learned, successes and pitfalls

This case study is a very short summary of the eHealth development during the last 20 years. More than 100 projects have been launched and contributed to a high level of digitalization of the Danish Health care sector – in an international perspective.

Lessons learned, successes and pitfalls in all these projects seems not to be related to concurrent use of standards but more to traditional project management. This is also because the national implementation was based on use case and took place within separated isolated projects, each of them with its own objectives and financing.
4.4 Case Study #10: “Documentation at the Source” Programme in the Netherlands

- Author of case study within the eStandards project: Michiel Sprenger <sprenger@nictiz.nl>
- Project name: Documentation at the Source
- Project type: The scope of this project is to reach large-scale deployment for sustained routine use.
- Project status (in 10/2015): The status of this project is: it has passed the definition phase by setting the appropriate standards for the information to be documented in the care process and is defining the communication standards for the patient referral use case.
- Countries / Regions: The scope includes national deployment. So, national institute is part of the project.
- Project partners: The 8 University Medical Centers (UMCs) in NL, the federation of UMCs, several general hospitals, the Dutch Hospital Association, and the national institute (Nictiz).
- Scale of deployment: National, with the ambition to expand to cross-border.

4.4.1 Project Overview

The project’s over-all goal is to greatly improve the consistency and completeness of clinical information, which is captured as much as possible in the clinical process (“the Source”). This information shall be reusable for multiple purposes, in particular:

- Direct patient care within an institution’s Electronic Health Record (EHR)
- Transfer of patients between institutions
- Connections between Personal Health Record (PHR) and EHR
- Extraction of quality indicators from EHRs and PHRs
- Clinical research
- Epidemiology
- Reimbursement
- …

4.4.2 Approach

4.4.2.1 Care Process

The main outcomes of this project in a semantic sense are the Clinical Information Building Blocks (CIBB) as we call them. These should be the basic elements of patient information in the Netherlands. See section 4.4.2.2 for a description. These CIBBs should, therefore, support all care processes, and not only care processes in the strict sense, but also secondary processes like Quality Registers, Reimbursement, etc.

Of course, projects in real life have a more limited scope. So we started with defining the CIBBs for the use case of patient transfer, and then the generic part of the information that is to be transferred along with the patient. Here all possible diseases and medical specialties were in scope.

After this the project transferred its focus to Head and Neck Tumours, which is much more specific. This was combined with two use cases: patient care within the institution (EHR functionality so to speak) and the possibility to extract quality indicators.
The current step is broadening to any kind of tumours.

**4.4.2.2 Information**

On the information layer the core of our activities goes to the CIBBs. We have ~90 of them defined right now, half of them from medical origin and half of nursing origin, although the difference is historic and not first principles.

These CIBBs are structured following the HL7 Detailed Clinical Models (DCM) methodology, although not to every detail that is required in DCM. This means that people and systems that can read and interpret DCMs are able to read and interpret our CIBBs.

The grouping and structuring of the CIBBs was derived from the Continuity of Care Record (CCR), but further developed for our case and usage, which goes beyond continuity of care.

The content of the CIBBs is in SNOMED CT wherever possible. But also fields are filled with LOINC, local standards like the required Dutch medication standard (G-standard) and even free text is allowed at certain points.

These building blocks are fully generic and not implementation specific. It is an explicit goal of our programme to strictly separate the layers of the Antilope refined eHealth European Interoperability Framework model (reEIF). That means that the CIBBs are defined independent of HL7 (CDA or FHIR) or any other usage, so that they can be later implemented in any of those.

**4.4.2.3 Applications**

It is in this layer where, in our view, that the specific usage of the CIBBs comes into play. For the usage of CIBBs in patient transfer HL7 is used: here a Consolidated CDA (C-CDA) document has been created in order to use the CIBBs for transfer purposes.

In every new application of the CIBBs (quality indicators, scientific research, etc.) this question will have to be repeatedly answered: which standard(s) to use in order to handle the CIBBs with software.

**4.4.2.4 IT Infrastructure**

This again is a separate question. Since we are at the phase of defining the above layers, no infrastructure has been chosen. We strive for separation between the layers, so several infrastructures are possible here: the broad AORTA based infrastructure (i.e., the Dutch national eHealth infrastructure) that handles HL7v3 messaging and CDA, and the more regional XDS clusters that can handle any document, thus also C-CDA.

**4.4.3 Concurrent Use of Standards and Specifications (De-facto Standards)**

Mapping between ICD10 and SNOMED CT.

**4.4.4 Governance**

Governance structure of the CIBBs is under construction.

**4.4.5 Lessons learned**

We have learned that it is indeed necessary, but also useful, to separate between the layers of the
Antilope refined eHealth European Interoperability Framework model (reEIF). That is the only way to provide the flexibility needed while yet standardising.

4.4.5.1 Successes
To get mutual agreement between the health professionals on the structure and content of the CIBBs.

4.4.5.2 Pitfalls and Remedies
The greatest pitfall is that many participants feel they should solve “it all”. Separation between the layers is crucial for this. Solve within each layer, clearly define the relationship between the layers and the way lower layers are derived from the layer above.

4.4.6 Resources

<table>
<thead>
<tr>
<th>[CIBBs]</th>
<th>“Generic Data for Patient Transfers”: Accompanying document and 37 clinical building blocks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Description:</td>
<td>Description of Clinical Information Building Blocks (CIBBs), partly still Dutch only, but also several translations are available.</td>
</tr>
<tr>
<td>Availability:</td>
<td>Freely available</td>
</tr>
<tr>
<td>Link:</td>
<td><a href="https://www.nictiz.nl/SiteCollectionDocuments/Overig/Accompanying%20document%20and%2037%20clinical%20building%20blocks.zip">https://www.nictiz.nl/SiteCollectionDocuments/Overig/Accompanying%20document%20and%2037%20clinical%20building%20blocks.zip</a></td>
</tr>
</tbody>
</table>

4.4.7 References and Further Information

4.5 Case Study #11: EHR Interoperability in Italy

- Author of case study within the eStandards project: Paolo Invernizzi <paolo.invernizzi@cnt.lispa.it>; Marcello Melgara <Marcello.melgara@cnt.lispa.it>.
- Project name: FSE-National eHealth networks in Italy: Technical Specifications for the interoperability of Regional Electronic Health Record Systems (FSE: Fascicolo Sanitario Elettronico) (Specifiche tecniche per l’interoperabilità tra i sistemi regionali di FSE)
- Project status (in 10/2015): Italian National Specifications of EHR interoperability
- Countries / Regions: Italy as scope
- Countries / Regions: Italy as scope
- Project partners: AgID (Agenzia per l’Italia Digitale), Ministry of Health, Economic and Finance Ministry, CNR (Consiglio Nazionale delle Ricerche), CISIS (Centro Interregionale per i Sistemi Informatici) and Representation Regions (Veneto, Emilia Romagna, Lombardia, Toscana, Puglia)
- Scale of deployment: not applicable.

4.5.1 Project Overview

The FSE (Fascicolo Sanitario Elettronico: i.e. Electronic Health Record) is the set of digital data and documents related to the health and social assistance of a citizen, generated during clinical events. The FSE has a time horizon that covers the entire life of the patient and it is continuously fed by the health professionals belonging to the National Health and Social Services (NHSS) and the Regional Health and Social Services (RHSS), who take part in the patient’s care. The FSE is made with the consent of the assisted citizen (opt-in approach, for the purposes of prevention, diagnosis, treatment and rehabilitation. All the Italian regions are investing in the development of solutions to the FSE. A National and Regional operational plan has to be defined, to ensure the adoption of the FSE by health professionals and the provision of related services to citizens in a nationwide consistent manner and to evaluate further developments, in accordance with the competent public administrations.

The study aims to detail and, where necessary, to complete the technical specifications for interoperability of electronic health records implemented by the national technical board involving AGID, Ministry of Health, Ministry of Economy and Finance, CNR, CISIS and Regions participating to the project (Veneto, Emilia Romagna, Lombardy, Tuscany, Puglia).
4.5.2 Approach

The approach used to define the current architecture and message speciation is based on the experience gained during different projects related to the national or European interoperability. The project specifications are defined starting from: epSOS and IPSE projects, AGID Technical Specifications and CISIS.

In order to analyze the robustness of the technical specifications, the approach involved the implementation of a prototype of the interoperable services. On the AGID proposal, the three regions that have offered to build and test a prototype of interoperable national FSE are: Veneto, Emilia Romagna and Lombardy. Messages interoperability made have been tested by an appropriate test platform prepared by CNR.

The result has been to consolidate and validate the detailed technical specifications of specific message related services based interoperability (interoperability interfaces) listed in [TAVOLO_FSE], approved by the Technical Board and the Public Authorities.

The technical specifications of the messages of interoperability cases take into account the possible evolution functions which, when specified, will be adequate. Finally, this document will serve as input for the completion of the documents of the technical specifications of the technical institutions listed above.

Following the specifications, the resources used to address the project are:

- [TAVOLO_FSE]: National “EHR Guide Lines”;
- [DPCM_FSE]: Decree of the President of the Council of Ministers for the National EHR (attached into TAVOLO_FSE);
- [BUSINESS]: Business Process supra-regional;
- [InFSE]: Interoperability message specifications into the EHR for the IPSE National Project;
- [Consenso]: Access Policy;
- [epSOS]: D3.4.2 epSOS Common components specifications.

During the project activities, the team decided to analyze different interoperability standards that
satisfy the following requirements:

- solution based on interoperability standards;
- availability of libraries to support the vendors in the development phases;
- simplicity and scalability of the exposed services.

The standards evaluated are:

1) XDS / XCA (IHE: Cross-Enterprise Document Sharing / Cross Community Access) with Retrieve action performed directly from the RDE (Region of treatment Execution, in Italian “Regione Di Erogazione”) to the RCD (Region Containing Document or Data);

2) XDS / XCA with Retrieve action executed by RDE to the RCD with the mediation of the RDA Region of Affiliation (in Italian is “Regione Di Assistenza”);

3) XDS.b (IHE Cross-Enterprise Document Sharing-b) with Retrieve action executed by RDE to the RCD with the mediation of the RDA;

4) RLUS HL7/OMG (Retrieve, Locate, and Update Service);

The team proposed to use the solution 3) XDS.b with Retrieve action executed by RDE to the RCD with the mediation of the RDA.

As it happened in epSOS, the most intense technical discussion was on the choice between IHE XDS/XCA, IHE XDS.b profiles and RLUS. The large majority of regions opted for IHE X*, being already implemented in some of the regions and being a solution largely adopted by vendors.

**4.5.2.1 Care Process**

The national interoperability of FSE actually works on the same care process where the FSE acts, taking into consideration the use cases when a health professional needs to access or generate documents of a patient from a different region.

The process of interoperability between the different systems of national FSE involves the use of RDA like a proxy model (RDA proxy), where all requests are directed to the Region of Affiliation (RDA: in Italian is “Regione Di Assistenza”) which is responsible for recovering any documents stored at RCD (Region Containing a Document) and send them to the RDE (Region of treatment Execution).

This model legitimizes the adoption of IHE XDS.b, modelling and implementation of inter-regional processes and services within the scheme of the “Decree of the President of the Council of Ministers”. It points out, in fact, that the citizen assisted by the national health system, whose data is present in the Registry Health Card System (STS: Sistema Tessera Sanitaria) and going to the National Assisted Registry System (ANA: Anagrafe Nazionale Assistiti), has always only one Region of Affiliation (RDA). From the architectural point of view this translates into the presence of a single Registry reference to a specific citizen. In this scenario that the system master reference, as regards the inter-regional processes, is supra regional, the system of the FSE of a region different from that assistance is configured as a consumer within the same Affinity Domain.
In this light the study focus is on the messages exchanged between the different actors involved as detailed in following figure which define the use case as basic framework of the FSE national interoperability. The use cases identified are:

- **UC01** anagraphic identification; registry, exposed by the system TS / ANA;
- **UC02** documents search; exposed by the RDA;
- **UC03** document retrieve; exposed by RDA and RCD;
- **UC04** index transfer (use case index transfer FSE, service exposed by RPDA);
- **UC05** metadata communication (use case indexing RDA, document produced / updated by RDE);
- **UC06** metadata cancellation (use case on the logical cancellation of metadata in RDA due to faulty transmission or invalidation index after the transfer of the FSE).

### 4.5.2.2 Information

The information model will be described using the following selected Use Cases: **UC01**, **UC02**, **UC03**, **UC04**.

#### 4.5.2.1 UC01 – Anagraphic identification

The implementation of the process that verifies the citizens’ data is a precondition for other processes involving the FSE, internal to the regional domain and interoperability. A region can implement this process according to the model and process infrastructure that is deemed more appropriate.

It has to be guaranteed the ability of the FSE and the enabling infrastructure to access, through application services, the systems that hold the authoritative reference data of the citizen.

In order to complete the identification process of a citizen not assisted in the Region of treatment Execution (RDE), pending the establishment of the ANA, the national register of reference will be the System TS.

In order to consider the **System TS / ANA** the primary reference for the identification registry, it is
necessary to guarantee the precise alignment with the central system. It is therefore requested that the regional and health care structure registers use properly the services provided by the System TS / ANA.

In light of these considerations, it is required that the system TS / ANA is able to offer:

1. A service Attribute Authority which complies with Security Assertion Markup Language SAML 2.0 Protocol <AttributeQuery> able to release, after a request from a regional domain containing the Italian fiscal code (CF) of a citizen, a SAML assertion identification format v2.0 signed, containing the following information:
   - List of all the Italian fiscal codes associated with the city, with an indication of their validity and the current fiscal code;
   - Directory of Regions Support of the citizen, indicating the current one. In particular, the overall listing of Regions of Affiliation is needed to meet both functional and robustness requirements related to the transfer process of the index of the FSE to move from an RDA to a new one (If a citizen does not ask for the transfer of the FSE downstream after the change of its RDA, its FSE may not be recoverable because the index is still stored in RPDA).

2. A service based on established international standards (in particular HL7 / OMG IXS: Identity Cross-Reference Service), can provide the necessary functionality for the identification registry, with particular reference to the recovery of data of a citizen (name, surname, address, etc.) by means of a query using the national id code.

The following figure summarizes one of the processes of interoperability of the FSE and particularly the interaction flow between the RDE and the RDA, which provides transportation of assertion of identification issued by the identification services exposed by the System TS / ANA.
4.5.2.2.2 UC02 – Document Search

The communication protocol to be used must comply with “IHE transaction [ITI-18]: RegistryStored Query”, which, according to the IHE terminology, is to send a query by an actor XDS Document Consumer (in this case the regional node of the RDE) to an actor XDS Document Registry (in this case the regional node of the RDA).

The request must also include the assertion of identification obtained through interaction with the system STS / ANA and the assertion attribute signed by RDE.
The standards used for the message fields in the use cases UC02 until UC06 are for example:

- Organization identifiers: Italian coding system HSP.11 – HSP.11bis – STS.11 – RIA.11, HL7 OID;
- Document Type: LOINC;
- Patient Identifier: IHE Specifications (ITI TF-3) and Italian Coding (from Ministry of Finance – MEF);
- Document Identifier: HL7 OID;
- Document Type: PDF / CDA.

4.5.2.2.3 UC03 – Document retrieve

The communication protocol to be used must comply with "IHE transaction [ITI-43]: Retrieve Document Set", which, according to the IHE terminology involves sending a document retrieval request from an XDS Document Consumer (in this case the regional hub of the RDE) to an actor XDS Document Repository (in this case the regional node of the RDA).

The infrastructure allows to mask the actor XDS Document Consumer RDE of the recovery process of the document to a possible RCD (than the RDA). The request to retrieve initiated by the RDE should thus be forwarded to the service XDS Document Repository of the RDA (identified inside the RepositoryUniqueId). The element RepositoryUniqueId of the retrieve request identifies the region and the
4.5.2.2.4 **UC04 – Index transfer**

The process of transferring the index must begin downstream of the notification by the STS / ANA of changing RDA of a patient, which must include the references of RPDA (Region of Previous Assistance). In such a case, the RDA requires to the RPDA the recovery of the whole index of the FSE, which includes both the list of metadata and the list of OIDs of access rules, comprising the visibility policy, consents and any obscurity. The request also includes the assertion of identification and attribute. In the event that the consents to the supply and / or consultation of the FSE in RPDA has been revoked before the change of the RDA, the index will still be transferred to the new RDA, while preserving its status invisible before. It is the faculty of the new RDA check that the citizen intends to maintain its active FSE in the new region. After the transfer, the RDA requires RPDA to invalidate the index for the patient who has changed the region of assistance.
4.5.2.3 Applications

Description: “On this level, agreements are made about the import and export of medical information, handled by the healthcare information systems. The technical specification of how information is transported is at this level (communication standards). The information systems must be able to export and import these communication standards”. Examples for standards used on this level are IHE XDS and XCA (for EHR-based non-directed communication), IHE XDR or HL7 messages (for directed communication), or IHE profiles like PIX, PDQ, XCPD.

The conditions defined in the national functional business processes [BUSINESS] enable to define the supra-regional infrastructure of cooperation between the regions as a single domain XDS, characterized by multiple independent registers (actors XDS Document Registry). This assumption does not constitute a deviation from the standard base since there is no interaction between indexes, and it is possible for each operation (query or indexing) identifying one and only one reference index for this operation (the index run of the RDA ). Each logical object (document, submission set) resides and is managed by a single registry. All registries share the same Affinity Domain.

The mode of interaction between the actor XDS Document Registry and the regional application that actually keeps the documents relating to their patients (index or other DB) are not in the scope of this study and can be made in proprietary mode.

4.5.2.3.1 Interoperability Services

The process of retrieving a document is based on two actions: Query and Retrieve.

In order to deal with these operations each region will implement as RDA:

- Interface of XDS Document Registry service integrated with its document management system of
the assisted. This service must be able to answer two types of stored queries conform to IHE specifications: FindDocuments and GetDocuments;

- Interface of XDS Document Repository service integrated with its system of storage of the documents produced by the hospitals, laboratories and all other health care units belonging to the same region;
- A System as XDS Document Consumer grouped with the XDS Document Repository service that is able to retrieve documents relating to their patients but kept in other regional domains.

Each region must implement as RDE the following services:

- A service which can request a statement of identification service Attribute Authority System STS / ANA;
- XDS Document Consumer service able to query a service XDS Document Registry identified as a function of the RDA of the patient for which you are searching;
- XDS Document Consumer service able to query a service XDS Document Repository identified as a function of the RDA of the patient for which you are retrieving a document;
- Embedded XDS Document Source and Repository service which can index a document at the RDA of the patient for which it creates the document. This service must be able to communicate the identifier of the structure that stores the document (repositoryUniqueld).

Each region will implement, as RCD:

- An XDS Document Repository Service integrated with your storage system of the documents produced by the facilities belonging to the same region, you can also check the ownership of the request.

4.5.2.4 IT Infrastructure
The state of the art of the project stage doesn’t address the generic communication and network protocols and standards.

4.5.3 Concurrent Use of Standards and Specifications (De-facto Standards)

The mapping between different code systems, currently used by some of the regions in view of achieving the full interoperability of the FSE, has been addressed for some of the documents, identifying the datasets and value sets (e.g. Patient Summary, coherent with the EC Patient Summary Guidelines). This is not a major constrain, being mainly documents in Italian. The nature of the infrastructure involved requires that the mappings will be resolved within each region. In this stage the document format exchanged will be CDA Level 1. The concurrent use of different standards as CDA-Level 2 and CDA Level 3 are out of scope of this document, because the use of the document is demanded at the regional level.

4.5.4 Governance
This project is currently in a working phase under the responsibility of AGID (Agenzia per l'Italia Digitale) and follows the results and decision taken by the working group described above.
4.5.5 Lessons learned

The lesson learned can be divided in different areas:

- Be motivated: the activity is governed by sets of Decrees and Laws aiming to achieve the eHealth interoperability in Italy aligned with EC eHealth Roadmaps and Guidelines

- Be practical: having selected a set of actors with previous real experience of EHR running for several years, most of the potential issues were experienced and solved in advance. Hence the convergence was driven by common goal and experience, on legal, organizational and technical dimensions

- Be coherent and compatible: apart from previous experiences that in many cases are based on proprietary implementations, the relevance to adopt International standards was felt as a facilitator of convergence and compatibility among the regions and in view of cross-border eHealth services, in line with the EC Directives.

4.5.5.1 Successes

The scope of the project is to create the functional and technical detail specifications which enable the development of Regional solution to interoperate with others region to share the EHR documents. The peer-to-peer solution adopted, without any central “subject” (apart the STS/ ANA system which is needed) is the success key factor in the project and their future implementations.

In this project stage has not been specified the modality of exchange the regional configuration (e.g. the addresses of the regional’s “end point”), because they will be addressed during the implementation phases probably using the same architecture used in the ePSOS project using a central configuration service.

4.5.6 References and Further Information


[InFSE] Infrastruttura Tecnologica del Fascicolo Sanitario Elettronico. Online: http://www.funzione pubblica.gov.it/media/994472/infse%20%20linee%20guida%20v1.2.pdf


[epSOS] D3.4.2 epSOS Common components specifications.


4.6 Case Study #12: Delivering 21st Century IT to the English NHS

- Author of case study within the eStandards project: Jeremy Thorp <jeremy.thorp@hscic.gov.uk>
- Project name: National Programme for IT in England
- Project type: “large-scale deployment for sustained routine use”: The solution is used for sustained routine operation in healthcare on a larger scale, e.g. regional or national eHealth network.
- Project status (in 10/2015): Complete
- Countries / Regions: England
- Project partners: Department of Health, NHS Connecting for Health, local NHS, suppliers, professional groups
- Scale of deployment: National: all hospitals (c 250 organisations), all primary care (c 8,300 practices), all community care (c 150 organisations)

4.6.1 Project Overview

The goals were to introduce integrated health and care records across the country to support improved patient care and lead to better outcomes.

4.6.2 Approach

The architecture for the National Programme was built around a national spine to which local systems would be linked. This relied heavily on the application of standards. In particular, contractors had to comply with a list of standards related requirements, an excerpt of which is set out in Table 7.

<table>
<thead>
<tr>
<th>No.</th>
<th>Requirement</th>
</tr>
</thead>
<tbody>
<tr>
<td>790.1</td>
<td><strong>Overview</strong>: The Contractor acknowledges that the NHS is operating in a heterogeneous environment. To enable the interaction of different systems, the Contractor shall ensure that the Service operates in accordance with the requirements detailed here</td>
</tr>
<tr>
<td>790.5</td>
<td><strong>Standards observation</strong>: The Contractor shall observe and keep track of NHS and industry standards as such standards evolve and emerge and are issued by the Authority.</td>
</tr>
<tr>
<td>790.6</td>
<td><strong>Standards migration</strong>: The Contractor shall ensure that the Service upgrades new and existing standards within a reasonable timeframe. Standards shall be agreed through the NHS Information Standards Boards. New standards, once approved by the ISB, shall form part of the Agreement.</td>
</tr>
</tbody>
</table>
| 790.7 | **Web services**  
SOAP v1.2: The Contractor shall ensure that where web-based services are required, they shall be developed and delivered in accordance with the SOAP v1.2 standard.  
WSDL v1.1: The Contractor shall ensure that where Web-based services are required, they shall be developed and delivered in accordance with the WSDL v1.1 standard.  
UDDI v3.0: The Contractor shall ensure that where web-based services are required to be published to a service directory, they shall be developed and delivered in accordance with the UDDI v3 standard. |
| 790.7.1 | **HTTP**: The Contractor shall ensure that where http is required, it shall adhere to the http 1.1 standard. |
| 790.7.2 | **FTP**: The Contractor shall ensure that where ftp is required, it shall support restart and recovery. |
### No.

<table>
<thead>
<tr>
<th>Requirement</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>790.8</strong> HL7: The Contractor shall ensure that where HL7 Messages are required, they shall adhere to the v3 specification, unless it is not possible to apply the v3 specification in a particular circumstance. In this case, v2 Messages may be used. In both cases, all Messages shall seek the approval of HL7-UK and NHS ISB.</td>
</tr>
<tr>
<td><strong>790.9</strong> EDIFACT: The Contractor acknowledges that pathology to GP messaging currently uses EDIFACT. The Contractor shall ensure that it continues to use EDIFACT, for the time being, in relation to this service and in relation to such other legacy services for which it had previously been used. The Contractor shall ensure that the Service does not use EDIFACT other than as specified above.</td>
</tr>
<tr>
<td><strong>790.10</strong> ICD: The Contractor shall ensure that where ICD encoding is required, it shall adhere to the ICD 10 specification.</td>
</tr>
<tr>
<td><strong>790.11</strong> OPCS: The Contractor shall ensure that where OPCS encoding is required, it shall adhere to the OPCS-4.2 specification.</td>
</tr>
<tr>
<td><strong>790.12</strong> SNOMED CT: The Contractor shall ensure that where SNOMED CT encoding is required, it shall adhere to the SNOMED CT standard.</td>
</tr>
<tr>
<td><strong>790.13</strong> UKCPRS: The Contractor shall ensure that all new systems shall support the UKCPRS standard.</td>
</tr>
<tr>
<td><strong>790.14</strong> DICOM: Pursuant to NHS Policy, the Contractor shall encourage the use of and use information management and technology standards (such as DICOM) in equipment and systems that transfer medical images and associated information.</td>
</tr>
<tr>
<td><strong>790.15</strong> Workflow: The Contractor shall ensure that where workflow information is to be exchanged, it shall be prepared to adhere to the WfMC standard (Workflow Management Coalition Standard – see <a href="http://www.wfmc.org">www.wfmc.org</a> for details).</td>
</tr>
<tr>
<td><strong>790.18</strong> Device communication: The Contractor shall ensure that where applicable the systems that are required to interface with medical devices of a type for which there is a current IEEE 1073 standard, are capable of communication conformant with the IEEE 1073 Medical Device Communication standard.</td>
</tr>
<tr>
<td><strong>790.19</strong> Directories: The Contractor shall ensure that the directories use LDAPv3 (Lightweight Directory Access Protocol version 3), which must be used for directory access. This is in line with the e-GiF.</td>
</tr>
<tr>
<td><strong>790.20</strong> Healthcare Resource Groups (HRGs): The Contractor shall ensure that the Service supports Healthcare Resource Groups</td>
</tr>
</tbody>
</table>

#### 4.6.3 Governance

The Design Authority was responsible for oversight of the blueprint and the testing strategy.

#### 4.6.4 Lessons learned

The technology component was a challenge, but worked well in the end. Securing end-user buy-in took a lot longer.

#### 4.6.4.1 Successes

The Spine components and the technical layer standards all went smoothly. A formal benefits study in 2013 [NHS13] reported the following:

Systems and services delivered as part of the programme are now an integral part of the NHS and they:

- **Support operations and service delivery improvements.** Trusts, for instance, now report an average of 42 hours from the start of producing a diagnostic image such as an x-ray to the time the clinical report is completed, compared with an average of 144 hours prior to the na-
tionwide introduction of Picture Archiving and Communications Systems (PACS);

- **Improve clinical quality and safety.** Accurate information is now available within a patient’s Summary Care Record, which is particularly valuable the first time a healthcare professional interacts with the patient on an unplanned basis such as during out-of-hours care;

- **Enable information sharing across organisational boundaries.** The secure transfer of electronic health records using GP2GP is improving the availability of medical information about patients when they switch from one GP practice to another, thereby enabling better clinical decision-making;

- **Provide information securely through electronic communication.** 63% of users of the NHSmail service use it to securely transfer patient identifiable data helping them comply with national information governance requirements;

- **Inform and support improvement in public health.** Commissioners and GP practices regularly accessed the Quality Management and Analysis System (QMAS) to analyse their achievement against a wide set of largely evidence-based clinical care indicators across the services they deliver to patients, enabling them to focus on where the need to improve patient services is greatest.

The overall quantified benefit to the end of life of the systems is forecast to be £10.7 billion, set against the cost of delivery of £9.8 billion. Not all elements of the programme have been successful at realising benefits to date. Realisation of benefits from the implementation of local care record services (excluding PACS) has resulted in £0.5 billion of quantifiable benefits; this low level of benefit realisation is also true for the Summary Care Record and Electronic Prescription Service and is primarily due to the speed of deployment of local systems being slower than was originally forecast. In contrast, where systems have been in use for an extended period of time, benefits have been realised through changing business processes and the sharing of best practice and demonstrated through case studies and user surveys.

The total costs for the programme to contract end have been reduced from £12.7 billion estimated by the National Audit Office in 2008 to £9.3 billion.

### 4.6.4.1.1 Improving operational and service delivery

Systems and services delivered as part of the programme are now contributing to improvements in operational and service delivery in the NHS, leading to reduced costs and improved efficiency and effectiveness. Whilst not comprehensive, the examples below give an indication of the kinds of operational and service delivery benefits that are being realised in the NHS.

Plymouth ICT Shared Services has used NHSmail to alert community workers if their patients have unplanned hospital admissions. They combine this with alerts to hospital staff where the patient being admitted is already being cared for in the community, ensuring that service delivery is coordinated across primary and secondary care.

Black Heath Medical Centre in the Wirral uses NHSmail to text patients to invite them to their annual flu inoculations.

The Cornwall and Isles of Scilly COIN links distant sites to the A&E department at Treliske hospital. Using Video Conferencing technology, this enables staff treating patients at remote clinics to gain
access to expert diagnostic opinion from consultants at the heart of the county; meaning better informed decisions can be made for the good of the patient.

NHSmail is a good example of national infrastructure provided through the programme replacing existing, locally-provided services. As a result of the introduction of NHSmail, 1,482 local email services have so far been decommissioned resulting in reduced costs and a more secure way of exchanging clinical information across organisational boundaries. Every month, around 250 million messages are sent and received through NHSmail. This has enabled local communities to provide innovative local services.

NHSmail also supports the booking process through provision of SMS text reminders, which are provided free to users. A survey in 2011 indicated that nearly 35% of the SMS messages sent via NHSmail are in the form of patient reminders contributing to reducing the number of missed appointments and as a result, reducing wasted clinical and administrative time.

Where Choose and Book has been implemented successfully, there has been a reduction in patients not attending their appointments, resulting in less time off work through better planning, and a reduction in overall treatment times. Processes in communities using Choose and Book are generally more effective when handling exceptions compared to paper-based/manual processes. Administrative time has also reduced with less time spent identifying where referrals are within the overall system.

At Pennine Acute Hospitals NHS Trust, 4.3% fewer patients missed their appointments when the referral was made through Choose and Book. If this reduction was seen across England, this would be equivalent to avoiding the cost of 292,000 appointments annually where patients did not attend.

The out-of-hours services at Medway on Call Care, based on a survey of 70,000 patient encounters, reports that where a patient’s Summary Care Record (SCR) is viewed when giving telephone advice, face-to-face follow-up appointments are reduced by between 3% and 7%. When the SCR is viewed as part of a face to face appointment with a clinician, subsequent follow-up appointments were reduced by between 8% and 14%.

Nottingham University Hospitals NHS Trust, the first organisation to take PACS in the Eastern region, became 80% film-less in just two weeks. Having learnt from experiences of other organisations Gateshead Health NHS Foundation Trust became filmless in just two days.

In practices with a high turnover of patients, such as Leeds Student Medical Practice who register in the region of 6,000 new students annually, GP2GP enables substantial administrative time savings.

The Summary Care Record, whilst primarily being designed to improve clinical safety, also brings operational benefits. For example, out of hours services are using the record to change their approach to delivering care, reducing the need for follow-up appointments.

The use of Picture Archiving and Communication systems has enabled Trusts to completely eliminate the need for film and chemicals for conventional image processing. This has removed the need to manage, transport and store physical images. Many Trusts moved more rapidly to a filmless environment than originally planned. PACS is also enabling diagnostic services to improve operational effectiveness. Trusts now report an average of 42 hours from the start of the diagnostic imaging pro-
procedure, such as an x-ray, to the time the clinical report is dictated, compared with an average of 144 hours prior to the nationwide introduction of PACS, enabling quicker diagnosis.

GP practices have cited that the totality of the (combined paper and electronic) record, through the use of GP2GP, is more structured and ordered, making it easier to find and confirm the existence of particular information. GPs said they save on average 3.3 minutes per transfer to review paper notes, also noting that it is invaluable to have an electronic health record available almost immediately when new patients register in comparison to the several weeks it takes to transfer paper records.

GP2GP record transfer has freed-up administration and clinical time, with patient notes transferred between practices electronically. The service reduces the need to prepare and print out electronic patient notes by the practice where the patient is leaving, saving around 10 minutes in administrative time per transfer. Similarly, the practice where the patient is joining saves 15 minutes in administration time by not having to rekey essential data from the patient notes.

NHS Camden is seeing financial savings equating to around £20,000 per annum as a result of using N3 Local Gateway Services, which provides lower cost telephone calls to people outside the NHS and free of charge calls to those also using the N3 network. They are making 10,000 formerly chargeable free calls a month, while 29,000 calls to mobile phones and premium rate numbers are charged at 30 per cent less than other available tariffs.

TPP SystmOne, implemented as part of local care record services in Kirklees PCT has dramatically improved access to their podiatry service by allowing booking of appointments by administrative and podiatry staff from any location.

At University Hospitals Morecambe Bay NHS Trust, Immediate Discharge Summaries are generated from the Lorenzo clinical record and supplemented by a narrative from the clinician. 2,500 electronic discharge summaries are now produced every month compared with 20 when the system was first introduced.

Two local health communities, NHS Leicester and Rutland and NHS Tees, have reported that using the Map of Medicine has reduced the time taken to develop patient care pathways by up to eight months. This is estimated to have saved between 45% and 60% of the cost of developing guidance by adopting national clinical standards as the baseline.

A secure broadband network – N3 – is now fully deployed across the NHS, giving access to a range of voice and data services. Savings have been realised by nationally negotiating the tariff for voice, video, and other data transmission methods. A reduction in power usage has been achieved by implementing more efficient equipment and reducing the need to travel, with total carbon savings of 56,950 tonnes. Across England, nationally-agreed tariffs have saved an estimated £149 million. The network is also now being used by Trusts for video conferencing and enables (for example) multidisciplinary teams to share clinical data when planning care for cancer patients.

Local care record service systems have been implemented across Trusts providing community, child health, mental health and acute services. In many instances, these systems have replaced paper based records or systems with limited clinical functionality and created a patient record which can be accessed across multiple clinical locations. This has enabled redesign and operational improvements
in local services.

GPs, nurses, pharmacists and other healthcare professionals from across Bolton, Bury and Rochdale and Medway indicated in a survey that using Summary Care Records in out of hours care had increased safety in treating patients. They reported fewer instances of patients being prescribed medication in the absence of information. In-built alerts and prompts upon receipt of the patient record encourage clinicians to review and identify any current relevant issues.

4.6.4.1.2 Improving clinical safety
Having the right information immediately available at the point of care is a key way to ensure that safe and appropriate treatment is given. The examples below show how systems and services delivered by the programme are contributing to improvements in patient safety.

The implementation of the NHS Spine services has increased the adoption of the NHS Number as the prime patient identifier, enabling safer care by linking and tracing of a patient’s records across NHS organisations. 40.2 million enquiries are made to the Personal Demographics Service (PDS) every month to confirm correct identification and contact details for patients. This has minimised misidentification of patients, assisted in linking health records, and improved data quality. It has also contributed towards reducing annual payments (made on the basis of population) that would have been made for inappropriate long standing duplicate records.

Improved access to clinical information and implementation of national standards and applications has supported clinicians in delivering safe and appropriate care. This is particularly true when unplanned episodes of care take place and where existing patient records may not be accessible.

As a result of introducing PACS, the risk of medical exposure to ionising radiation has been reduced by cutting clinically unnecessary repeat x-rays, estimated at a rate of 5% prior to the implementation of PACS across England has now fallen to below 1%.

Local care record services, where implemented, have created a patient clinical record, which has enabled clinical information to be readily available from which trends can be identified more easily to facilitate earlier intervention, increased sharing of information across services, improved reporting of outcomes and potentially earlier identification of children and adults who are vulnerable.

The Electronic Prescription Service is enabling prescribers, including GPs and practice nurses, to send prescriptions electronically to a dispenser of the patient’s choice. The service has enabled the implementation of a standard drug dictionary, the NHS Dictionary of Medicines and Devices, across GP practices and pharmacies in primary care. As at March 2012, over 665 million electronic prescription messages had been transmitted in parallel to the existing paper prescriptions, ensuring consistent descriptions and codes for medications are used across the system, reducing the potential for errors to occur.

The use of Choose and Book for referral from primary to secondary care has led to fewer referral errors. Users have clarity on the referral criteria and certainty around the status of a referral. This, combined with simplified processes, aids earlier identification of errors that could occur. The approval of referrals electronically, where implemented in secondary care, saves times for consultants and provides an audit trail of referrals made, increasing patient safety.
4.6.4.1.3 Providing Information Securely
The confidentiality of patient records is of paramount concern and systems and services delivered as part of the programme have been instrumental in helping the NHS to move away from the physical storage and movement of records to secure electronic storage, transmission and retrieval of information. Some of the ways in which this has been done are described below.

Every individual accessing NHS Care Record services does so using a smartcard which is unique to them. Over 676,000 such smartcards have now been issued. Through a link with the NHS Employee Staff Record, this has meant reduced administration and helps to reduce the risk of errors in providing access. It is now easier to identify control and audit legitimate access to patient administrative and clinical information.

NHSmail is being used by 63% of users to securely transfer patient identifiable data. The service provides greater security, both in terms of authentication (identifying who the email is from) and encryption (ensuring that the recipient alone can read the email).

Systems and services are now delivered more securely, with data stored in safer environments and physical access restricted to only those with a genuine requirement to do so. Accuracy of data has also increased through the adoption of standards for recording and transmitting data across systems.

4.6.4.1.4 Providing high quality management information
As systems and services provided by the programme have moved into widespread use, they have begun to provide valuable information for strategic planning, service development and operational management, in addition to enhancing care delivery. This has supported organisations in becoming more responsive to changes in care requirements for their local populations.

The Kent Cardiovascular Network is using the N3 network to link local facilities with main centres of expertise in London. Consultants can send angiograms instantly and view them in real time with colleagues in London. Invasive cardiac procedures can now be conducted locally with the knowledge that experts are on hand. In the last year, nearly 400 angioplasty procedures were safely carried out in Kent. Before the network was implemented, all patients had to travel to London for those procedures. This is saving a huge amount of patient inconvenience and travel. The network estimates that 30,000 miles of travel have been eliminated in one year alone.

The Audit Commission report “Improving data quality in the NHS: 2010” found that the accuracy of clinical coding improved from 2007 to 2011. The identified coding error rate dropped from 16 per cent to 11 per cent in this period.

For example, management information from Choose and Book on referral demand and capacity enables capacity issues in locally provided services to be highlighted and more easily addressed so that resources can be reallocated.

The Secondary Uses Service (SUS) has enabled a consistent Payment by Results policy to be implemented across England, supporting providers and commissioners to reconcile charges made against services delivered. In the financial year to March 2011 this assisted the NHS in assuring payments of over £40 billion. In addition to supporting reimbursement, SUS has also made a consistent dataset available to both commissioners and providers, and supported local and national performance moni-
toring to improve performance in the NHS. The Hospital Episode Statistics and NHS Comparators provided by the NHS Information Centre for Health and Social Care, and the Payments by Results National Benchmark tool provided by the Audit Commission, all rely on the information derived from SUS.

Performance management organisations and GP practices have used the Quality Management and Analysis System (QMAS) to analyse their achievement against a wide set of evidence-based indicators across the services they deliver to patients, such as care provided to patients with chronic diseases. This has shown patterns and prevalence of common chronic diseases such as asthma, diabetes and coronary heart disease, which enables organisations to plan and make better utilisation of their resources addressing the needs of their local population.

The Offender Health IT programme has introduced a national clinical IT system for all prisons across England. This has removed the need to search through reams of paperwork – from hospital referrals to medication history – in order to locate the information most important to the prisoner’s health. This is particularly true for prescriptions, ensuring prescribing issues can be identified so that they can be addressed, limiting the potential for errors.

Mental health trusts in London have used their clinical system (CSE RiO) to support the implementation of a care programme approach (CPA). This has resulted in significant increases in the number of clients (50% community, 70% inpatient) who have a CPA review within six months and over 77% increase in the number of clients on a CPA with a care plan intervention.

Initial deployment has been completed for all contracted Community and Mental Health Trusts; 53,000 users were registered to use community and mental health systems, with approximately 5,500 users accessing the system concurrently.

Lorenzo is one of the strategic products provided in the North, Midlands and East region. At University Hospitals Morecambe Bay NHS Trust, the implementation of Lorenzo has enabled the Infection Prevention Nurses to keep track of patients carrying infections and be alerted when they are admitted to hospital, reducing the risk of cross infection.

GP Systems of Choice is a national contractual framework which provides GP practices with a choice of nine accredited GP clinical IT systems. The framework has improved value for money to the NHS by working with local organisations to negotiate and publish pricing across the range of services provided by the suppliers. It has also facilitated changes to the clinical systems to deliver services such as Choose and Book, the Electronic Prescription Service, GP2GP and Summary Care Record. Over 80% of practices in England now have a clinical system provided under the framework, with the rest having systems provided by the local service provider for the North Midlands and East. A key benefit of these arrangements is that 41% of GP practices in England now use data centre hosted systems, meaning sensitive clinical data is now stored more securely.

4.6.4.1.5 Providing an enabling infrastructure

The national infrastructure was a pre-requisite to enable delivery of the products and services which have in turn, enabled delivery of benefits across the health system. For example, information services such as NHS Evidence (a service that enables access to authoritative clinical and non-clinical evidence and best practice through a web-based portal) are now readily available throughout the
NHS because of the N3 network. Such facilities have also supported service changes, e.g. through support for the work of geographically-dispersed multi-disciplinary teams. A study by the Department into Mobile Health Workers identified significant

4.6.4.2 Pitfalls and Remedies

4.6.4.2.1 Security Standards Difficult to Implement
The specification for the "care record service" contained tens of different modules. The longest, with the most requirements, was for "information governance", a term used in England to incorporate security, confidentiality, data quality, etc. Our model for security included the creation of legitimate relationships (between health professionals and doctors) and our model for confidentiality included "sealed envelopes" whereby patients could seal part of their record so that only some users could see that data. This latter proved sufficiently complex (how granular? who determines which users can or cannot see the sealed data?) that it was left to one side while other features were implemented.

4.6.4.2.2 The Use of HL7 v3 Messaging Much More Complex than Expected
The move from HL7 v2, with its numerous implementations, often incompatible, has led to the definition of HL7 v3 with its underpinning reference information model (RIM), which was designed to provide a coherent set of specifications and tools to enable suppliers to implement them. In practice, the developers found this complex; the suppliers found the concepts and the tooling difficult to manage, and progress of HLv3 messages has been universally slower than hoped and many projects have reverted to HL7 v2 messages. Only latterly, with the introduction of FHIR, have we seen updated tools and everyone is commenting on the ease with which FHIR can be taken, learned and implemented.

4.6.5 Resources
Not Available.

4.6.6 References and Further Information

4.7 Case Study #13: Greek National Patient Summary Design

- Authors of case study:
  - Dr Alexander Berler <a.berler@gnomon.com.gr>,
  - Dr. Anastassios Tagaris, <tassos.tagaris@gmail.com>
- Project or Initiative name: Greek National Patient Summary Design
- Project type: limited deployment for experimental use
- Status (in 10/2015): deployed for experimental use
- Countries / Regions: Greece
- Partners: This use case is the combined work of two parallel teams.
  - Team No. 1: The Ministry of Health of Greece has started the Health Reform Support Programme 2013 – 2015 in the framework of Health in Action Initiative, with ten pillars, to strengthen the development, performance and sustainability of its health system. A Contribution Agreement was signed between the Ministry of health and the WHO Regional office for Europe WHO/Europe for mutual collaboration and support. Seven out of ten pillars were subcontracted to GIZ (Deutsche Gesellschaft für Internationale Zusammenarbeit GmbH). Under the Health Pillar of this programme, GIZ will provide support to the Greek Health System Reform. For that purpose GIZ Collaborated with GNONON Informatics S.A., in the context of the eHealth pillar for implementing Deliverable 5 “Study and recording of the current decentralised Electronic Patient Record systems in NHS hospitals; Suggestions for horizontal or vertical interconnectedness (umbrella); Description of the next steps”. Deliverable 5 focuses on proposing the needed interoperability architecture for deploying a national patient summary infrastructure based on the EU guidelines as set as of November 2013.
  - Team No. 2: The SOHealth (Smart Open Internet Services for Health) project is an initiative co-funded by the Greek Secretariat of Research and Technology and the European Union, which is a national extension of established European innovation projects and networks (epSOS, Calliope, Antilope). SOHealth Team members are the Infolab of the Aristotle University of Thessaloniki as the coordinator, Gnomon Informatics SA as the technical coordinator, ELOT SA as the quality manager and pilot validator, Pharmaxis and IDIKSA SA at the pilot implementations. SOHealth focuses on proposing innovative eHealth interoperability services and tools enabling cross platform, cross border and inter-regional healthcare scenarios based upon the reuse of international standards (HL7, IHE, etc.)
  - Reusing National Common components (SSN registry, etc.)
  - Merging Greek epSOS NCP to the National NCP
  - National connector NCP-A for e-Prescription
  - Building a Patient Summary Reference Implementation
  - Incorporating Medication Related Overview – MRO
  - Healthcare Encounter Report – HCER
  - Expanding the Greek ePrescription Interoperability Framework
  - Creating the national connector for cross-border healthcare PS NCP-A
  - Proposing a Patient Consent framework
  - Proposing Patient Access and Patient engagement scenarios
SOHealth evolves the concept of re-usable Basic Common Components for eHealth. 

- Scale of deployment: National and Cross Border

### 4.7.1 Project Overview

SOHealth’s main approach is to support the nation-wide implementation of eHealth by demonstrating how the epSOS concepts and approach may be transferred at the national level around a service of added value to the national e-prescription project. Specifically, the main scientific and technological objectives of the proposed project are to:

- Define value added use cases for users and patients, focusing on medication summaries, built around the current national e-prescription priorities and projects implemented by IDIKA
- Introduce new innovative concepts of collaborative business models and value chain approaches to value added eHealth services
- Establish the business case for medication summaries as a value added service around the e-prescription national infrastructure (currently the pilot infrastructure with a view to migrating to the final national infrastructure)
- Establish proactively a firm, eHealth specific national interoperability framework of standards supporting implementation of e-prescription and medication summaries
- Improving trust and acceptability via an integrated Information Governance framework
- Establish, supported by the well-regulated consensus building processes of ELOT, a national stakeholder forum for eHealth, for the localization and adoption of EU standards emerging from projects like epSOS, STORK, Netc@rds and HPRO in the eHealth and social security domains
- Implement the technical components of electronic medication summary application
- Implement the semantic interoperability requirements to ensure patient safety
- Design, implement and test a practical technical solution (technical interoperability framework) which will enable the secure access to patient health information. The following basic modules (Basic Common Components) have been identified as key elements of any proposed solution:
  - Identification, authentication & authorization mechanisms (eID based solutions for healthcare practitioners and patients)
  - Security and trust enabling mechanisms (security and audit management subsystems)
  - Patient consent (policy management subsystem)
  - Semantic and syntactic interoperability between diverse codification systems (master code sets, master value catalogues, nomenclature and codification management)
  - User friendly GUI via explicit CDA Display tools that is compliant to epSOS specifications
- Demonstrate the practical implementation of the solution in a pilot application
- Evaluate the results of the practical implementation and draw the strategy for the commercial exploitation of the project outcome
- Disseminate the results to targeted audiences (policy makers, public and private healthcare provider organizations, etc.) and contribute to the development of relevant interoperability standards
Through this approach the project furthermore aims:

- **to build knowledge and excellence** in the research teams of AUTH and involved IT industry partners, though building capacities for policy support oriented research, which are effectively rather low in Greek technological research institutions.

- **To produce direct benefits for the two public sector organizations, IDIKA and ELOT** by means of embedding the results as part of their core activities and own innovation challenges.

- **To produce value** in terms of health benefits for citizens and quality of practice benefits for professionals.

- **To produce financial benefits** and contribute to the sustainability of the national health and social care system through preventing medication related errors and associated harm to patients. In addition indirectly support the national key service industry of tourism through embedding cross border eHealth into the national infrastructures and capabilities.

SOHealth was seconded by the work done during the Health in Action initiative from the Ministry of health which was led by WHO and supported by GIZ (Deutsche Gesellschaft fuer Internationale Zusammenarbeit (GIZ) GmbH) for the implementation of the eHealth Pillar. D5 “Study and recording of the current decentralised Electronic Patient Record systems in NHS hospitals; Suggestions for horizontal or vertical interconnectedness (umbrella); Description of the next steps” focused on proposing the needed specifications and interoperability architecture to create a national patient summary infrastructure.

### 4.7.2 Approach

Interoperability has been identified as one of the greatest challenges in healthcare IT. It is about bringing to life fruitful collaborations between different healthcare environments, with electronic means. Standards are essential in this context, but more is needed than just standards. In order to achieve end-to-end interoperability, an interoperability framework has to be set in place, maintained, and validated all the time. An interoperability framework is a living document. For such a document to be functional 4 domains needs have to be taken into account.

- **Need 1:** to set scope for now and in future. This is achieved by setting up and maintaining a current list of **use cases for health information exchange** that apply to day to day operation in the healthcare sector.

- **Need 2:** to outline the general distribution of responsibilities (technically and organizationally). This is done by proposing an overall **High-level Interoperability Architecture** which has to be independent from specific systems or entities.

- **Need 3:** to have “clear boundaries” so that different parties may develop and conform to these interfaces. This is achieved by proposing standard-based, industry-accepted, use case-driven **interoperability specifications**, detailed enough so that they can be tested, labelled, and certified.

- **Need 4:** to have “clear policies” for:
  - Health information exchange (e.g. privacy and security)
  - Governance rules for implementation (e.g. testing and certification)
  - Govern evolution of the framework
The domain of proposing and maintaining a complete National eHealth Interoperability framework is a time consuming, consensus based procedure. D5 of pillar 8 of the health in action program build upon those concepts and proposed a full interoperability architecture and framework. This case study emphasises the use cases related to patient summaries as defined in the EU eHealth Network Guidelines of November 2013, as an example that can be easily ported to any other future set of interoperability use cases. This document is an early adoption of terms and concepts proposed by the Antilope Project\textsuperscript{15} that are customised to support the Greek adoption of a patient summary framework for all Greek citizens. The result of this work was reused and emphasized by the SOHealth project which implemented a healthcare encounter report module based on HL7 FHIR, HL7 CDA and IHE XDS.

The set of specifications created for the implementation of the national patient summary are depicted below. Parts of those specifications were validated by IHE Europe interoperability experts.

1. Sharing Patient Summary Use Case Specification
2. Core Interoperability Specification for Sharing Patient Summaries
3. Security and privacy Interoperability Specifications
4. Patient Identification Interoperability Specification (not Patient Summary specific)
5. Document Sharing Interoperability Specification (not Patient Summary specific)
6. Patient Summaries Content Interoperability Specification
7. Patient Summaries Terminology Interoperability Specification (Value Sets)
8. Health information Exchange Policies (HIE policies and Security and Privacy Policies)
9. General terminologies for XDS registry

The Antilope layers of interoperability, as depicted in Figure 1 (page 13) were re-used as methodological pillars to reach a commonly accepted interoperability architecture for Patient summaries in Greece.

### 4.7.2.1 Care Process
The uses cases described in this case study are based on those proposed in the Antilope EU funded project. Antilope’s use cases have been studied to fit most European countries. Ideally, all Antilope Use cases are fitted for Greece. A thorough analysis though of each domain needs to be further processed in order to reach the needed level of information that will make the framework an operational tool in its totality (integration profiles, interoperability specifications, codifications, testing tools, etc.). This case study provides a deeper analysis of the patient summary use cases.

<table>
<thead>
<tr>
<th>#</th>
<th>Medical domain</th>
<th>Description</th>
<th>Scale</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Medication</td>
<td>e-Prescription and e-Dispensing</td>
<td>1a) Cross-border</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>1b) National</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>1c) Intra-hospital</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>1d) Citizens at home</td>
</tr>
<tr>
<td>2</td>
<td>Radiology</td>
<td>Request and results sharing workflow for radiology</td>
<td>2a) Regional</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>2b) Intra-hospital</td>
</tr>
<tr>
<td>3</td>
<td>Laboratory</td>
<td>Request and results sharing workflow for laboratory</td>
<td>3a) Regional</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>3b) Intra-Hospital</td>
</tr>
</tbody>
</table>

\textsuperscript{15} The Antilope Project, \url{http://www.antilope-project.eu/}
Patient Summary related use cases

There are two major categories of patient summaries: a) A summary of an encounter which is either related to a Hospital Stay (often called a Discharge Summary) or to an GP/Specialist visit and b) an aggregate view across multiple care providers/encounters: summarizing the up-to-date state of a patient health and on-going treatments. The epSOS project picked the aggregate view; nevertheless some of the participating countries instead of creating aggregate reports just share the most recent discharge/encounter summary. Picking one versus the other patient summary is a hot debate. Both have pros and cons and in fact both are needed for different reasons:

Pros of a summary of an encounter are amongst others that it is coherent and attested by a physician (that assumes responsibility), and the fact that it is actually a set of consistent and related information. On the other hand, the major drawback of this kind of encounter level PS is that access to an aggregate view requires the local point of care IT system to retrieve a set of encounter PSs and perform this overview if needed by the health professional. Meanwhile, an aggregate view across multiple care providers/encounters has the major advantage that it can serve as an easy entry point for getting an overview of a patient’s health but there are also drawbacks. Sometimes the aggregate view is imprecise for certain care situations, has no associated medical responsibility (aggregation is software driven) and it is quite challenging to handle textual data.

The next two Use Cases focus on the transferral of patient-related information, in the form of patient summaries. As has been described by IHE, patient summaries can be classified in three categories: collaborative, episodic, and permanent16:

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• **Collaborative**: A collaborative summary is defined as serving the interests of a specific provider by “providing the most relevant information about the patient”. A referral letter may serve as an example of this type of patient summary. This type of summary is the subject of Use Case 5a (i.e. Referral of patient from primary to secondary care).

• **Episode**: “Episodic summaries have the primary purpose of highlighting the most relevant details of focused periods of time in a patient history. Examples include discharge summaries”. A discharge summary is a concise summary of the recent episode, and highlights the diagnosis, therapy, and recommendations for further treatment at the end of a healthcare episode. It is a transfer of information, often to the primary healthcare professional that referred the patient to the specialist. This type of summary is the subject of Use Case 5b (i.e. Discharge report from secondary care).

• **Permanent**: Permanent patient summaries “summarize the entirety of a patient’s medical history and therefore cover a broader range of patient problems”. A permanent patient summary is often referred to in the context of a longitudinal medical record. It summarizes the medical history of the patient, and provides information about the current health status, including the actual discharge summary. A Patient Summary is meant as a general overview of the patient’s health history and current situation. It is a concise clinical document that provides an electronic patient health data set that is applicable both for unexpected as well as planned healthcare contact. The content of the patient summary is defined, at a high level, as the non-exhaustive data set of information needed for health care coordination and continuity of care. This type of summary is defined as a Patient Summary, and is the subject of Use Case 4a (i.e. cross border), 4b (i.e. national) and 4c (i.e. citizens at home).

All types of Summary contain information such as:

• **Demographic information** about the patient (e.g., name, birth date, gender)

• **A medical summary** consisting of the most important clinical patient data (e.g. medical history, past surgical procedures, allergies, current medical problems, medical implants)

• **A list of the current medication**. There is much debate as to what constitutes a “current medication list”. Generally, it consists of prescription and dispensing information. Information about the patient summary itself (e.g., author, date that the patient summary was generated).

<table>
<thead>
<tr>
<th>Table 9 – Patient Summary Use Case</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Title</strong></td>
</tr>
<tr>
<td><strong>Purpose</strong></td>
</tr>
<tr>
<td><strong>Domain</strong></td>
</tr>
<tr>
<td><strong>Scale</strong></td>
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</tbody>
</table>
### Business Case
For the exchange of medical information about a patient, a Patient Summary provides the participants in a healthcare pathway with the basic medical background information. In collaborative healthcare, in the transfer of a patient to another hospital, and in a multidisciplinary board review, the Patient Summary functions as the standardised information set of medical information. The structuring of basic information such as current medication, allergies, advance directives, diagnoses and therapies allows the different healthcare information systems to absorb the information from any other healthcare information system. The treatment of patients without proper medical background information is hazardous and should be avoided. This Use Case proposes a way towards solving this problem.

### Context
The growing number of chronic healthcare conditions, together with a more multidisciplinary approach to chronic disease management, have increased the need for the exchange of medical information between healthcare organisations and individuals. Since this involves the exchange of information between different healthcare information systems, a standardised patient summary containing the basic medical background information of the patient, in a uniform and structured manner, is seen as an important step towards healthcare integration.

Several countries in Europe are working towards a national set of structured and standardised data, to be used as starting point for a national Patient Summary.

There are challenges, though. The selection of data elements, the level of granularity, the terminologies and coding system, and the formatting of the message or document, depends on national principles and requirements, on legislation, architecture vision and on choices made in the past. It requires a lot of effort, and a lot of consensus, to get a broadly accepted (and implemented) Patient Summary.

In a number of countries, initiatives have been taken towards the definition of a national dataset for the exchange of health information. Typically, they start with the core pieces of medical information that are relevant to all healthcare professionals.

### Information
<table>
<thead>
<tr>
<th>Patient Summary</th>
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</thead>
<tbody>
<tr>
<td>Other information (referral note, specialism-related information, diagnostic studies, diagnostic study reports, etc.)</td>
</tr>
</tbody>
</table>

### Participants
<table>
<thead>
<tr>
<th>Patient</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physician in a healthcare organisation A</td>
</tr>
<tr>
<td>Physician in healthcare organisation B</td>
</tr>
</tbody>
</table>

### Workflow steps
The patient consults a health professional in a point of care site.

The HCP decides that the patient needs to receive surgical intervention in another healthcare organisation (healthcare organisation B)

The patient gives consent to the HCP for the sharing of the medical information with a HCP or specialist (role) in healthcare organisation B

The HCP refers the patient to an HCP in healthcare organisation B

An appointment is made in healthcare organisation B, and the patient consults the HCP there

The health professional retrieves the Patient Summary and uses it for the consultation. In the following two Realisation Scenarios, different methods are described, which can be briefly described as “push” and “pull”. These are actually simplified depictions of the actual workflow and technology involved in the exchange, but illustrate the fact that the same Use Case can be realised differently.

<table>
<thead>
<tr>
<th>Title</th>
<th>Patient Summary sharing with “push” of the information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Related Use Case</td>
<td>Patient summary sharing on a National/regional scale</td>
</tr>
</tbody>
</table>
**Scenario context**

In this Realisation Scenario, the Patient Summary (along with other necessary documents and/or images) is sent by information system A in healthcare organisation A to the information system in healthcare organisation B. This is sometimes being referred to as “push”. Usually, this will be the scenario, especially if the sender of the information knows exactly to which HCP and hospital the patient is referred.

**Actors**

- Document Source
- Document Consumer

**Transactions**

- Record patient consent
- Notification of document availability
- Sending of documents

**Information**

- Patient Consent
- Referral Note
- Patient Summary
- Other relevant documents

**Data flow**

- Storing of patient consent to repository
- Sending selected documents to remote location
- Viewing these documents from an external location

**Process flow**

Healthcare information system A (HIS A) stores the patient consent. After selection of the relevant documents by the HCP, HIS A sends the relevant documents to HIS B through a secure electronic connection. HIS B receives the documents, and stores them. It shows a notification for the HCP in healthcare organisation B.

**Associated profiles**

- Policy: --
- Process flow: --
- Information: XDS-MS (or other Patient Summary such as epSOS PS)
- IT Infrastructure: XDR
- Access control: BPPC

**Possible issues**

Governance of the data definition of the national Patient Summary

---

Table 11 – Patient Summary Realisation Scenario 2

<table>
<thead>
<tr>
<th>Title</th>
<th>Patient Summary sharing with “pull” of the information</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Related Use Case</strong></td>
<td>Patient summary sharing on a National/regional scale</td>
</tr>
<tr>
<td><strong>Scenario context</strong></td>
<td>In this Realisation Scenario, the Patient Summary (along with other necessary documents and/or images) is retrieved by information system B in healthcare organisation B from the information system in healthcare organisation A. This is sometimes being referred to as “pull”. In the case of an emergency intake of a patient, available information is drawn from another system. At the time of arrival of the patient in the A&amp;E department, no information about the patient is available.</td>
</tr>
<tr>
<td><strong>Actors</strong></td>
<td>Document Consumer</td>
</tr>
<tr>
<td></td>
<td>Document Registry</td>
</tr>
<tr>
<td></td>
<td>Document Repository</td>
</tr>
<tr>
<td><strong>Transactions</strong></td>
<td>Record patient consent</td>
</tr>
<tr>
<td></td>
<td>Requesting Patient Summary</td>
</tr>
<tr>
<td></td>
<td>Retrieval of Patient Summary</td>
</tr>
<tr>
<td><strong>Information</strong></td>
<td>Patient Consent</td>
</tr>
<tr>
<td></td>
<td>Patient Summary</td>
</tr>
<tr>
<td><strong>Data flow</strong></td>
<td>Store Patient Consent</td>
</tr>
</tbody>
</table>

---

17 Cross-Enterprise Document Reliable Interchange (XDR) provides document interchange using a reliable messaging system. This permits direct document interchange between EHRs, PHRs, and other healthcare IT systems in the absence of a document sharing infrastructure such as XDS Registry and Repositories.

18 Basic Patient Privacy Consents (BPPC) provides a mechanism to record the patient privacy consent(s) and a method for Content Consumers to enforce the privacy consent appropriate to the use. This profile complements XDS by describing a mechanism whereby an XDS Affinity Domain can develop and implement multiple privacy policies, and describes how that mechanism can be integrated with the access control mechanisms supported by the XDS Actors (e.g. EHR systems).
Request information from another healthcare organisation, including the patient consent
Retrieve Patient Summary

Healthcare information system A (HIS A) stores the patient consent
After selection of the relevant documents by the HCP, HIS A sends the relevant documents to HIS B through a secure electronic connection
HIS B receives the documents, and stores them. It shows a notification for the HCP in healthcare organisation B.

Policy: --
Process flow: --
Information: XDS-MS (or other Patient Summary)
IT Infrastructure: XDS, CT, ATNA, PIX/PDQ
Cross-domain: XUA, XCPD
Access control: BPPC

Possible issues
Governance, versioning of the Patient Summary.

4.7.2.1.2 Patient Summary Patient Access use cases
It was an important design decision that the epSOS project decided to support a patient’s access to his/her personal patient summary\(^{19}\). This is a service that adds value to the existing national patient access services. Therefore, the implementations of relevant requirements for patient identification, authentication and authorisation have been delegated to either regional or national access services.

Note: In the following Use Case description, some epSOS abbreviations are used:

- **NCP** stands for “National Contact Point”, which is the connection point for the information exchange between countries in the epSOS architecture.
- **epSPA** – epSOS Patient Access Service. In the original Use Case work, the epSOS Patient Access Service was abbreviated to *epSPA*. Later, when elaborating the Use Cases into Service Specifications (Deliverable D1.4.3_EED SERVICES including Specification for all services, the abbreviations **PAC** (Patient Access) is used for the same concept. In the project glossary, only the final abbreviation appears.

<table>
<thead>
<tr>
<th>Table 12 – Patient Access Use Case</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Title</strong></td>
</tr>
<tr>
<td><strong>Purpose</strong></td>
</tr>
<tr>
<td><strong>Domain</strong></td>
</tr>
<tr>
<td><strong>Scale</strong></td>
</tr>
<tr>
<td><strong>Business Case</strong></td>
</tr>
<tr>
<td><strong>Context</strong></td>
</tr>
</tbody>
</table>

\(^{19}\) A patient’s access to his/her personal patient summary is limited to the information created for the cross-border care. It is not about the access to the full patient summary in his/her home country.
should also receive access to their personal data. In addition, a patient should be supported by other value added services, in particular with an adequately translated version of his/her patient summary which s/he may in turn want to make available to medical service providers of his/her personal choice. The patient is in the case of epSOS only able to view his/her Patient Summary, not to add or record any data.

<table>
<thead>
<tr>
<th>Information</th>
<th>Patient Summary</th>
</tr>
</thead>
<tbody>
<tr>
<td>Participants</td>
<td>Patient at home or on the move</td>
</tr>
</tbody>
</table>

**Workflow steps**
The health professional in the country of the patient’s origin updates/produces the medical information used in the patient summary on the basis of an encounter.

Patient requests his or her patient summary from the national patient access service (through the secure web service of the NCP in country A). The national patient access service (including patient identification, authentication, and role authorisation) verifies that the patient access rights to the information, including his or her age, is sufficient to allow access to the data.

Patient requests list of available Patient Summaries.

The national patient access service provides the requested document/list of existing PSs for the identified patient.

Patient selects Patient Summary to consult through the NCP from country A. The epSPA/PAC service (see above) is invoked to produce a translation of the coded content of the document into the language of the country that is being visited. The PAC service uses the MTC (Master Translation/Translation Catalogue) for the language of the country visited, produced by that country.

NCP A requests data set of the Patient Summary to the NCP of the country that holds selected Patient Summary.

The patient receives the translated document.

The patient reads, copies, uses and distributes the document as he or she considers appropriate.

### Table 13 – Patient Access Realisation Scenario

<table>
<thead>
<tr>
<th>Title</th>
<th>Sharing a Patient Summary with a healthcare provider</th>
</tr>
</thead>
<tbody>
<tr>
<td>Related Use Case</td>
<td>Patient Summary sharing on a patient-level scale</td>
</tr>
</tbody>
</table>
| Scenario context | One possible way in which the patient may want to distribute the information is to give it to a new health professional on the occasion of a new medical encounter, whether this intervention is scheduled or unscheduled. This step is relevant only if the health professional does not, for some reason, have access to the patient summary.²¹

NOTE from epSOS: “It is important to note that the patient access service is a national prerogative. As such, neither functionality nor requirements there to are regulated by epSOS”. (quote from D4.E.1)

| Actors | PHR System
NCP-A (National Contact Point A, own country)
NCP-B (National Contact Point B, other country)
Translation Service |
|---|---|
| Transactions | Patient identification
Patient Summary retrieval |
| Process flow | Patient requests information about Patient Summaries via NCP-B using (for example) his/her PHR System. |

²⁰ This workflow is only valid for ePrescription and the patient summary. In Use Case Patient Access, the document will be translated into the language of the home country of a patient. For example, an Austrian patient will receive ePrescription and the patient summary always in German.

²¹ Suitable mechanisms that meet organisational information security policies would need to be agreed.
Patient is authenticated by the NCP-B.
Patient requests Patient Summary from country A.
NCP presents the selected Patient Summary.
*Translation* of the selected Patient Summary in country A is made available by a Translation Service.

**Associated profiles**
- Policy: --
- Process flow: --
- Information: XPHR, RTM (translation)
- Infrastructure: XDS (Consumer), ATNA, CT, XCA
- Access control: BPPC, XUA(++)

**Possible issues**
- Document management: when the HCP makes a copy of the Patient Summary, is the provenance of that document safeguarded?
- How to determine that the patient is who s/he says s/he is (authentication)
- Does patient authentication provides same level of trust and security of HCP’s authentication?

For more issues/disadvantages of patient access please see D3.2.2. of epSOS 4.7.2.1.3

### 4.7.2.1.3 Patient Consent Use Cases

#### Table 14 – Patient Consent Use Case

<table>
<thead>
<tr>
<th>Title</th>
<th>patient consent</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Purpose</strong></td>
<td>The purpose of this use case is to develop realization scenarios of electronic patient consent so that authorized users can have access to patient data only in the case the patient has given consent.</td>
</tr>
</tbody>
</table>
| **Domain**      | Medication
                 - Patient Summary
                 - Multidisciplinary consultation |
| **Scale**       | National/Regional
                 - Intra-hospital
                 - Cross-border
                 - Citizens at home and on the move |
| **Business Case** | EU Directive 93/46/EC and the Greek legal transposition (N2472/97) demand that the patient has full knowledge on who is handling his sensitive data, and associated healthcare information. The process can be implemented into the following ways:
  - An opt–in approach where a patient consent mechanism is available to patients and citizen to use and depict their level of consent. This is an active patient consent where the patient can select different rules that may apply to his data fully or partially (users, geography, time frames, etc.). If the patient is nor giving himself or delegates in legal terms the consent to access the data, his data will not be reachable, until he decides so.
  - An opt–out approach where a preselected patient consent profile has been applied to all citizen. Those who are not in favor of this public profile may use specific tools to ban access to his information per case, for specific periods, etc.
  Both options but especially the second option require a strong auditing process that monitors the access to the patient’s information and to which s/he need to have a view and be informed of his/her medical information use. |
| **Context –**   | There are implemented scenarios in other European countries (Denmark, Portugal). There are international standards to design and implement access control as well as security and policy procedures. There are audit trail standards that can establish security measures which, together with Security Policy and Procedures, provide patient information confidentiality, data integrity and user accountability (ex. IHE ATNA). |
Information

| Patient Summary |
|-----------------|------------------|
| Healthcare Provider Registries |
| Access Control Rights |

Participants

| Patients |
| Healthcare professionals |

Workflow steps

In the opt-out scenario, a global predefined patient consent mechanism is applied to all citizens. When a healthcare encounter occurs, the patient reaffirms his/her consent (informed consent) with the HCP. If the patient wishes s/he has the ability to access the patient consent mechanism and alter the rules to access his information. The set of possible rules should be legally attested and validated. A break glass approach should be legally described to access information in case of emergency or other legally constrained situation.

In case of the opt-in scenario, no healthcare encounter can be monitored or documented if no patient consent path is depicted by the patient. Patient is informed that restraining access to his/her medical information may be life threatening in certain conditions and s/he assumes full responsibility.

Break glass policy may legally apply by law.

The patient can enter the patient consent system and establish a patient consent policy, or revoke an existing one.

Break Glass procedure should apply by law in the following cases:

- Emergency healthcare delivery
- Delegation procedure should be foreseen to allow relatives or foster individuals to allow access on behalf of patient (age criteria, mental health criteria, consciousness criteria, etc.)
- Other extreme legal situation (public health issues, etc.)

Table 15 – Patient Consent Realisation Scenario

<table>
<thead>
<tr>
<th>Title</th>
<th>Patient consent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Related Use Case</td>
<td>Patient Consent</td>
</tr>
<tr>
<td>Scenario context</td>
<td>EU regulation on sensitive data access. The most commonly used approach in European countries is the opt-out approach.</td>
</tr>
<tr>
<td>Actors</td>
<td>Patient National Common components infrastructure</td>
</tr>
<tr>
<td>Transactions</td>
<td>Patient identification Patient Consent or Patient consent revocation</td>
</tr>
<tr>
<td>Process flow</td>
<td>Patient accesses the patient consent facility and sets up his/her personal profile. Patient accesses the patient consent facility and revokes consent. Patient may give or revoke patient consent at the point of care via the point of care systems. Patient may delegate a third party for handling his consent (relative, healthcare providers, etc.)</td>
</tr>
</tbody>
</table>
**Possible issues**

| Patient consent regulation must be compliant with EU and Greek regulation. |
| HPC should not be excluded from providing care via patient consent mechanisms. |
| Patient consent is informed, thus, it refers to the proven knowledge on who is accessing the information and for what purpose. |
| How to determine that the patient is who he says he is (authentication)? |

### 4.7.2.2 Information

A series of healthcare encounter reports need to be collected, to create the aggregated view of the patient summary. The Greek Patient summary proposes to use CDA formats. HL7 FHIR was proposed as an REST API that is mapped server-side to a CDA document to facilitate creating the summary from encounter reports. The implementers must be familiar with the content of the following documents:

- The 1st DSTU version (v0.0.82) of HL7 FHIR protocol, specifically: Resource List (Clinical, Administrative & Infrastructure)
- Integrating the Healthcare Enterprise, Patient Care Coordination CDA Content Modules-Trial Implementation Supplement, August 10, 2009.

#### 4.7.2.2.1 The Patient Summary encounter reports

The encounter reports presented in this case study are:

- Medical Doctor’s (GP) Office encounter report
- Hospital Discharge Letter
- ePrescription

Table 16 below depicts the information that needs to be registered when a patient pays a visit to a GP and the corresponding FHIR resource to be used to code this piece of information. It is obvious from this table that some of the initially identified pieces of information from the Encounter Report are already part of the FHIR Resource structure, for example “Date” and “Reason of Visit” though identified as separate “entries” in the Encounter Report (and in epSOS Patient Summary where this structure comes from), they are both (correctly) included in the Resource “Encounter”. The same happens with the Administrative and other information of the Patient who is all in the “Patient” resource and also regarding information like “Vital Signs”, “Physical Findings”, “Lab Results” etc., which are parts of the Resource “Observation”.

Another (similar) remark is about the “Active Problems” and “Medical History” entries. These have been “assigned” to the “List” resource, as it is not a single entry, but rather a list of entries i.e. a set of information summarized from a list of other resources (see the “List” resource).

**Table 16 – FHIR Resources for Medical Doctor’s Office Encounter Report (MDO-ER)**

<table>
<thead>
<tr>
<th>Data Element</th>
<th>FHIR resource</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date</td>
<td>Encounter</td>
</tr>
<tr>
<td>Data Element</td>
<td>FHIR resource</td>
</tr>
<tr>
<td>--------------------------------------------------</td>
<td>--------------------------------</td>
</tr>
<tr>
<td>Reason of Visit</td>
<td>Encounter</td>
</tr>
<tr>
<td>Medical History of present problem</td>
<td>Encounter</td>
</tr>
<tr>
<td>Active problems</td>
<td>List / Condition</td>
</tr>
<tr>
<td>Active medication</td>
<td>MedicationPrescription</td>
</tr>
<tr>
<td>Allergies</td>
<td>AllergyIntolerance</td>
</tr>
<tr>
<td>Medical History of previous diseases</td>
<td>List</td>
</tr>
<tr>
<td>Surgeries-Operations</td>
<td>Procedure</td>
</tr>
<tr>
<td>Vaccinations</td>
<td>Immunization</td>
</tr>
<tr>
<td>Family History</td>
<td>FamilyHistory</td>
</tr>
<tr>
<td>Social History</td>
<td>Observation</td>
</tr>
<tr>
<td>Vital Signs</td>
<td>Observation</td>
</tr>
<tr>
<td>Physical Findings</td>
<td>Observation</td>
</tr>
<tr>
<td>Lab test results</td>
<td>Observation</td>
</tr>
<tr>
<td>Treatment plan (new medication, order lab tests, etc.)</td>
<td>CarePlan</td>
</tr>
<tr>
<td>Doctor/Facility Details (AMKA, Specialty etc.)</td>
<td>Practitioner</td>
</tr>
<tr>
<td>Patient Identification (AMKA)</td>
<td>Patient</td>
</tr>
<tr>
<td>Patient Demographic Details (Address, Phone No etc.)</td>
<td>Patient</td>
</tr>
<tr>
<td>Patient Insurance details</td>
<td>Patient</td>
</tr>
</tbody>
</table>

**Table 17 – FHIR Resources for Hospital Discharge Letter Encounter Report (HDL-ER)**

<table>
<thead>
<tr>
<th>Data Element</th>
<th>FHIR resource</th>
</tr>
</thead>
<tbody>
<tr>
<td>Admission Date</td>
<td>Encounter</td>
</tr>
<tr>
<td>Discharge Date</td>
<td>Encounter</td>
</tr>
<tr>
<td>List of Physicians during hospitalization (using AMKA, AFM, Name and Specialty)</td>
<td>List / Practitioner</td>
</tr>
<tr>
<td>Discharge Letter Details (Year and Doc No.)</td>
<td>Encounter</td>
</tr>
<tr>
<td>Admission Diagnosis (one or more)</td>
<td>List / Condition</td>
</tr>
<tr>
<td>Medical History of Present Problem</td>
<td>List</td>
</tr>
<tr>
<td>Discharge Diagnosis (one or more)</td>
<td>List</td>
</tr>
<tr>
<td>Medication during hospitalization</td>
<td>MedicationPrescription</td>
</tr>
<tr>
<td>Allergies</td>
<td>AllergyIntolerance</td>
</tr>
<tr>
<td>Vital Signs</td>
<td>Observation</td>
</tr>
<tr>
<td>Relative Diagnostic Tests and Reports</td>
<td>Observation / Diagnostic Report</td>
</tr>
<tr>
<td>Treatment Plan</td>
<td>CarePlan</td>
</tr>
<tr>
<td>Surgeries-Operations</td>
<td>Procedure</td>
</tr>
<tr>
<td>Hospital Details</td>
<td>Organization</td>
</tr>
<tr>
<td>Patient Identification (AMKA)</td>
<td>Patient</td>
</tr>
<tr>
<td>Patient Demographic Details</td>
<td>Patient</td>
</tr>
<tr>
<td>Patient Insurance Details</td>
<td>Patient</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Data Element</th>
<th>FHIR resource</th>
</tr>
</thead>
<tbody>
<tr>
<td>ePrescription Date</td>
<td>Encounter</td>
</tr>
<tr>
<td>Prescribing Physician</td>
<td>Practitioner</td>
</tr>
<tr>
<td>Dispensation Date</td>
<td>Encounter</td>
</tr>
<tr>
<td>Diagnosis</td>
<td>List / Condition</td>
</tr>
<tr>
<td>Medication</td>
<td>MedicationPrescription</td>
</tr>
<tr>
<td></td>
<td>MedicationDispense</td>
</tr>
<tr>
<td></td>
<td>MedicationAdministration</td>
</tr>
<tr>
<td>Allergies</td>
<td>AllergyIntolerance</td>
</tr>
<tr>
<td>Surgeries-Operations</td>
<td>Procedure</td>
</tr>
<tr>
<td>Pharmacist Identification &amp; Details</td>
<td>Practitioner</td>
</tr>
<tr>
<td>Patient Identification (AMKA)</td>
<td>Patient</td>
</tr>
</tbody>
</table>
The content and corresponding FHIR resources are based on the combination of the Greek Healthcare environment and the epSOS Patient Summary Guidelines. As a consequence those specifications reuse and propose a solution to create a universal healthcare encounter report mechanism for any healthcare encounter related to patient summary that covers in full the European guidelines for patient summary implementation. As such, those specifications also cover cross border healthcare and the use of the Greek patient summary for that purpose.

4.7.2.2 Patient Summary Data Model
The patient summary data model follows the proposed EU guidelines for cross border patient summaries.

4.7.2.3 Applications
Medical information for the Greek patient summary follow a list of IHE integration profiles, which are part of a high level interoperability architecture. The high level Interoperability Framework and Basic concepts document proposes a stable national eHealth Interoperability framework for eHealth in Greece. This framework is further refined by an analysis of the Use Cases that need to be supported to cover the needs in eHealth, and result in Greek Interoperability Specifications based on selected profiles and the underlying standards. These Interoperability Specifications not only reference such profiles and standards but also localise them for the Greek context to meet regulations, local terminology needs, and processes. In the context of the Sharing Patient Summary Use Case, a set of related specifications are involved:

![Diagram of Interoperability Specifications (IS) related to the Patient Summary Use Case](image)

**Figure 56: Example of Interoperability Specifications (IS) related to the Patient Summary Use Case**

The scope of this section is to address the Core Interoperability specifications for the Patient Sum-
mary Use Case. It is the point of entry into the Interoperability Specifications, organizing the various supporting Interoperability Specifications that address specific elements of the Use Case. It provides the core references to the Integrating Healthcare Enterprise (IHE) Profiles involved in the realization of the Patient, as well as reference to other Standards such as Health Level Seven (HL7) and vocabulary required by this Core IS or the supporting ISs.

![Figure 57: Core Interoperability specifications for the Patient Summary Use Case](image)

**Table 19 – Interoperability Conformance Requirements for Clinical Summaries Content Creator**

<table>
<thead>
<tr>
<th>SHARING Summaries</th>
<th>OF PATIENT</th>
<th>Mapping to Technical Constructs of Interoperability Specifications</th>
</tr>
</thead>
<tbody>
<tr>
<td>Use Case Actor</td>
<td>Service Supported</td>
<td>Opt</td>
</tr>
<tr>
<td>Clinical Summaries Content</td>
<td>Publish Document(s)</td>
<td>R</td>
</tr>
</tbody>
</table>
### Table 20 – Interoperability Conformance Requirements for Clinical Summary Content Consumer

<table>
<thead>
<tr>
<th>SHARING OF PATIENT Summaries</th>
<th>Mapping to Technical Documents of Interop. Specifications</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Use Case Actor</strong></td>
<td><strong>Service Supported</strong></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

R=Required, O = Optional, C= Conditional

Note 1: Required if the Clinical Summary Content Creator is serving a Secondary or Tertiary Care Facility

Note 2: Required if the Clinical Summary Content Creator is serving a Primary Care Facility

Note 3: Required if the Clinical Summary Content Creator is sharing unstructured content

Note 4: Required if the Clinical Summary Content Creator is serving the national Prescription System

---

22 Reserved for Future Use (RFU)
<table>
<thead>
<tr>
<th>Use Case Actor</th>
<th>Service Supported</th>
<th>Opt Technical Actor</th>
<th>OPT</th>
<th>PROFILE/Standard</th>
<th>Referenced Specification and Comments</th>
<th>REFERREMENT #</th>
</tr>
</thead>
<tbody>
<tr>
<td>Content Consumer</td>
<td>R</td>
<td>HL7 CDA R2</td>
<td>ER</td>
<td>Patient Summaries Content Interoperability Specifications – Section 1.3 ePrescription Encounter Report (eP-ER)</td>
<td>GRCC-0023</td>
<td></td>
</tr>
<tr>
<td>Content Consumer</td>
<td>R</td>
<td>HL7 CDA R2</td>
<td>ER</td>
<td>Patient Summaries Content Interoperability Specifications – Section XXX Dispensation</td>
<td>GRCC-0024</td>
<td></td>
</tr>
<tr>
<td>Content Consumer</td>
<td>R</td>
<td>IHE – Cross-Enterprise Scanned Document (XDS-SD)</td>
<td>ER</td>
<td>Patient Summaries Content Interoperability Specifications – Section YYYY PDF Document</td>
<td>GRCC-0025</td>
<td></td>
</tr>
<tr>
<td>X-Service User</td>
<td>R</td>
<td>IHE – Cross-Enterprise User Assertion (XUA)</td>
<td>ER</td>
<td>P8_D5.6_3 Security and privacy Interoperability Specification 3.4.1</td>
<td>GRCC-0026</td>
<td></td>
</tr>
<tr>
<td>Secure Node</td>
<td>R</td>
<td>IHE Audit Trail and Node Authentication (ATNA)</td>
<td>ER</td>
<td>P8_D5.6_3 Security and privacy Interoperability Specification 3.2 and 3.3.2</td>
<td>GRCC-0027</td>
<td></td>
</tr>
<tr>
<td>Time Client</td>
<td>R</td>
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### Table 21 – Interoperability Conformance Requirements for On-Demand Document Source

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<th>Technical Actor</th>
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<th>Referenced Specification and Comments</th>
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R=Required, O = Optional, C= Conditional

### Table 22 – Interoperability Conformance Requirements for Document Registry

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R=Required, O = Optional, C= Conditional
### Table 23 – Interoperability Conformance Requirements for Document Repository

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### 4.7.2.4 IT Infrastructure

#### 4.7.2.4.1 A modular approach for interoperability architecture

The proposed interoperability architecture is enabling all types of existing systems to participate and exchange information under one unique information model. The next figure represents this architecture with the different flavours of exchanging data. For this to happen, a certain number of common components need to be at a central level reachable for all point of care systems irrespectively of their physical location, technical complexity, technological model or other specificity driven by point of care variations. Those common components may reside in one physical location or be located in various locations interconnected through telecommunication protocols. In this way existing systems can be widely reused reducing both the time and implementation cost of a national eHealth strategy in Greece.
Some parameters to take into accounts that are analysed next:


- Semantic interoperability relies on the reuse of terminologies widely used in Europe and tested in the epSOS reference implementation on Patient Summary that either are used in Greece or can be mapped to national similar terminologies.

- Organisational interoperability is supported by the use of Integrating the Healthcare Enterprise (IHE) integration profiles, where those profiles exist and are applicable to the Greek context. Where this is not the case, other profile based solutions may be used.

- Collectively, the above define a standards-based data services fabric or maintenance shop referred as the eHealth Platform.

- For the eHealth Platform to operate in the future an operational model need to be foreseen where standardization, testing and specification tasks are clearly allocated. Different models may be analysed for this. Some examples:
  - Assign the tasks to one of more MOH entities to act as competence centres and custodians. Such organisations may already exist such as AEMY SA, EKAPTY SA or other or may be created as a fusion of other entities and departments.
  - Assign some tasks to SDOs and or other accredited bodies under the hospice of the ministry of health.
  - Assess the model of operation proposed by EXPAND at a European level to support and expand epSOS functionalities.
• Underpinning the architecture is a services based approach, where a service can defined as specific functionality that can be invoked using defined interfaces that are implementation agnostic – such as web services, REST, JSON, HL7 FHIR or other technologies.

• Where electronic patient records, electronic medical record or electronic healthcare records are established at the point of care those may use the EHR System Functional Model (ISO/HL7 10781:2009), which also helps to categorise services required in interoperability scenarios.

• The Registry-Repository Model (e.g. IHE XDS) will provide a solution to the problem of locating information quickly at a regional and national level.

• The core of the interoperability architecture is based on the IHE IT Infrastructure which is represented by the Cross-Enterprise Document Sharing (XDS) profile. From the IHE Wiki23, Cross-Enterprise Document Sharing (XDS) is focused on providing a standards-based specification for managing the sharing of documents between any healthcare enterprise, ranging from a private physician office to a clinic to an acute care in-patient facility and personal health record systems. This is managed through federated document repositories and a document registry to create a longitudinal record of information about a patient within a given clinical affinity domain. These are distinct entities with separate responsibilities:
  o A Document Repository is responsible for storing documents in a transparent, secure, reliable and persistent manner and responding to document retrieval requests.
  o A Document Registry is responsible for storing information about those documents so that the documents of interest for the care of a patient may be easily found, selected, and retrieved irrespective of the repository where they are actually stored.
  o Documents are provided by one or more Document Sources
  o They are then accessed by one or more Document Consumers.

• The model is based on the concept of Affinity Domain; a group of healthcare enterprises that have agreed to work together using a common set of policies and share a common infrastructure. This fact implies that the XDS model is not just a technological artefact, but it crosses to the organizational and policy domains.

• Regional Clinical Data Repositories are not excluded if such need arises and then, will follow a registry-repository model; this will support a federated approach, allowing that national systems be frontline repositories. This approach improves data quality by preserving the authoritative data source. The use of the XDS.b registry will ensure fast response times of patient information and provide granular security of the information.

• HL7 CDA documents form the common coin of exchange. Mapping to the Exchange Content Model, CDA documents carry the clinical information being transferred, with the services around them providing the workflow.

• Point of care systems should be certified and be compliant within a predefined period of time.

• The IHE Audit Trail and Node Identification (ATNA) profile should be considered the basis for audit of information exchange.

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• Edge systems and exchange services shall have support for consent directives in the exchange of health information. This includes the ability to record consent directives, attach them to subject health information as necessary, and at all times respect and enforce them.
• Document messaging point-to-point shall adhere to XDR/XDM integration profiles, especially in patient mediated scenarios.

4.7.2.4.2 Assessing the interoperability architecture in practice: the case of the patient summary

4.7.2.4.2.1 Patient Summary

As described earlier the patient summary has two forms: One form being the list of encounter summaries and the other the aggregated view of all existing summaries.

A Patient Summary Service allows creation and access to a standardized set of basic medical data that includes the most important clinical facts required to ensure safe and secure healthcare. This data is intended to aid health professionals in providing better coordinated care as well as unscheduled care. An encounter summary (e.g. GP visit, hospital discharge, etc.) consists of general information and clinical patient data (e.g. allergies, current medical problems, implants, or major surgical procedures, current prescribed medications.

This service should ensure that:

• health professionals' access to information either from specific encounter or review and aggregate information across time
• Professionals’ Attribution, consistency, and accountability
• Patients’ control over access to shared information

The schema in Figure 59 depicts the interoperability architecture for the patient summary services. The proposed architecture implies that both types of summaries are necessary.
Each point of care system is creating the same or a portion of what is described as an encounter report, by using the same information model, thus the same CDA document, the same taxonomies and codifications. As such, different type of healthcare providers may extract different information related to the patient summary.

Those are collected and indexed in an XDS repository using XDS metadata. XDS metadata are described in the interoperability specification of the document. From those encounter reports (can be...
into two formats depending on the maturity of the point of care system, either in coded format as a CDA R2 L3 or with a scanned or automated printed version as a CDA R2 L1), an aggregated version of the patient summary is created through an XSLT transaction. This model seems to be better suited and operates in a push fashion. Additionally, as stated before, the XDS affinity domain allows multiple repositories and the sharing of pointers to repositories thus keeping the information at the point of care and use pointers to indicate the source of the information. This model refers to implementing a federated XDS affinity domain where the information is pulled from the data consumers each time they need the information.

4.7.2.4.2.2 Extending the Patient Summary Interoperability architecture

By expanding this approach, other clinical data repositories expected for patient summary repositories can be served at the same time. Namely:

- **Population of public health data.** IHE QRPH domain and its profiles can be used to expand the architecture and integrate public health data reporting.
- **Population of Healthcare analytics systems** for business intelligence. All IHE domains need to be assessed to finalize the list of needed profiles, thus standard XDS profile can provide an operable solution.
- **Send and Get prescription and dispensation documents in the ePrescription system as encounter reports** directly from the edge systems. For this, the extended XDS profiles within the pharmacy technical framework of IHE could be assessed to enable more complex workflow such as hospital medication records, pharmaceutical advice, etc. **IHE PHARM** has published the following profile supplements for implementation:
  - Common Parts Document
  - Community Medication Prescription and Dispense [CMPD]
  - Hospital Medication Workflow [HMW]
  - Pharmacy Dispense [DIS]
  - Pharmacy Pharmaceutical Advice [PADV]
  - Pharmacy Prescription [PRE]
- **Send reimbursement and prior authorization reports** to EOPYY to populate the insurance health record. For this scenario **IHE PAM** profile needs to be assessed, already used in that context in France and Germany.
- Reuse the IHE XDS affinity domain to exchange other type of documents in order to move from a patient summary aggregator to an EHR aggregator for each citizen. **IHE XDS-I** and **IHE XD-LAB** can expand the clinical data repositories with imaging and laboratory data.
- All the relevant IHE profiles can be located at http://wiki.ihe.net/index.php?title=Profiles#IHE_Patient_Care_Coordination_Profiles

4.7.2.4.2.3 Independence from physical location

The proposed architecture is totally independent from any technical or physical constraints. XDS repositories may be centrally managed, or allocated and federated to healthcare regional authorities. They can reside in cloud-based structures in a public, private or hybrid cloud model. In the case of Greece, the patient summary e-service may be located in the institutions below, each of them having pros and cons for their selection:

- **IDIKA data centre** is one obvious option since many common components such as eID, securi-
ty, logging and others may be collocated for both ePrescription and Patient summary. IDIKA is also running a prototype implementation of a patient summary under the SOHealth project.

- EOPYY data centre since by law EOPYY is appointed the National contact point for cross border healthcare, where the patient summary case is nominated as one of the two predefined and tested use cases.
- AEMY which is a primary care institution fully digitised and having an ISO 27001 assessed security model.
- EDET is one of the nominated G-cloud repositories to which MOH has ongoing agreements for elearning and imaging storage scenarios.
- Information Society SA is already hosting some of the regional healthcare information systems on behalf of the MOH.
- Taxisnet if the last G-cloud elected governmental site to host eGov applications.

In any of the above cases network connectivity and PKI enabled cryptography can be assured by the eGov VPN named syzeyxis.

4.7.2.4.2.4 Linking IHE profiles to the patient summary architecture
Finally, the next figure depicts the patient summary interoperability architecture where all IHE profiles are annotated.
4.7.2.4.3 Security and Data Privacy Basic Services Concepts

4.7.2.4.3.1 Trust and Security Services

The current security and privacy policies and practices of the Greek ePrescription service are being reviewed and strengthened to support generalized eHealth applications and secure an appropriate Circle of Trust (CoT). The CoT is established by legal means and is subsequently implemented technically. At the technical level, it consists of mutually trusted nodes (health service providers and regional OPSY) consuming and providing information. Each linked system will be publishing a Trust...
Service List (TSL) containing the endpoint address of the services offered and the digital certificate in order to safeguard the authenticity and integrity of the connection. This aspect is enabling nodes to work in a directed manner and to avoid any broadcast-alike behaviour.

Data exchange will be based on a security and privacy policy and application specific safeguards. Transmission will be over the public internet with additional security measures based on international standards and protocols for handling sensitive information, that enable information handling and sharing.

Data sharing between healthcare practitioners will be enabled via a patient consent mechanism.

Parties that are members of the Circle of Trust are expected to implement and be audited against Information Security requirements. All transactions regardless of whether in the role of a service consumer or provider are logged to document all critical message exchange operations. Patients will also access these logs. All information transmission nodes will be monitored and audited.

The security policy of the organizations will be based on a risk assessment and deployed through Information Security management systems commissioned by service providers. Such systems will be subject to external audit focusing on system and data security. Base service information providers (IDIKA, Regional Healthcare Authorities, etc.) should be certified for secure information handling and storage procedures (i.e. ISO 27001 or similar).

4.7.2.4.3.2 II. Electronic Identification Services
Identity management, i.e. the allocation of a unique identifier (token) and additional attributes (traits) to the concerned actors (citizens/patients and their informal carers, health professionals and healthcare providers and payers is a pre-requisite for trustful eHealth Services.

Electronic identification services also includes Authentication, i.e. the process of validating the identity token inclusive of its attributes in the context of a healthcare or social service and Authorisation, i.e. the permission to access health information such as patient summaries or – in general – to fulfil a particular function or task within the social, healthcare or eHealth Service by a person (or organisation) that is identified as competent to access this information.

The process of granting access rights to personal health data is also linked to patient consent. The current authentication and access practices of the ePrescription service will be reviewed and aligned to the security and Circle of Trust (CoT) policies and extended to also address patient consent.

It should be also noted that the eID Regulation specifies the criteria for National systems to be notified to the EC and hence suitable for cross border services. Aligning the national electronic identification services framework to the Regulation is expected to be a horizontal national activity, which shall however have influence on the review of e-Identification services associated to the current e-Prescription service.

4.7.2.4.3.3 III. Trusted Sources
Health Professional roles – as defined by professional qualifications, status (e.g. employed by a hospital, managing a ward) and current responsibilities (e.g. providing emergency services across the whole hospital) would determine the right to access health data.
As a first step, the national eID framework will address implementation of policies and legislation. For this it will rely on the availability of trusted sources in the form of professional registries managed and maintained under the responsibility of the national regulatory professional organizations representing the 5 health professions regulated in Directive 2005/36/EC – doctors, nurses, pharmacists, dentists and midwives.

The current status of professional registries in Greece varies considerably across the professional organizations. In order to implement this first Authorization step, criteria for their functionality and trustworthiness of their content need be set together with an assessment against these criteria and a roadmap of actions towards fully trusted sources for participation in the national eHealth system of services.

4.7.3 Concurrent Use of Standards and Specifications (De-facto Standards)

The Greek Patient summary case study revealed two main challenges regarding concurrent standards and specifications as reflected in the implemented component systems:

1. lack of proper terminologies in Greece
2. immaturity of information systems implementers into following interoperability architecture.

As such the following remedies where proposed:

1. For the terminology part, patient summary clinical data where mapped to epSOS Master Value Catalogue. Where terminologies or codifications where inexistent, the terms of epSOS were adopted. Where other terminologies were used, they were mapped to epSOS MVC.
2. For the immaturity of interoperability implementation, this case study proposed to use a simplified approach based on HL7 FHIR, to allow simple web calls via REST architecture. This requires minimum implementation skills for the point of care systems implementers and made easier the integration of data sets into their own data schemes or data bases. From an architecture point of view a server side FHIR server allows the proper transformation of FHIR resources to HL7 CDA documents. The use of CDA is needed for two main reasons:
   a. Full compatibility with epSOS Patient summary CDA documents to allow cross border healthcare information exchange
   b. Establishment of an IHE XDS network to allow future exchange and document discovery over a National healthcare network. This requires the establishment of a structured XDS metadata model to allow this information exchange. The patient summary case study proposed both a full OID structure for the CDA documents, and an initial set of XDS metadata to be expanded for additional use.

The software architecture for this was introduced in a previous section of this document.

4.7.4 Governance

The Patient summary case study also proposed a full governance model that may be replicated for the further eHealth scenarios. In order to address interoperability challenges, it is necessary to establish a continuous collaborative process, which will allow for extensive synthesis around the diversity of issues and the many visions of the key stakeholders. The breadth and complexity of the issues that need to be addressed as well as the integrity imperative for such a process require that Governance
for eHealth to be set up. The governance framework should support effectively innovation in both the ICT and health services sector. In this highly dynamic environment this framework should provide for regular review and update.

A four layer governance is established to co-ordinate the diverse activities and maintain a common vision and alignment. The eHealth governance addresses concurrently legal, organizational, semantic and technical interoperability challenges. Funding for this structure should be budgeted and secured within the eHealth fiscal plan.

**Figure 61: From policy to adoption: a four layered eHealth Governance approach**

### 4.7.4.1.1 National Governance Council for eHealth

**ESDHY** is established by means of a Ministerial Decision, as an advisory body to the Minister of Health, supervised by the General Secretary for Public Health. Its regular memberships have been defined by the MoH Ministerial decree of 6 November 2015 (No85140) is consisted of the Secretary General for Public Health as the Chairman as the rest of the members appointed as below:

1. One member from the Minister of Health Bureau,
2. One member from Associate Minister of Health Bureau
3. One member from the General Secretariat of the Government (Prime Minister’s Office)
4. One member from the eGovernment department of the MoH
5. One member from GRNET (Greek Research Network – EDET)
6. One member from the Social Security eGovernment Center (IDIKA)
7. One member from the Greek National Security Fund (EOPYY)
8. One member from Information Society SA (KtPAE)
9. One member from National Health technology and assessment institute (EKAPTY)
10. One member from HL7 Hellas
11. One member from Ministry of Interior and Administrative Reconstruction
12. One member from the General Secretariat of Research and Technology
13. One member from the Athens Medical Society
14. One member from the Greek Free/Open Source Software Society (ELLAK)

Other Representatives of eHealth Stakeholders — health professionals, payers, scientific organizations, patients and industry may also invited to its meetings. The eHealth Strategy, eHealth priorities and associated policies are elaborated at the policy level within the National Council for eHealth Governance (ESDHYY) and are major enablers to drive successful implementation. These are catered to by two Standing Committees operating within ESDHYY: the eHealth Strategy Committee and the Legal and Organizational Committee.

4.7.4.1.2 Executive Secretariats for eHealth—the programme office
ESDHYY may also establish two Executive Secretariats to manage technical and semantic interoperability activities: The Executive Secretariat for Semantic Interoperability with the mandates to coordinate the semantic interoperability activities and the Executive Secretariat for eHealth Standardization with the mandate to coordinate the technical interoperability activities, including interoperability testing and Certification. Together with the ESDHYY executive secretariat they will act as the day to day operation coordination unit for the implementation of the National eHealth Strategy and action plan.

4.7.4.1.3 Purpose Specific Work Groups
Implementation projects follow guidelines to be released by ESDHYY and rely upon a set of published technical specifications and semantic assets. These are elaborated within Purpose Specific Work Groups, the composition and scope of which are proposed by the respective Secretariats and approved by the ESDHYY. The implementation projects in addition rely on the national eHealth Infrastructure that should be completed and operated effectively and to a sufficient level of capacity to support Competence Centers and other implementers.

4.7.4.1.4 Competence Centers
Competence centers are organizations with the technical and organizational capacity and expertise to address the challenge of implementing one or more areas of eHealth. Such competences may already exist, for example in IDIKA for implementation of national eHealth services and ELOT for standardization or emerge in the process of eHealth implementation projects. For example, the Athens Medical Society for the electronic clinical protocols, clinical reference centres for integrated care management, organizations addressing Interoperability and quality labelling (i.e. HL7 Hellas, etc.) or the production and/or localization of semantic assets. Whether under the direct oversight of the Ministry of Health or other government or non-government sectors, their priorities and activities related to eHealth will be coordinated by ESDHYY and its standing co-ordination Secretariats.

4.7.4.1.5 National Partners
The eHealth infrastructure is established and maintained by the ESDHYY in cooperation with its na-
tional partners as indicated below and it includes:

**The Ministry of Administrative Reform and eGovernment** has a pronounced responsibility for basic cross-sectorial services and infrastructures and specifically eID services, electronic signatures, secure networks for health data exchange etc. eHealth has specific needs that need to be addressed within this cross-sectorial infrastructure.

**ELOT** is the national organization, mandated with the adoption and/or elaboration of national standards without however any specific sectorial focus, hence it is agnostic to domain-specific issues. HL7 and IHE are standard setting organizations gaining increased recognition in the European Standardization Scene. **HL7 Hellas** has therefore a substantial added value, being the focal point of their activities in Greece.

**Medical/professional organizations** elaborate clinical governance and clinical protocols, which formally adopted by **KESY**. The **Athens Medical Society** has contributed actively to the digitization of such protocols to be used in association with the ePrescription service.

Testing, labelling and certifications are typical standards related processes and their operation by **ESYD (Greek National Accreditation Body)** and also private accredited bodies is based on international standards. eHealth specific activities do not exist in Greece. Options to be explored range between establishing own national scheme (i.e. via EKAPTY or other similar body accredited by ESYD) to recognizing European (i.e. IHE Conformity Assessment Scheme[^24]) certification and actively supporting our industry to participate in it.

**Owners of Authentic Sources** holding information that will be shared and as such must be trusted are also key actors in this process. They include **Health professional organizations** which maintain registries of health professionals with a right to exercise a health profession; **IDIKA** which maintains the AMKA registry for identification of citizens; **EKAPTY** which maintains the registry of medical devices and has a mandate for quality auditing and certification of health care providers; the newly established **ESAN** will maintain DRGs and **EOPYY** maintains registries of persons, insurance and reimbursement information and entitlements as well as contracted health care providers.

### 4.7.4.1.6 eHealth Stakeholder Platform

The community of eHealth stakeholders is appropriately involved in the design of solutions and the implementation of assets, validates proposals and feeds information into the policy making process. This should lead to user-friendly solutions supporting clinicians and patients in their daily work and hence speed up adoption and deployment.

For this purpose, ESDHYY will establish an eHealth Stakeholder Platform comprising a community of organizations that need to be consulted, according to the issue at hand. Towards this objective,

- ESDHYY will define the criteria for organizations to be included in the eHealth Stakeholder Platform
- A dedicated section with application to membership, acceptance to membership and registration of members will be provided on the eHealth Platform.

[^24]: [http://ihe.net/Conformity-Assessment/](http://ihe.net/Conformity-Assessment/)
• The platform will comprise a pool of experts to draw from for the manning of the specific purpose work groups.

4.7.4.1.7 Network of eHealth Services

The Network is established through the Common Ministerial Decision delegated through Article 13 of Law 4213/2013, as an advisory body to ESDHY. Its regular membership consists of the parties sharing involvement in the development, maintenance and management of all components of the national eHealth infrastructure and specifically: eHealth services operations (IDIKA), eID and trust services (Ministry of Interior and Administrative Reconstruction), eHealth standardization (ELOT), testing and certification, authentic sources and semantic assets (professional organizations and associations), eHealth Industry representatives, etc. The signatories of the Common Ministerial Decision appoint the members.

The Decision will establish the National center for eHealth. It will also establish a cross-sectorial committee for eHealth eID and trust services with membership, priorities and mandates defined cooperatively. Membership will include representatives of the parties involved in eGov and eHealth eID policy as well as the development and maintenance of authentic sources. The committee will operate under the oversight and the rules of procedure applying to the EDSHYY Specific Purpose Groups and will report to ESDHYY. The same decision establishes the eHealth Stakeholders Platform. The ESDHYY, DHYY and its associated eHealth Stakeholder Platform operate as an integrated mechanism.

4.7.5 Lessons learned

This cases study brought to light some important open issues that need to be settled for large scale deployment. Two teams worked in parallel to create the infrastructure and interoperability layer needed to implement a national patient summary service. The first team under the health in action initiative monitored by WHO in Greece created the proposed architecture and set of interoperability specifications needed to implement this case study.

The second team which was the SOHealth project consortium analysed those specifications and built an initial reference implementation to be tested by IDIKA SA. During this pilot implementation the following prerequisites where met:

1. Do not reinvent the wheel, so epSOS patient summary work, HL7 CDA, HL7 FHIR standards and IHE integration profiles were introduced and reused.
2. Foresee the upcoming future and European requirements under the cross border healthcare directive. As such interoperability architecture and governance that were proposed, were conceived in such a way to allow cross border healthcare compatibility by design.
3. Focus of establishing security and data privacy guidelines from early design. As such eIDAS architecture, STORK eID scenarios, Greek eID infrastructure, EU friendly patient consent mechanism allowing break glass scenarios for unplanned care were integrated in the architectural model.
4. Think big, start small. The use of HL7 FHIR even if at a DSTU level is a key simplified interoperability asset that can be easily remodelled and expanded as HL7 FHIR resources mature and grow from the international community. Complexity is hidden from edge systems that handle medical information at the point of care allowing easy access to point of care infor-
5. A central FHIR server was introduced to convert HL7 FHIR messages in a RESTful architecture to be centrally converted to HL7 CDA encounter report documents to be stored for future reference and aggregations.

6. The use of HL7 CDAs allow that more than one end user application can be built to visualise medical content to fit physicians requests. As a minimum GUI, the epSOS CDA display tool was used to validate proper conversion from FHIR to epSOS compatible HL7 CDA format, ensuring compatibility with EU guidelines for patient summary.

7. Three main sources of information are collected:
   a. ePrescription data (dispensed drugs, etc) are directly introduced as encounter reports to the patient summary
   b. Hospital discharge letters are also considered as encounter report for the patient summary
   c. Primary care system can insert information of episodes of care as encounter reports to the patient summary.

A live pilot is scheduled to run in the forthcoming period to further analyse and validate stakeholder's requirements.

4.7.5.1 Successes
Since this use case was built as an extension of existing standards and best practices, mostly at a European level, a lot of technical and semantic issues were streamlined according to those best practices. This cases study had the following successes:

1. Introducing in Greece a high level interoperability architecture and an interoperability framework based on widely used eHealth standards and integration profiles
2. The proposed system is in line with EU decision to identify 27 IHE profiles for use in the EU.
3. The patient summary case study can be seen as the first step to implement similar services in other domains (laboratory, radiology, telecare, etc.)
4. The proposed approach is in favour of open standards that promote open competition of skilled IT implementers.
5. The use of HL7 FHIR ensure portability to mobile devices also for future scenarios and simplicity of technical integration of system.
6. No interoperability integration via the HL7 FHIR server took more than 2 weeks of work, which proved the viability and proper selection of the architectural approach.

In order of course to move from the reference implementation to a large scale implementation a series of technical and legal analysis activities need to be done to secure full and continuous service to physicians and patients. Those are non-exhaustively stress testing, vulnerability testing, interoperability testing of third party applications, etc., just to name some of them.

4.7.5.2 Pitfalls and Remedies
Most of the pitfalls are located in the legal and semantic domains:

1. Serious work and planning need to be done to secure semantic interoperability and govern-
2. Legal and administrative tasks need to be fulfilled by the Ministry of Health to initiate and operate the proposed governance in conjunction with Greek laws (N4013/2013, N4238/2014).

3. Incentives should be provided to point of care information data sources to populate the patient summary in a large scale process.

This case study proposed remedies for all pitfalls based on common sense and international best practices.

### 4.7.6 Resources

<table>
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<tr>
<th>GrPS1</th>
<th>HL7 FHIR server for Patient Summary</th>
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<tr>
<td>Description</td>
<td>Server side interoperability API to convert HL7 FHIR resources into HL7 CDA documents for patient summary</td>
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<th>GrPS2</th>
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<td>Link</td>
<td><a href="http://www.sohealth.gr">http://www.sohealth.gr</a></td>
</tr>
</tbody>
</table>

### 4.7.7 References and Further Information

- [HL7FHIR](#) The 1st DSTU version (v0.0.82) of HL7 FHIR protocol, specifically Resource List (Clinical, Administrative & Infrastructure)
- [ITICDA](#) Integrating the Healthcare Enterprise, Patient Care Coordination CDA Content Modules-Trial Implementation Supplement, August 10, 2009.
- [IHEPRO](#) IHE integration profiles at [www.ihe.net](http://www.ihe.net)
4.8 Case Study #14: Spanish Implementation of the EU Patient Summary

- Author of case study Arturo Romero <aromerog@msssi.es>
- Project or Initiative name: Spanish implementation of the EU patient summary
- Project type: limited deployment for experimental use
- Status (in 10/2015): planning (internal test deployment, roll-out planned)
- Countries / Regions: 18 regions (communities) of Spain
- Partners: Ministry of Health and the 18 regions
- Scale of deployment: cross-region, cross-border

4.8.1 Project Overview

A patient summary is currently available to 25 million citizens in Spain, but the different regions (communities) use different formats. The goal of this project is to offer a unified patient summary that patients can use in particular when travelling abroad.

4.8.2 Approach

In practical terms, the project aims at demonstrating the feasibility of consolidating the data coming from 7 regions (communities), and to construct a multiple-section patient summary that can represent the data from the whole set of communities. A region/community is defined here as one of the political divisions of Spain, representing between 50,000 and 8.5 million inhabitants. The IT infrastructure and capabilities of these regions are quite diverse.

Project planning started in 2011, and the active development phase started in October, 2013. The project involves 8 people from the Ministry of Health (MoH), and about 25-30 people from the various communities. The roll-out of the project is performed stepwise, one community at a time, through workshops. The focus is on training of the health professionals, and the sharing of terminology and clinical information models (archetypes) developed by the health professionals. For the sharing of clinical information models and terminology, the project operates a central model server, and a central terminology server.

Four communities have already decided on the implementation of their own terminology server (in different stages of development, from “in procurement” up to “mature, in routine use”), and contact has been established with 15 of the 18 communities.

The project mostly focusses on the “Information Layer” according the Antilope taxonomy, i.e. on the development of clinical information models and related terminology bindings.

4.8.2.1 Care Process

The care process includes the following aspects: how users can enter information into the EHR, and how to make it easy for others to read the information within an EHR, which requires a good rendering of the information to the reader. However, these usability aspects are out of scope of this document.

4.8.2.2 Information

The project has developed a three-step approach for the development of patient summary arche-
types (or other clinical information models):

1. Domain modelling
2. Clinical information modelling, using mock-ups
3. Full archetyping

According to the project experience, clinical modelling is best done using tools built according to the preferences of clinicians, who work differently than engineers. Clinicians prefer forms over abstract diagrams. Therefore, in the second step of the approach, initially the clinical information models were represented as a mock-up form on screen. Meanwhile the project has an application that captures the data from the clinicians, including a mapping to terminology, and finally produces a PDF or XML document representing the clinical model and terminology binding. Once this step is completed, it is easy to convince the clinicians to perform full archetyping, i.e. to convert the clinical information model into HL7v3, a CDA document template, a FHIR message or an HL7v2 message containing an embedded PDF document.

ISO/EN 13606 plays an important role in the modelling process because 13606 offers EHR communication concepts and terminology that is easily understood by clinicians. This helps in the construction of the clinical information models, where bindings to adequate terminologies or classifications are required. The combination of the clinical information model plus the terminology binding provides a complete semantic model, which can then be customized to specific clinical environments, and mapped to concrete document formats. The project has also carefully examined ContSys (EN 13940), and HISA (EN 12967), however, while the terminology from ContSys is well understood at the MoH, it is (too) difficult for clinicians at the hospitals to understand.

The components for interoperability of relevance for the project are shown in Figure 62. ISO/EN13606 provides a reference model and domain terminology. Input forms (mock-ups) are used...
during the clinical information process, which results in a clinical information model (archetype/template) and a binding of the concepts and values to terminologies or ontologies. This model can be exported to XML or PDF format and mapped to existing standards such as HL7, CDA or FHIR.

4.8.2.2.1 The Role of Terminology Bindings

One of the defects of the classical information modelling process is that if one publishes a clinical model and leaves it for others to refine it, this process becomes very difficult to govern, because the refined models rapidly introduce variability in the way people implement requirements. The approach pursued by this project is, therefore, to put as much variability or customization as possible into the binding component, not into the clinical model. For example, a patient summary for ophthalmology and a patient summary for gynaecology should be able to use the same clinical model (structure), but with different terminology bindings. The project is looking for a language for expressing this, but has not yet found any.

4.8.2.2.2 The Role of Ontologies

The project gives much importance to the use of ontologies. The reason is that the change from free-text to formal clinical models is a major change for the clinicians, and will be accepted only if there are strong arguments supporting this change. One of these arguments is the ability to “drive” clinical decision support systems (DSS) with information from the EHR, for example to identify risk situations. This absolutely requires the use of ontologies. Simple terminologies (labels and values) are not sufficient.

The project aims at using SNOMED-CT as the default terminology and default ontology for the complete EHR. When other terminologies are used in the clinical records, a mapping to SNOMED-CT will be required to combine EHR content with knowledge bases using SNOMED-CT expressions, which would introduce additional risk.

SNOMED-CT is used in the project to specify both concepts (meanings) in the clinical model and the associated values in the terminology binding (which together establishes one semantic unit), section headings, and metadata. Furthermore, SNOMED-CT is used in the project to establish knowledge bases (independent from clinical records) consisting of Subject/Predicate/Object triples. This enables reasoning (determination of equivalences and subsumptions) over the combined information encoded in the EHR (clinical record) and the knowledge base. This can be used, for example, to generate alerts about known drug incompatibilities, prescription of the wrong drug (not authorized for treatment of the current diagnosis) etc.

Nevertheless, many clinicians will still ask for free-text fields, so free-text comment fields must be provided. This is something the project will have to accept. One reason may be that terminologies, like SNOMED-CT, especially when translated from a different language, may not be perfect from the perspective of the clinician.

4.8.2.3 Applications

The project does not develop applications on its own. The primary objectives are to convince healthcare professionals to use a common terminology to model information, and to provide easy access to such models, which should be available for download (like in the ART-DECOR [AD15] and openEHR [OE15] initiatives). The project tries to make it easy for the health professionals to access
the clinical information models, terminologies, and design guidelines.

The project then tries to convince the engineers that the clinical information models represent the result of a consensus effort of the healthcare professionals, and that implementation of this consensus would be beneficial. Implementation is voluntary, but recommended.

4.8.2.4 IT Infrastructure

Not addressed. The engineers who will implement the clinical information models on a voluntary basis have experience from the epSOS connectathons, therefore it is assumed that they understand how to address interoperability on the transport layer.

4.8.3 Concurrent Use of Standards and Specifications (De-facto Standards)

While many people say that eHealth standards are competing, the author of this case study does not believe that this is the case. Supposedly competing standards actually complement each other. One goal of the project is to identify, and use, the best features of each standard, and to use these in a systematic manner.

There is a struggle between using structure and encoded terminology, and using free text. Some people believe that the future is free text, others believe that the future is SNOMED-CT. The author believes that the future is in the coexistence between structured/coded and free text information. Some facts, such as a timeline, are difficult to express in SNOMED-CT and may expressed much easier in free text, resulting in the better readability that clinical readers demand. Coexistence, in the future, with more powerful free text analysers, could be an opportunity, but we currently have no solution for this. The way to move forward is to fund research into this topic.

One practical problem is that the support for SNOMED-CT is very poor in most EHR applications; the US meaningful use of legislation is very important to rectify this. Furthermore, companies need to be more precise in explaining which SNOMED-CT features they actually support, if they support SNOMED. For example, the support for post-coordinated SNOMED-CT expressions is very limited – essentially nobody supports it.

Another practical problem is that health professionals – both doctors and nurses – are used to encode cases using the ICD classification. However, when information is exchanged between health professionals for the purpose of continuity of care, then ICD is not suitable because it is (only) a classification. A clinician would not be happy with a diagnosis saying “other abdominal problem”, which is, however, a valid ICD code. The challenge here is to put more powerful controlled terminologies such as SNOMED-CT at the hands of the health professionals, and to enable them to complement the coded information with free text according to a robust model.

The one place where the project looks into mapping between terminologies is a mapping between SNOMED-CT procedures and the ICD-10 PCS (procedure coding system) classification. Belgium and Portugal are also adopting this classification, and together with them we are looking into ways of mapping between these terminologies. Since SNOMED-CT is a (limited) ontology, and ICD-10 PCS is a classification, it might be possible to utilize the underlying structure to help human experts in establishing the mapping.
4.8.4 Governance

The national Ministry of Health (MoH) in Spain is responsible for the coordination between the regions (communities) in the country. Therefore, this project is under the responsibility of the MoH. The project is carried out under the umbrella of the larger HCDSNS (Historia Clínica Digital del Sistema Nacional de Salud, i.e. “Electronic Medical Record of the National Health System”) project, which focuses on content exchange and is guaranteed for a long time. The experience within this project is that the regions as the “customers” of the MoH are quite happy to accept coordination, guidance and shared resources, because all regions profit from this process.

4.8.5 Lessons learned

4.8.5.1 Successes

The success of the project is related to the understanding that the citizens have the right to see their information exchanged. Since the scope of care is the whole country, somebody needs to take care of coordination. Therefore, the project installed a central node as an enabler for communication across regions, following a set of standards, quality guidelines, security rules, and innovative approaches that can be tested by the regions and thus help in reaching consensus among all regions. The capability to innovate depends on the existence of this central node.

Another success factor for the project is that it is quite flexible with regard to the type of information that is exchanged. If a health professional is “only” able to provide a PDF document, then this is not “semantically enabled”, but still very useful information for the recipient – a good first step that should not be neglected just because the solution is not perfect.

Finally, one factor contributing to the project’s success is that the people involved in the project had the possibility to participate in international projects like epSOS and EXPAND, which has improved the project team’s understanding, and control of, standards and standardization processes.

4.8.5.2 Pitfalls and Remedies

The worst “enemy” the project has found is poor implementation of standards, guidelines and specifications in products. Poor implementation is the result of poor knowledge, i.e. insufficient training of the developers with regard to the standards that need to be supported.

4.8.6 Resources

None.

4.8.7 References and Further Information

4.9 Case Study #15: e-SENS ePrescription and Patient Summary pilot for Greece

- Author of case study: Dimitrios G. Katehakis <katehaki@ics.forth.gr>
- Project or Initiative name: e-SENS (Electronic Simple European Networked Services)
  http://www.esens.eu/
- Project type: large-scale deployment for experimental use
- Status (in 10/2015): deployed for experimental use, work in progress
- Countries / Regions: Greece, Italy, Luxembourg, Portugal, Spain for ePrescription / Patient Summary
- Partners: Greece is involved in the project with the following partners: Aristotelian University of Thessaloniki, Foundation for Research and Technology – Hellas, Hellenic Ministry of Administrative Reform and E-governance, and University of Piraeus Research Centre
- Scale of deployment: cross-border, piloting in ePrescription / Patient Summary (PS-B, eP-B – later PS-A)

4.9.1 Project Overview

e-SENS (Electronic Simple European Networked Services) is a large-scale project (LSP) that consolidates, improves, and extends technical solutions to foster electronic interaction with public administrations across the EU. Technical solutions of e-SENS project constitute the following competence clusters: e-Delivery, e-Documents, e-Identity and e-Signatures, and Semantics. These are not developed from scratch but are based on the released LSP products from the following projects: PEPPOL (Pan-European Public Procurement Online) [PEPPOL], SPOCS (Simple Procedures Online for Cross-border Services) [SPOCS], STORK (Secure idenTity acrOss boRders linKed 2.0) [STORK], epSOS (European Patients – Smart open Services) [epSOS], and e-CODEX [e-CODEX]. Six domains have been identified for intended piloting: Citizen Lifecycle, e-Agriculture, Business Lifecycle, e-Health, e-Justice and e-Procurement. The project is expected to develop the digital infrastructure for improving the quality of public services in EU, supporting the implementation of European policies, in particular the Digital Agenda for Europe.

e-Health domain pilot plans have been prepared for the ePrescription/ Patient Summary use case for five countries: Greece, Italy, Luxembourg, Portugal, and Spain. The project aims to enhance the cross border services originally developed in epSOS by integrating e-SENS generic Building Blocks for non-repudiation, trust establishment, eSignatures, metadata locator service and eID. Non-repudiation and basic eID (electronic identification) scenario have already been integrated within the latest versions of OpenNCP (epSOS open national contact point) and piloting in pre-production has started. Currently work is being conducted towards the transition from a TLS-enabled solution (transport layer security) to an SMP/SML (Service Metadata Publisher / Locator) enabled one, as well as the implementation of the extended eID scenario to use STORK PEPSes (Pan European Proxy Services).

The piloting in e-SENS is the next step for Greece to foster European wide cross-border eHealth services and a logical next step to the epSOS pilot services. Greece is a country with a high influx of tourists throughout the year. The opportunity to dispense electronic prescriptions and access patient summaries from other countries in a Greek pharmacy and health care facilities respectively is a great
advantage.

The provision of the current cross border pilot services and the future extensions will take place within the framework of existing European regulations, such as eIDAS (electronic identification and trust services), policy tools such as eHealth Network, and on the Directive 2011/24/EU on the application of patients’ rights in cross-border healthcare, which has been transposed into national law. Both ePrescription and electronic patient records are regulated by national legislation, with the latter being currently in process of preparation.

The e-SENS Greek consortium pilot is implemented in close cooperation with the Ministry of Health and under the co-ordination of the Ministry of Administrative Reform and e-Governance of the Hellenic Government.

### 4.9.2 Approach

The technical approach taken by the e-SENS project, as far as the e-Health domain pilot for eP/PS is concerned, is that of the epSOS project [epSOS] with the incorporation of the generic set of ICT Building Blocks that support the creation of ICT cross border interoperability solutions that are being used in the 1st and 2nd Wave of the e-SENS Pilots, including support in determining the solution architectures in the Pilots [e-SENS D6.3].

Greece has implemented the epSOS OpenNCP and will maintain the NCP (national contact point) with any further extensions whether delivered in e-SENS or in other projects (such as EXPAND). It is anticipated that the currently expressed political commitment will also result in sustainable operation of the NCP under the legal agreements to be established within the Subgroup.

Greece has piloted, in the framework of epSOS, ePrescription as country of treatment for the patients (country B). National cross border initiatives are focusing on expanding current services to services as country of affiliation for ePrescription and also initially as country B for Patient Summary. In anticipation of the latter, the epSOS national implementation team has already implemented and tested the epSOS MTC (master translation catalogue), which is necessary for the semantic transformation of the PS. However, the needed legal and organizational framework for electronic health records, currently in process of development, will need to be secured before Greece can expand into the electronic prescription / patient summary (eP/PS) use case beyond pre-production. It is also understood that the e-SENS eHealth pilot will take place with test data only. E-SENS extensions to be piloted need to be able to follow existing current situation in Greece, especially in the eID domain where end to end security via smart card technology for example is not supported. As such a STORK-based eID approach seems to be more in-line with future developments at the Ministry of Administrative Reform and e-Governance of the Hellenic Government (MAREG) which is a partner of the e-SENS Greek National Consortium.

#### 4.9.2.1 Care Process

The business processes to be piloted are based upon the ones described in the epSOS use cases, with the exception of the identification process which will be aligned to e-SENS processes. In practice, in the epSOS Portal / OpenNCP, the component that manages the identification will be replaced by the e-SENS eID building block. Also the PEPPOL Simple Metadata Publisher (SMP) will be used as a Record Locator Service. The integration of the new building blocks is not expected to change the original
use case business processes. The pilot will create and test the national infrastructure for the establishment of a national service for cross sectorial eID for eHealth purposes.

4.9.2.2 Information
Through the concept of semantic signifiers, the epSOS Semantic Framework provides data consumers and data producers with end-to-end semantics: the data consumer receives medical information with the full semantics as intended by the data producer. Semantic services of the epSOS Semantic Framework provide usability-enhancing and patient-safety-enhancing services on top of epSOS shared medical documents. The exchanged documents are HL7 CDA v2 Level 3 documents, structured and coded.

4.9.2.3 Applications
Greece is both a highly touristic destination and has also a highly digitized health sector. Embedding e-SENS/epSOS functionalities into the local apps is likely to increase doctors’ buy-in and active collaboration. Launching and running includes the following actions:

- Implementation of national extensions
- Development of CDA Level 3 structure for patient summary (national representation)
- Development of end-user GUI
- Integration with national PEPS (Pan European Proxy Service) and epSOS NCP (National Contact Point)
- Implementation of Schematron validators for CDA document validation (extended from epSOS/e-SENS)
- VPN connections
- Certificate management
- Create national MTC (master translation catalogue) based on extended MVC (master value catalogue)
- Terminology maintenance and update related to MVC/MTC
- Parameterization / Configuration

4.9.2.4 IT Infrastructure
IT infrastructure standards used per Building Block is as follows:

- Non-repudiation to emit electronic evidence on transactions (i.e. ATNA Audit Trails, ETSI REM [ETSI]). Evidence Emitter implementation was made in conjunction with OpenNCP, and e-Codex (OpenNCP included the code, e-Codex provided ETSI REM). The integration of the Evidence Emitter ABB (architecture building block) aims at enhancing the OpenNCP approach to manage audit trails with a more formal account of Evidence based on based on XACML (eXtensible Access Control Markup Language) policies and ETSI REM evidence. The OpenNCP Community has released a new stable release from the OpenNCP (2.2.0), following the full integration of the Evidence Emitter Building Block from e-SENS. The version of the ‘Evidence Emitter’ building block for the e-Health domain, tested at the Connectathon, is a modification of the IHE ATNA profile. Tests were performed during the 15th European IHE Connectathon event at Luxembourg (April 2015).
- SMP (PEPPOL/OASIS Simple Metadata Publisher) integration currently in progress.
• STORK integration in progress.

An SMP will be hosted by the EC on behalf of the eHealth community, based on the experience gained and the results of the e-SENS pilot. There is a process for a memorandum of understanding to be signed between DG SANTE and DG DIGIT along those lines.

Moreover, it will be important if the eHealth infrastructure opens up and links to the STORK infrastructure. This can be done in a way that is least intrusive to the epSOS installed base, if a technical solution is found and requirements are met. It is important to note that STORK 2.0 is coming up with an eID solution for eHealth; however it is only in e-SENS that this solution can be piloted as integrated with the epSOS infrastructure.

4.9.3 Concurrent Use of Standards and Specifications (De-facto Standards)

e-SENS tries to fill the gaps left open by epSOS. The need for the Central Services comes from the fact that every NCP must be an ATNA (IHE Audit Trail and Node Authentication Profile) Secure Node. The PEPPOL Service Metadata Locator is exploited to evolve the epSOS Central Services rationale (architecture and services) by adopting e-SENS Building Block features such as Capability Lookup and Service Location. This step will have impact also at NCP level where refactoring will have to be made in order to allow the improved articulation model between NCPs. The new approach leaves the current TLS-based ad-hoc model behind in favor of a more standardized and robust architecture. Work is still in progress. Three alternative solutions (standards based) have been examined [OpenNCP2] and the final implementation will depend on project extension and CEF plans. The objective is to deploy the new architecture and operation paradigm for configuration services, based on specifications for cross-border and cross-sector trust establishment and certificate layouts according to the eIDAS regulation.

In addition, the means for establishing a robust patient identification within epSOS rely on several technological and organizational prerequisites originally designed and specified in order to accommodate national specialties, unavailability of suitable technology, and the former absence of pan-European procedures to identify and authenticate patients in a cross-border scenario. The e-SENS eID Building Block is set to overcome the inefficiency and merely fundamental robustness of the original epSOS process by establishing the means to operate purely electronic identification for not only identifying but ideally authenticating patients for the clinical workflows, while preserving a full compatibility with the existing epSOS technology. Work is still in progress. The objective is to release for member state adoption a new version of the NCP reference implementation that combines two methods of patient identification: a manual one (as it was on epSOS), and an electronic one (according to the e-SENS eID BB). In practice it is expected for several, alternative methods of electronic identification (levels) to be supported [OpenNCP1].

4.9.4 Governance

In the medium-term the service platforms are proposed to be integrated in the CEF (Connecting Europe Facility) Regulation. During this phase, an imbalance will exist between net beneficiaries and net contributors. The main focus will be on migrating aspects towards a long-term scenario, after the CEF program (beyond 2020).
4.9.5 Lessons learned

The establishment of the NCP systems and the set-up of the legal and administrative rules for making the services running have revealed critical paths and the need to elaborate solutions to be validated by the political level.

The eHealth domain is expected to greatly benefit from mitigating non-domain concerns such as those for electronic identification, endpoint detection, non-repudiation, and the use of electronic signatures and trust establishments for basic cross-border public services in Europe.

Practical implications are related to the cooperation, European level compatibility and sustainability of the underlying national infrastructures required to support reliable and secure exchange of medical data, as well as the readiness to address continuously evolving interoperability, legal and security requirements in a cross-border setting.

4.9.5.1 Successes

Domain work conducted in a coordinated manner has helped project partners avoid pitfalls and reach a level of coordinated development, testing and resolution of architectural issues no single partner could have resolved on its own.

For example, after months of uncertainty, the eHealth pilot has agreed inside e-SENS and with EX-PAND and the EC to implement Dynamic Discovery and Evidence Emitter in order to refactor and replace the epSOS central services.

In addition, the handover of STORK to e-SENS and the increased mandate towards e-SENS for helping Member States migrate to eIDAS, makes it possible for the eHealth pilot to link its eID solution with the STORK/eIDAS infrastructure.

Work is still in progress.

4.9.5.2 Pitfalls and Remedies

After long discussions, the pilot adopted the use of Capability Lookup, an architecture building block that is part of the eDelivery SAT (Solution Architecture Template), and the use of the OASIS SMP/SML (BDXL, Business Document Metadata Service Location) specification for replacing the epSOS central configuration services to support the eHealth trust model.

The prospect of using patient identification and healthcare professional authentication as well as mandate services from STORK is progressing. There are privacy requirements and legal issues that need to be clarified. There have been significant advances in setting up requirements and using the FutureID solution [FutureID] to provide smart card-based authentication of citizens. The use of STORK is planned to enable the use of national, notified eIDs but this requires some infrastructure to be set up internally by the member states. The client integration of FutureID is already quite advanced, whereas the timing of the STORK-related work is a challenge as it is foreseen to take place in 2016.

This pilot requires rather advanced electronic signature services that cannot be comprehensively provided by a single existing technology provision from any underlying activity (STORK, epSOS, etc.). For reasons of resource and time availability this work has been left out of scope.
The epSOS pilot runs with incompliant certificates because of lack of appropriate/suitable certification authorities. These relaxations have been set by the epSOS SEG (Security Expert Group) in the various years of operations. The e-SENS Trust Establishment SAT (Solution Architecture Template) aims at providing a trust framework that would overcome the SEG relaxations. The use of this building block in the pilot is expected to mark an evolution of the eHealth trust model through the reuse of e-SENS and CEF building blocks.

4.9.6 Resources

<table>
<thead>
<tr>
<th>[e-SENS EIRA]</th>
<th>e-SENS EIRA repository</th>
</tr>
</thead>
<tbody>
<tr>
<td>Description:</td>
<td>Resources about e-SENS Building Blocks</td>
</tr>
<tr>
<td>Availability:</td>
<td>freely available</td>
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<tr>
<td>Link:</td>
<td><a href="http://wiki.ds.unipi.gr/display/ESENS/">http://wiki.ds.unipi.gr/display/ESENS/</a> WP6++Building+Blocks</td>
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<td>Link:</td>
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</table>

4.9.7 References and Further Information

| [ETSI] | ETSI TS 102 640 Electronic Signatures and Infrastructures (ESI); Registered Electronic Mail (REM); |
4.10 Case Study #16: Electronic Prescription of Drugs and Pharmaceutical Products (PEM)

- **Author of case study within the eStandards project:**
  - Wilson Oliveira <wilson.oliveira@spms.min-saude.pt>
  - Nilton Nascimento <nilton.nascimento@spms.min-saude.pt>
  - Nuno Mesquita <nuno.mesquita@spms.min-saude.pt>

- **Project name:** PEM – *Prescrição Eletrónica Médica*
- **Project type:** Large-scale deployment for sustained routine use
- **Project status (in 10/2015):** Deployed for sustained routine use
- **Countries / Regions:** Portugal (national wide)
- **Project partners:**
  - Portuguese Ministry of Health Shared Services (SPMS)
  - Central Administration of Health Services (ACSS)
  - Directorate-General of Health (DGS)
  - National Authority of Medicines and Health Products (INFARMED)
  - Ordem dos Médicos
  - Portuguese Data Protection Authority (CNPD)
  - Centro de Conferência de Faturas (CCF)
  - Associação Nacional de Farmácias (ANF)
  - Associação Portuguesa de Farmácias (AFP)

- **Scale of deployment:** Cross-region (National)

4.10.1 Project Overview

The Portuguese government considers the prescription by active ingredient, through the control of prescription and encouraging the use of generic drugs, as structural elements for the more rational use of medication. Therefore, in 2012 the Health Ministry defined a new context for the use of drugs, holding a substantial reform of the medical prescription.

The use of electronic means to support the prescription, dispensing and billing processes for all kinds of medicines and the health care products is also within the priorities set by the Ministry of Health. The Portuguese *ePrescription* project was implemented for increasing patient safety by providing integrated access to prescription history, chronical medication and alerts for known drug allergies; monitoring adherence to the prescribed therapy; simplifying the process of prescribing, dispensing and conference; reducing costs with medication; and to provide prescribing indicators for governance.

The workgroup assembled for achieve these goals include:

- Portuguese Ministry of Health Shared Services (SPMS) as the implementer;
- Central Administration of Health Services (ACSS) which provides the legal background for all the process including prescription, dispense and conference;
- Directorate-General of Health (DGS) which provides the clinical guidelines for the prescription process;
- National Authority of Medicines and Health Products (INFARMED) which provides information on...
what drugs and pharmaceutical products are authorized as well as their allowed prices;

- Ordem dos Médicos for contacting the doctors;
- Pharmacy Associations for contacting the pharmacies;
- Portuguese Data Protection Authority (CNPD) for ensuring the security and privacy aspects of the process;

### 4.10.2 Approach

In order to implement the national *ePrescription* project three main components were created:

- The National Prescription Database stores information on the prescriptions and dispenses made;
- The *ePrescription* and *eDispense* Application Programming Interfaces (API) allows an application to interact with the National Prescription Database;
- The *ePrescription* and *eDispense* Applications are used by doctors to prescribe drugs and pharmaceutical products, and pharmacists to register dispense to the patient once it occurs.

The *ePrescription* and *eDispense* APIs are based on Simple Object Access Protocol (SOAP) web services and they are used by applications to register and retrieve information on prescriptions and dispenses.

The SOAP messages (based on XML) were custom defined to satisfy the information needs for the process from prescription to invoicing, including patient identification, doctor identification and medical specialty, prescription place identification, responsible financial entity, prescription identification, prescribed items and dispense information.

The SOAP web services are available through the Healthcare Data Network (a private network available for healthcare institutions) and open for the web over HTTPS (available for all the software prescription and dispense market). The web services implement WS Security 1.1 using basic authentication.

Several *ePrescription* and *eDispense* applications are available and certified. For the purpose of this case study, the SPMS ePrescription application (Serviços Partilhados do Ministério da Saúde, the ICT department of the Ministry of Health) will be taken into consideration.

As suggested, the Layers of Interoperability as defined by the ANTILOPE project [vPS14] (see Figure 1 on page 13) are described below, focusing the lower four layers (care process, information, applications, and IT infrastructure).

#### 4.10.2.1 Care Process

During an encounter a doctor may need to prescribe drugs or other pharmaceutical products and most times he does this through the *ePrescription* application available on the local Electronic Health Record system. The information on the prescription is integrated into both the Patient Health Record and the National Prescription Database, and in this way made available for a pharmacy to access. Once the patient arrives at a pharmacy and provides the necessary access codes, the pharmacist provides the patient with the prescribed products and registers that the patient got them. This confirmation is also made available to the doctor, ending the care process – A patient got a prescription,
went to the pharmacy to get the prescribed medicine and the doctor got the confirmation that the patient got it dispensed.

The *ePrescription* project though goes a little beyond the care process and also registers prescription and dispense information so that the Central Administration of Health Services can check and pay the ministry contribution to the pharmacy.

### 4.10.2.2 Information

There are three main documents supporting the *ePrescription* project:

- **ePrescription** is the document containing information about the prescription itself. It is structured as a XML Document when exchanged over the *ePrescription* API to and from the *ePrescription* database. As for the integration in the Patient Health Record, the *ePrescription* document is structured using HL7 v2.5 (OMP^009 messages).

- In both cases the document includes information on:
  - Patient identification
  - Physician identification
  - Prescription Place Identification
  - Prescription Identification
  - Prescribed product Information
    - Product identification
    - Pharmaceutical form
    - Quantity
    - Strength
    - Usage instructions

  For registration in the national database, the document includes the entity financially responsible for co-payment and references to the legal documents that apply for special access to the medication.

- **Therapeutic Guide** is a PDF document that contains information on the prescribed products and usage instructions, as well as the access codes (necessary for the pharmacist to access the *ePrescription* content from the national database). This document can be either printed or emailed to the patient.

- **eDispense** is an XML document containing information on the pharmacy identification as well as each dispensed product’s registration number and price.
4.10.2.3 Applications

![Figure 63: ePrescription Logic Workflow](image)

4.10.2.4 IT Infrastructure

![Figure 64: ePrescription Infrastructure Use Case](image)
4.10.3 Concurrent Use of Standards and Specifications (De-facto Standards)

None.

4.10.4 Governance

In 2011, by Decree-law n. 108/2011, of 17th of November, the ICT department of ACSS was transferred to SPMS (Serviços Partilhados do Ministério da Saúde, a public enterprise for shared services of Ministry of Health – the unique ICT department for MoH). ACSS is the Portuguese National Authority, a public administration entity with the responsibility, among other activities, of national coordination related to legal and regulatory issues, standardization or policy activities, disclosure of the initiative and other efforts that might be deemed necessary. SPMS is the technical partner with the main responsibility of technical implementation and operation of Health Information Systems to be used in the Portuguese Nation Health System.

In the ePrescription project, each partner has a responsibility on different areas and creates complementary documentation, which is available online. A significant change in a specification is usually notified to the partners by email, and an adaptation period is established if changes in the software are required. During the adaptation period, both implementations are available. Published specifications include business rules and technical specifications containing information on the reference data tables and the structure of the messages.

4.10.5 Lessons learned

During this project the cost of low standard adoption became clear. Low standard adoption resulted in longer development times, since it was necessary to come up with solutions for integrating information from a number of different systems into a centralized ePrescription application.

IT clients are perhaps more concerned about how fast the solution is available and less concerned about the quality of the implemented solution. This pressure on the project team leads it to ignore the evaluation of the standards that could have been implemented for achieving better outcomes. The project team is also lacking professionals with expertise on the use of standards and there is also little time for the team members to learn about standards. Including interoperability experts into the project team is, therefore, recommended. Finally, it is important that the European guidelines are taken into account on the planning phase of the project.

4.10.5.1 Successes

By implementing the ePrescription project it was possible to achieve some goals including:

- Easy access to prescription history and current medication in the public health system.
- Update the patient’s current medication and prescription data in the patient record.
- Access to known registered allergies and decision support implementation at the time of prescription.
- Updated information of authorized pharmaceuticals and health products.
- Support for the standardization of good prescribing practices.
- Cost savings for the patient and public health system.

The use of HL7 allowed the ePrescription application to exchange information on patient allergies.
and current medication with the different patient health record applications. Using ATC for coding drug allergies was also a good option because this code was already available in the drugs and pharmaceutical products database.

The ePrescription project deals with approximately 300,000 prescriptions per day.

4.10.5.2 Pitfalls and Remedies

During the project implementation, difficulties have been identified related to the volume of HL7 messages exchanged between central prescription systems and local systems. There is still the need to strengthen the message delivery and reprocessing mechanisms. Another challenge is the identification mechanism for foreign citizens in central identification system.
4.11 Case Study #17: « LIGHT – Local Integration Gateway for eHealth »

- Author of case study within the eStandards project: Rita Cunha
- Project name: LIGHT – Local Integration Gateway for eHealth
- Project type: limited deployment for experimental
- Project status (in 11/2015): deployed for experimental use
- Countries / Regions: Portugal
- Project partners:
  - SPMS (Sonhov2, RNU) (PT),
  - CHL – Centro Hospitalar de Leiria (PT),
  - HGO – Hospital Garcia da Orta (PT),
  - CHP – Centro Hospitalar do Porto (PT),
  - ULSLA – Unidade Local Saúde do Litoral Alentejano (PT),
  - IPOLG – Instituto Português de Oncologia de Lisboa (PT),
  - Saudaçor,
  - ST+I (PT),
  - Roche (PT),
  - Maxdata (PT),
  - First (PT),
  - ByMe (PT),
  - Glintt (PT),
  - Mobilwave (PT).
- Scale of deployment: cross-region

4.11.1 Project Overview

For the last twenty years, interoperability involving the National Health System has been limited to the data connection layer. Hospitals and Health Care Units have purchased several systems, from different suppliers, which were integrated with NHS via peer-to-peer connections placed in the database. These kind of “ad-hoc” interfaces have been customized in order to map the specific requirements of each system, each time they come up in local ecosystems.

The national infrastructure of information systems of Health Ministry is mainly distributed, with local repositories in all Hospitals, ACES (Primary Unit Care Groups, which assure that the Primary Health Care is provided to population in a determined geographic area) or Primary Care Units. Nowadays, there are around 65 hospital local databases and around 350 Primary Care related ones. Furthermore, there is also a set of central applications that respond to specific business units and that need to interact in real time with the local repositories. Taking into account all of the scenario, one can easily conclude that the number of peer-to-peer connections has increased exponentially, in a way that managing and maintaining the integrations already occurring in the field can really become a nightmare.

The main purpose of the LIGHT design architecture is to provide the internal systems with an integration engine that allows them to throw-out an event driven architecture (EDA), to manage their integrations in a standardized, reliable and highly parameterized way. The designed architecture intends to promote the separation of the different layers of the software, in order to maximize the reuse of
the code in the several project modules. The way this software engine works must be independent from any system and/or technology connected to the applications that interact. The main purpose is to withdraw the components of third parties with extremely high license costs from the architecture, and in this way make sure that they don’t prevent the installation of the platform in small environments.

Concerning the safety of the systems, removing direct access to the database of the SPMS’s products will strongly increase the control level and the protection they are exposed to, becoming less vulnerable to external factors and at the same time increasing safety and reliability. This way we intend this platform to replace all integrations between local and central systems in Hospitals and Primary Care Units that interact directly with the database. Also by using HL7v2 to exchange all this messages, we aim to unitize the national institutions and, thereafter, this can facilitate future international workflows.

To materialize the fulfilment of this purpose it will be necessary for the team to interact with different stakeholders, which will use the platform to normalize the communication between SPMS local applications and all other systems that already relate between themselves but not in a normalized way. Soon, Hospitals, Primary Care Units and other parties will necessarily have to adopt new communication forms between them, using LIGHT as a middleware solution, which will allow to manage all the integrations in a reliable, normalized and transversal way. At the moment, LIGHT is not yet in production environment. However, there are installation pilots in four hospitals, in which we already perform integration tests between SONHO (SPMS Hospital Information Integrated System) and other local systems using HL7v2 as the main communication language means. LIGHT is expected to be installed in production environment up until the end of this year (2015) in at least one Hospital. This will be the ultimate test to all expectations and the work done so far.

**4.11.2 Approach**

**4.11.2.1 Care Process**

Once the organisations have agreed to work together, several meetings are scheduled with the providers from other systems in order to line up the workflow of the different departments or services. First the business analyst draws a diagram with the workflow as it is now and then describes the To Be workflow, which represents the “ideal” integration scenario, which is discussed and agreed between all involved in the project.

The framework represented in Figure 65 (as shown below) is a workflow in a “To Be” scenario, from the Laboratory Service. The professional from System B can make a lab request or cancel it and send the notification to SONHO. In SONHO, a lab episode can be scheduled or cancelled. It is also in SONHO that the patient who comes for the lab episode is admitted. This information is sent to System A, which may cancel the admission. System A may also send the request cancellation or the information that the lab exam has been performed. The information with the lab results is sent to SCLINICO. The patient can register his admission in Kioske and cancel it, as well as search for the fees, and pay them.
4.11.2.2 Information

Since one of the main purposes of the platform is to reduce the ambiguity of the information between systems and improve semantics used in the exchanged information, the HL7 protocol v2 (2.5) was the choice to communicate between systems.

To interface with the systems where HL7 interface development is not viable and in order to establish an independence towards the protocol used in communication between connectors, the LIGHt platform has defined an own format, called “Entity Exchange Schema Definition” (EXSD). This format is a set of XSD schemas, which are registered in the SPMS Event Controller (SEC) and are used to validate the sending information format associated with the created events. The structure of EXSD reflects, in a purposeful way, the HL7 structure itself, to facilitate the transformation between EXSD and HL7v2 and at the same time to contribute to the evolution of the systems themselves. SEC will allow many versions of the same EXSD, taking onto account the subscribed version of an event validation. It is also possible to invoke database APIs for the internal notification cases and when there are systems that share the same database.

Finally, it is also possible to exchange information via FTP. In cases where very long information lists are produced as the response to a query, these can be returned in an asynchronous manner via FTP file transfer. External systems that intend to do their queries in such way will make the request to the platform, and the platform will confirm the receipt and process the query, placing an XML file with the search result into an account on an FTP server belonging to the provider. Following authentication to the FTP server, these files can be downloaded by their recipients.
4.11.2.3 Applications
The platform doesn’t address the application layer, as described below; however, there is a BackOffice available, which allows to perform, via a graphic interface, the platform configuration tasks, in an intuitive and more visually appealing way. The main purpose of this component is to fulfil the requirement of removing the liability of a direct access to the production environments from the development and support teams.

4.11.2.4 IT Infrastructure

Figure 66: LIGHT Architecture

The LIGHT platform uses a publish/subscribe architecture and it is event oriented. This architecture encourages the detachment of the different software layers, maximizing the reuse of the code in the several modules of the project. This way, this part of the software becomes independent of any other system and/or technology related to the applications that interconnect.

Figure 66 illustrates the architecture that underlies the platform. For instance, to make sure that the system B communicates with the system A, and at the same time system C gets informed about the performed changes, it will be necessary that the systems subscribe to services in the platform, which realises the events notifications. This was the working base thought to create the LIGHT architecture, the modules of which are shown in Figure 67.
Figure 67: LIGHt Architecture

SPMS Event Controller (SEC)

The SEC module is the LIGHt architecture component that will allow the implementation of an event driven architecture (EDA). It is responsible for the tenacity of the events created in the platform, for their status and history management, allowing a wide and centralized view of the integrations status, in the installation process. All the reprocessing events logic, errors processing and logging will be implemented in this layer.

Event Queue

The created events that are configured in the SEC are stored in an Event Queue, where all the relevant information related with each occurred integration is stored, including its current status.

Events

An event works as an operations aggregator and represents a restricted workflow. SEC offers an event type catalogue, which is updated as long as the different interfaces, from several areas, are migrated to platform, having as priorities the infrastructure planning and the identified integration key requirements identified by the operation teams.

Operations

An operation has to be a part of an operations set, available by a determined kind of event. The operations specify in a more detailed way all the possible interactions that the platform allows to accept and process.

Actors

The management of the output and input systems throughout LIGHt is defined through the “actors
table”, which allows for the customization of the actors (systems) that intend to connect to the platform in a simple and easily accessible way. Besides the description that will work as its identifier in the exchange messages, the interface type must be configured, and it must be defined if it is an internal or an external actor.

**Subscriptions**

This is the main configuration table of the platform. It allows for the management of access permissions to the customized interfaces in the SEC module, through association between income and outcome players. This subscription should contain information related to configured outcome players endpoints, as well as the responsible channels for the subscription of the processed events.

**Errors**

All the errors occurring in the scope of the LiGHT events are properly catalogued and managed by the APIs in order to assure that the information related to a certain error, occurred during the processing of a message, is provided to its recipients in a codified and standard way.

**Logs**

All LiGHT system activity is registered at a database level, in a log table. Therefore, thanks to a set of specified filters, with which it is possible to filter the log, it is possible to have a precise perception of all the routes that a certain interaction makes in the platform, allowing for a fast and efficient detection of the problems.

### 4.11.3 Concurrent Use of Standards and Specifications (De-facto Standards)

To establish the connection between the “third parties” and LiGHT a communication standard is needed that is independent from the product and the way the product represents its several information models. The approach is this:

- **HL7** – the information is supposed to follow the already well-defined principles in HL7 to all kinds of information that need to be represented, whether it is clinical or administrative. In this case, there is a double involvement: the information to be represented should follow HL7 minimum data “set” recommendations, and the representation should follow the definitions in the HL7 tables, whenever there are any.
- **XML** – all the messages should be in XML, accordingly to the XSD Schemas defined by LiGHT. This way, the information transmission isn’t dependent of the database technology or even the application.
- **EXSD (Entity Exchange Schema Definition)** – The XSDs made by SPMS, with XML definition, to be used in each operation.
- **XLST** – The transformations between the product XML and LiGHT XML are performed through XSL templates. This way the transformations can be made be in any in other software frim XML «», and then the final template is fulfilled is downloaded with a configurations chart.
- **XSLT Transformation Principles:**
  - **Transformation from product-specific XML to EXSD XML and vice-versa:** To transform the two XML representations, XSLT transformations are used. As an example (below), there is a transformation of the Patient’s Name between EXSD and product-
specific, and vice versa

![XML code for transformation from EXSD to product-specific XML representation.]

**Figure 68: Transformation from EXSD to product-specific XML representation**

![XML code for transformation from product-specific XML representation to EXSD.]

**Figure 69: Transformation from product-specific XML representation to EXSD**

- **Value mapping:** To map values, a table is used that contains the XPath of the value to be mapped, the value domain and the source system.

<table>
<thead>
<tr>
<th>XPath</th>
<th>Domain</th>
<th>Source System</th>
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<tr>
<td>//ide:HealthPlans/ide:Country/text()</td>
<td>COD_PAIS</td>
<td>PIS</td>
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<td>//ide:HealthPlans/ide:HealthPlanID/text()</td>
<td>EFR</td>
<td>PIS</td>
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<td>PIS</td>
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</tr>
<tr>
<td>//OBITO_FLAG/text()</td>
<td>SN</td>
<td>SONHO</td>
</tr>
</tbody>
</table>

**Figure 70: Value mapping from product-specific XML representation to EXSD**

### 4.11.4 Governance

The entire development of LiGHt project is managed by the interoperability team of SPMS. This team has the responsibility of working together with the product teams that request the need to install LiGHt, providing the adequate version of LiGHt that fulfils the operational needs previously identified. All of the operational process (including developing the suitable connectors) is under responsibility of the products teams that install LiGHt to manage their integrations.

### 4.11.5 Lessons learned

Since LiGHt is not yet operating in a production environment, no “lessons learned” analysis has yet been done.
4.11.5.1 Successes
There are some great goals that will be achieved along with this implementation:

- Managing interfaces in a standard, reliable and configurable way,
- Prevent direct and/or unauthorized access to databases,
- Implement access auditing,
- Monitoring,
- Reprocessing,
- Fail treatment,
- Troubleshooting.

4.11.5.2 Pitfalls and Remedies
As it happens in any structural change, even if it is for a better end, people may be opposed to change. This involves changing some processes and sometimes people involved don’t collaborate. What also happens is ambiguity in the communication – sometimes the team involved and the “third party” are not in the same line, meaning that it is often that the workflow has to be repeated several times, with changes and adjustments included.

4.11.6 Resources

<table>
<thead>
<tr>
<th>[MIRTH]</th>
<th>Mirth Connect</th>
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<tr>
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<td>Link:</td>
<td><a href="http://sourceforge.net/projects/mirth/">http://sourceforge.net/projects/mirth/</a></td>
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</table>

The integration engine that enables messaging between SPMS products and other third party systems is Mirth Connect [MIRTH], an open-source HL7 interface engine published by the Mirth Corporation. Mirth Connect is used for the integration with external systems based on HL7v2 interfaces. Mirth is also responsible, through a set of channels that are notified of new outbound events, for processing the messages (HL7 interfaces) or forwarding the event information to the matching web services. The main purpose is to drastically reduce the dependency on external systems developments, since most of them already integrate via HL7.

The synchronous workflows are different from the asynchronous ones since the messages received from LIGHT are directly processed by the receiver channel. This way, there is no persistence in the queue, nor any re-processing messages capacity. In the synchronous mode, each time they send messages, the external applications must wait until the end of processing to receive their acknowledgments.
Figure 71: Mirth Connect Services – Channel Architecture (asynchronous)

Figure 72: Mirth Connect Services – Channel Architecture (synchronous)
4.12 Case Study #18: Portuguese eHealth National Contact Point

- Author of case study within the eStandards project:
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  - Alexandre Santos <alexandre.santos@spms.min-saude.pt>
  - João Gonçalves <joao.cunha@spms.min-saude.pt>
- Project name: PT-NCP
- Project type: Large-scale deployment for experimental use
- Project status (in 10/2015): Deployed for experimental use
- Countries / Regions: Portugal, Italy, Luxembourg, Greece, Spain, Croatia
- Project partners:
  - Portuguese Ministry of Health, Shared Services (SPMS)
  - Portuguese Data Protection Authority (CNPD)
  - EU Projects: epSOS, EXPAND, e-SENS, Trillium Bridge;
- Scale of deployment: Cross-border

4.12.1 Project Overview

The aim for the Portuguese eHealth National Contact Point (PT-NCP) is to provide a logical extension of national eHealth services (e.g. Patient Summary and ePrescription) towards a cross-border scenario where Portuguese citizens are treated in any EU member state, as well as to provide the same quality of treatment to foreign EU citizens receiving treatment in a Portuguese Point of Care (PoC).

Until 2015, the PT-NCP was fully oriented to the provision of cross-border Patient Summary service, both as country of origin and country of treatment, interconnecting all major public health providers in Portugal (i.e. about 60 Hospitals and 360 Primary Healthcare Units). The PT-NCP had a diverse set of stakeholders, each one looking for different objectives:

- Patients
  - Security on healthcare providing due to patient info access;
  - Tranquility feeling by the awareness of easier communication at the PoC;
  - Empowerment – more info to take a better “participation” on her/his health; access to her/his own health information
  - Knowledge about healthcare delivery (where, within Europe)
- Healthcare professionals
  - Conditions for providing better healthcare by overcoming language difficulties with foreign patients and overview of clinical info, allowing for better diagnoses and treatment
  - Improvement of the awareness for the importance of standard documentation in local records.
- Healthcare providers
  - To ease healthcare delivery and make it safer for patients while abroad or for Portuguese physicians when dealing with foreign patients;
- SPMS/NHS
  - Being successful in providing the Patient Summary cross border service as country of origin or country of treatment.
Involvement in the specification and design from service scenarios and use cases in order to provide the knowledge for national convergence with European countries.

Learn from the experience of working with other EU countries, namely in knowledge sharing and competence acquisition concerning Healthcare Information Technologies implementation based on standards alignment and adoption (e.g. HL7 and IHE).

Understand the full context and possibilities of health care information terminologies, as well as to comprehend a national solution how be designed based on principles and best practices recommended and adopted through the epSOS Large Scale Pilot (LSP).

Reduce expenditure avoiding duplication of exams;

Access to information allowing policies definition while monitoring its implementation.

The current status of the PT-NCP is the large-scale deployment for experimental use of a cross border eHealth gateway as well as an International Portal for Health Professionals. During the epSOS large scale pilot, the gateway and the portal were allowed to exchange real patient data. After the end of the project, the gateway and portal are only available for a pre-production testing environment allowing for use by research projects like e-SENS and Trillium Bridge.

Benefiting from the objectives of the EXPAND project (‘... to support the moving from point-solution pilots to large-scale deployment’) the PT-NCP has been prepared to be the Portuguese digital infrastructure to provide services promoted by the Connecting Europe Facility (CEF) eHealth Digital Service Infrastructure (DSI).

4.12.2 Approach

4.12.2.1 Care Process
The PT-NCP, until 2015, has provided IT support for emergency care treatment by providing a Patient Summary containing the most important clinical information for this kind of health encounters. The benefit expected for the care process is the assurance of better conditions for providing better healthcare by overcoming language difficulties with foreign patients and overview of clinical info, allowing better diagnosis and treatment.

4.12.2.2 Information
Taking in consideration the nature of emergency care encounters, the PT-NCP exchanges the following information: Allergies, Medical Alerts (other than allergies), list of current problems, Medical Devices (or implants), Major Surgical Procedures, Medication Summary (current medications).

The Patient Summary information is exchanged using an HL7 CDA document in which the information is encoded according to a Master Value Set Catalogue that defines a reference code system (e.g. SNOMED CT, ICD-10, ATC, EDQM, UCUM, HL7) to be used for each section of the HL7 CDA.

4.12.2.3 Applications
The PT NCP provides and consumes the following information services:

- Identification Service (consumer and provider), implemented according to IHE XCPD;
- Patient Service (consumer and provider), implemented according to IHE XCA. IHE XCF was
envisioned to replace IHE XCA but has not been adopted so far;
- Consent Service (consumer), implemented according to IHE XDR.

### 4.12.2.4 IT Infrastructure

Regarding the protocols supporting the PT-NCP infrastructure and communication, the following ones apply:

- ETSI Trust-service Status List (TSL): used in the current solution for publishing National Contact Point (NCP) capabilities in the central services infrastructure;
- In the current central services solution, SFTP and HTTPS are used both for upload and download of the aforementioned TSL files;
- OASIS Service Metadata Publishing (BDX-SMP) & Business Document Metadata Service Location (BDX-Location): introduced as part of the current refactoring of the central services. The latter provides the means of locating the NCP-declared capabilities defined by the former. The lookup makes use of the DNS protocol and its U-NAPTR records (URI enabled Naming Authority Pointer, RFC 4848). Service Metadata Publishing (SMP) records are exposed as REST resources (accessed through HTTP/HTTPS operations).
- IHE XUA: the profile used for claiming the user authenticity by means of an OASIS SAML v2.0 Identity Assertion; OASIS SAML v2.0 Assertions are also used for establishing the treatment relationship confirmation context;
- ITU-T X.509: in order to participate in the so called Circle-of-Trust (CoT), PT-NCP uses X.509 certificates for trust bootstrap and trust establishment;
- ISO 3166-1 Alpha-2 values are used for the country code, name of country and country subdivision;
- ISO 639-x is used for defining the language code;
- The Audit trail is subject to the principles behind the IHE ATNA profile (using an OpenATNA repository), even though the audit files format still conform to RFC 3881 and not to the DICOM schema;
- Synchronization of local terminology database is performed by means of a SOAP web service relying on the HTTPS protocol;
- The services described in 4.12.2.3 are implemented by SOAP web services protected by the HTTPS protocol and WS-Security;
- Encryption of communication channels at the network layer is ensured by means of a Virtual Private Network based on IPSec and the exchange of X.509 certificates;

### 4.12.3 Concurrent Use of Standards and Specifications (De-facto Standards)

The following types of mapping are used in the project:

- Mapping between controlled terminologies (coding systems): YES
  - CPARA to SNOMED CT
  - ICD-9-CM to ICD-10
  - ICPC-2 to ICD-10
- Mapping between identifiers: YES, International Search Mask
- Mapping between clinical concepts: NO
- Mapping between document formats: YES: XML to PDF through XSLT
• Mapping between messages (e.g. notifications, queries and responses): NO
• Mapping between different reference information models: NO

The mapping between terminologies expected by the PT-NCP and those coming from the National Infrastructure has been achieved by implementing in the National Infrastructure a set of tools based on XSLT and Mirth (using its native mapping capabilities).

HL7v3 CDA is used in two fashions: either as a “friendly” CDA derived from the National Infrastructure which, after transcoding and translation, produces the “pivot” CDA that is the asset transmitted to other NCPs. Both CDAs are specifically crafted according to the project needs, therefore deviating from the standard CDA.

4.12.4 Governance

In 2011, by Decree-law n. 108/2011, of 17th of November, the ICT department of ACSS was transferred to SPMS (Serviços Partilhados do Ministério da Saúde, a public enterprise for shared services of Ministry of Health – the unique ICT department for MoH). ACSS is the Portuguese National Authority, a public administration entity with the responsibility, among other activities, of national coordination related to legal and regulatory issues, standardization or policy activities, disclosure of the initiative and other efforts that might be deemed necessary. SPMS is the technical partner with the main responsibility of technical implementation and operation of Health Information Systems to be used in the Portuguese Nation Health System.

Since August 2014, the Portuguese Ministry of Health published a new law that establishes rules for the access to cross-border healthcare and promotes cross-border cooperation, transposing the Directive in 2011/24 / EU of the European Parliament and European Commission.

In September 2014, the Portuguese Ministry of Health establish SPMS as the national authority for eHealth cross border cooperation. Since then SPMS is the national body responsible for the orchestration of efforts towards standardization activities related to Health Information Systems used for cross border purposes, as well as to learn from the experience of working with other EU countries, namely in knowledge sharing and competences acquisition concerning Healthcare Information Technologies implementation accordingly to standards alignment and adoption (e.g. HL7 and IHE).

4.12.5 Lessons learned

• Security has to be addressed at different levels and needs to be analysed for each step of the supported workflows;
• More than one level of security should be set in place, preferably at different layers;
• Security mechanisms should built on top of robust standardized solutions and not ad-hoc ones;
• A decoupled architecture should be set up to make it easy to comply to the separation of responsibilities and security requirements;
• The use of standardized coding systems allows for better levels of semantic interoperability both between nationally implemented solutions and cross-border access points and between
different instances of the latter;

- Interfaces for transferring health data between clients and servers should favour the use of health standards like those promoted by IHE;

- There must be an engagement from the National Infrastructure in supporting, from the beginning, the use of standards, both semantic and technical like SNOMED, IHE profiles, HL7, etc.

4.12.5.1 Successes

- The project drove the National Infrastructure to use standards for the first time, like HL7 CDA and IHE profiles;

- The capability to map national specific coding systems such as CPARA, the Portuguese national catalogue for allergies and other adverse reactions [CPARA15], to international standard ones;

- The exchange of meaningful clinical data between different countries.

4.12.5.2 Pitfalls and Remedies

- All the stakeholders have to be involved in the project regarding the use of standards, leading them to the perception of the real importance and necessity of them, being committed to the project and its success.

- Lack of component decoupling makes it harder to comply with security requirements and hardens the task of delivering new compliant components. Some workarounds had to be implemented;

- Not all nationally-stored clinical data is using an international standard coding system nor even a national-wide one (different healthcare institutions using different coding systems for mapping the same patient clinical data). This reduced the capability of delivering this information to other countries.

4.12.6 References and Further Information

4.13 Case Study #19: Portuguese National Broker

- Author of case study within the eStandards project:
  - Rita Cunha
  - Hugo Soares
- Project name: PNB – Portuguese National Broker
- Project type: large-scale deployment for sustained routine use
- Project status (in 10/2015): deployed for sustained routine use
- Countries / Regions: Portugal (all regions)
- Project partners: Portuguese Ministry of Health, Shared Services (SPMS)
- Scale of deployment: Cross-region

4.13.1 Project Overview

There are several centralized eHealth systems in the Portuguese national infrastructure that need to communicate data with local facilities – hospitals and primary care units. In order to achieve data synchronization between these both sides we have been implemented large-scale interfaces that are responsible for managing the interoperability process. The scope of these integration engines encompasses such diverse workflows as the patient summary or the electronic prescription.

However, with the continuous spread of centralized applications or information repositories through other workflows (e.g., vaccines), there has been a significant increase of this type of interoperability needs that makes its error-free maintenance a very hard task. Currently, despite the thousands of messages that are processed daily, we still deal with constraints caused by design problems of the Portuguese National Broker’s (PNB) initial solution. That is the reason why we have been working on a new version of PNB. This “PNB 2.0” aims to be a robust generic architecture to support nationwide interfaces in Portugal. The main goal we want to reach with this approach is to provide technical reliability to cross-region exchange of critical information using international standards, regardless of the workflow involved. To achieve that, we will pay particular attention to relevant issues such as high availability, scalability of the solution, monitoring or alarms. The main purposes of the PNB can be summed up in four aspects:

- to centralize the transfer of health data between NHS institutions or internationals;
- to improve the capacity of maintaining and upgrading the recent transfer workflow;
- to facilitate the adoption and implementation from third parties to PNB’s ecosystem;
- to contribute to the promotion of interoperability in health care data.

4.13.2 Approach

4.13.2.1 Care Process

The PNB intends to define transversal rules, based on recognized standards that will be adopted by all the teams in the institution. By implementing these standards, we will address the concerns related to technical implementation “rules” to a common scope; not only to the National Health System, but also to an international level.

The core-project PNB team is working on is the “Vacinas” (e-Vaccines) project. The main purpose of this project is to have a centralized management of The National Immunization Program to the Na-
tional Health System users. The Vacinas project intends to replace the current immunization registration, made in SINUS (application used on Primary Care Units for the immunization record) by the nurses, in Primary Care Units. The main goal of this project is to centralize the management of the Immunization National Programme to the National Health System users. Due to its complexity, it needs to have several products working together with it.

**Figure 73: e-Vaccines Workflow**

### 4.13.2.2 Information

The PNB has the following functionality:

- **Message reception**: The information providers should send **HL7 FHIR** messages to the Broker. The information will be received by a **Mirth channel** available for this purpose, which implements the **REST API** used by the **HL7 FHIR** standard for the Bundle resource type “Message”. The Bundle Resource type is an infrastructure type of resource, which generally provides useful information, and/or are referenced directly from base FHIR framework. The client will receive an immediate response, indicating the validation status of the message and act accordingly. If the client doesn’t receive the answer message, he must act according to the “Reliable Message” specification – the FHIR messaging framework [FHIR]. The figure below shows an example of such a HL7 FHIR call, with information encoded in JSON.
"resourceType": "Bundle",
"id": "aeb61be5-fd56-4716-5b45-5cb356a64b3",
"meta": {
  "lastUpdated": "2015-10-26T11:57:26.932+00:00"
},
"type": "message",
"entry": [
  {
    "fullUrl": "8a49d56b-5eac-4041-9517-1b48d78f100c",
    "resource": {
      "resourceType": "MessageHeader",
      "id": "ce368d1c-2678-4e35-8ac3-7a854da660c4",
      "contained": [
        {
          "resourceType": "Patient",
          "id": "715355290",
          "identifier": [
            {
              "type": {
                "text": "SN8"
              },
              "value": "715355290"
            }
          ],
          "name": [
            {
              "text": "JoAO00c3\u00a3o Pedro Feixeira Da Azevedo"
            }
          ],
          "gender": "male",
          "birthDate": "2015-08-16"
        },
        {
          "resourceType": "Immunization",
          "id": "51af2eb3-03af-4129-94ba-7a8adcfb9249",
          "meta": {
            "lastUpdated": "2015-10-26T11:57:26.932+00:00"
          },
          "status": "Completed",
          "date": "2015-10-26",
          "vaccineCode": {
            "coding": [
              {
                "system": "Vaccines\VAC_VACCINE",
                "code": "Hib",
                "display": "Hib"
              },
              {
                "system": "Vaccines\VAC_BO_COMMERCIAL_NAME",
                "code": "03",
                "display": "Act-Mib"
              }
            ],
            "text": "Hib"
          },
          "patient": {
            "reference": "&715355290"
          },
          "wasNotGiven": false,
          "reported": false,
          "performer": {
            "reference": "7899"
          }
        }
      ]
    }
  }
]
• **Validation of FHIR Messages:** The message received in the PNB will be validated according to the HL7 FHIR standard also in line with the specific rules of the implemented workflow, e.g., vaccines.

• **Forwarding of FHIR messages:** If the message is successfully validated, it will be sent to a specific place, defined by the message, in the field “destinations”. The receptor should ex-
pose an API, if there is the need to reprocess/re-send a vaccine intake.

- **Central monitoring and Logging:** All HL7 FHIR interactions will be registered in a central log and this log enables the user or the administrator to verify the message status (processed with error or success), and to generate statistics based on message contents.

### 4.13.2.3 Applications

The immunization recommendation refers to the point in time of a patient’s last immunization and a recommendation forecasting a patient’s immunization eligibility according to a published schedule, with optional supporting justification. The business rules defined by the National Immunization Plan (PNV), such as the age, gender, health condition, which are provided by the National Health System (SNS), for instance sending the notice to immunization, are managed on a local level.

The immunization describes the event of a patient being administered a vaccination, or a record of a vaccination as reported by a patient, a clinician or another party and may include vaccine reaction information and which vaccination protocol was followed.

In this use case, the standardized HL7 FHIR interface helps in connecting two workflows, central and local: The information about the control of the administration or non-administration, adverse reactions and justification for non-vaccination is registered centrally, but the clinical file is stored locally. The standard interface allows the required information to travel “from local to central”.

### 4.13.2.4 IT Infrastructure

![Figure 75](image.png) describes the outgoing and incoming connections, as well as the modules that internally comprise the PNB solution. The input flows are initiated by the *Data Producers* or *Data Clients* which insert or query data. PNB is responsible for exposing a *HL7 FHIR Messaging API* through a network layer that can assure reliable and safe access.

Internally, the *Broker* has a *HTTP* server component that implements the clinical information exchange standard *HL7 FHIR (DSTU2)* and assures that the received data are compliant with this standard. Following the internal processes, all the requests are sent to its target connector that can be a contact point with an external FHIR server (through *HTTP*) or an external database (via *JDBC*). The forwarding rules are defined accordingly, taking advantage of the workflow engine that composes the *Broker* and the metadata that is managed via *Backoffice*. The workflow engine is composed of configurable routing rules implemented by the Asynchronous Mirth Channels. This metadata is mainly related to National Health System local catalogues (*Distributed Data Repository Systems*). All internal modules of the *Broker* report their status to the Monitoring & Analytics module, enabling troubleshooting and real-time control of the workflows implemented in the PNB.
4.13.3 Concurrent Use of Standards and Specifications (De-facto Standards)

We chose to use HL7 FHIR because this standard allows us to abstract from certain details that the PNB doesn’t define, it abstracts from the “codeable concepts”. “A codeable concept represents a value that is usually supplied by providing a reference to one or more terminologies or ontologies, but may also be defined by the provision of free text. This is a common pattern in healthcare data.” [CodC]

Each coding is a representation of the concept as described above. The concept may be coded multi-
ple times in different code systems, where multiple forms are possible. The different codings may have slightly different granularity due to differences in the definitions of the underlying codes. There is no meaning associated with the ordering of codes with a codeable concept. The codeable concepts are recognized both by the receiver and the subscriber of those data. The de-facto standards used were the “Catálogo de Vacinas da DGS” and the “Reacções Adversas”.

4.13.4 Governance

The entire development of the Vacines project is managed by the interoperability team of SPMS, by the PNB team. All of the operational process (including developing the suitable connectors) is under responsibility of the products teams that provide the roll-out of the Vacines and manage their interfaces.

4.13.5 Lessons learned

The work group involved during the complete project is, for certain, an added value in this kind of major projects. The fact that there was a representative of each team, in permanent communication, was without a doubt a valuable aspect.

The HL7 FHIR knowledge had to be distributed among all the teams, so the investigation effort to keep up with all the updates concerning the standard semantics as well as the implementation of new product requirements affecting the interfaces was extremely important.

The tools used to implement the required distributed information rules were extremely useful since they provided the needed flexibility to implement this project. The utilization of the Mirth connect services allowed some kind of flexibility during the all process of implementation. The usage of Java and .NET FHIR Reference Implementations helped kick-starting the project.

The requirement of having a previous functional analysis in the interoperability component (which was performed in a later phase of the project) had some negative impact. The consequences were that it has interfered in the time needed for the development in the interoperability and made it more difficult to implement the workflows needed. The main lesson learned here is that before the implementation, a requirements analysis must be done.

4.13.5.1 Successes

The use of the HL7 FHIR standard was a huge success: it contributes to simplify the technical implementation and to address functional and semantic questions to the standard itself instead of having to deal with these issues internally by building those guidelines ourselves. That has accelerated the entire process. The fact that HL7 FHIR is very well documented and structured also helped.

4.13.5.2 Pitfalls and Remedies

We consider the poorly selected time in which the functional analysis occurred a pitfall in the project. The Vacinas project started with a wider scope and didn't include the local interoperability component. As the project was progressing, we were able to identify some gaps in the first functional analysis, in what concerns the patient notices to the immunization as well as in the Business intelligence part. The workaround we found in order to fulfil these requirements was to implement a mechanism of information propagation that would be now in the Vacinas to the local repositories where the absence of that information would be noticed.
4.13.6 References and Further Information


5 Conclusions

In the introduction of this document, we stated that the purpose of this document is to provide a collection of evidence on concepts for managing the coexistence of competing or overlapping standards in large-scale eHealth deployment nationally and cross-border. When analysing the complete set of case studies, we have to conclude that we have been unable to find evidence for a significant use of competing and overlapping standards in the real-world eHealth deployment projects discussed in chapter 4, other than in the epSOS project described in section 4.1. In the other case studies, the use of competing/overlapping standards, and approaches to translate between standards, are mostly limited to mappings between different controlled terminologies:

- In Denmark, International Classification for Primary Care (ICPC) codes are mapped to ICD-10 diagnoses when a GP sends a referral to a hospital, or a hospital sends a discharge letter to a GP.
- In the Netherlands, a mapping between ICD-10 and SNOMED-CT has been defined.
- In Italy, work is ongoing to map terminologies defined by, and used in regional implementations to a nation-wide terminology used for the longitudinal electronic health record. However, this is not a major problem because all regional terminologies are defined in Italian and thus readily understandable to the health professionals even if not mapped.
- In Greece, local terminologies used for patient summary content are mapped to the epSOS Master Value Catalogue.
- In Spain, a mapping between SNOMED-CT procedures and the ICD-10 PCS (procedure coding system) classification is planned.

The epSOS project developed an elaborated concept for converting between a document (patient summary, ePrescription/eDispensation and patient consent) in the sending country’s format and language, to a document in the receiving country’s format and language, based on the concept of a “pivot document”, an intermediate format for the document conversion, for which a mapping from and to each national format has to be defined. Within the epSOS network, only the pivot documents are exchanged, and it is the task of a national contact point to “hide” the conversion process (from or to a national format) from the other epSOS actors. A “Master Value Set” and a “Master Transcoding Catalogue” support the national contact point in the terminology mapping that may be needed as part of a conversion between a national document format and the epSOS pivot document. As a safety measure, the original document is always delivered along with the translated document in PDF format, offering a human-readable representation of the document prior to conversion. The complete process is presented in more detail in section 4.1.3.

There is one more case study in the “eHealth deployment projects” chapter discussing competing standards at a level other than terminology mapping: e-SENS, the follow-up large-scale project to epSOS, is actively refining and improving the epSOS software architecture, and in this process replacing several standards and specifications by new, improved ones. This includes the adoption of the PEPPOL Service Metadata Locator, and a revision of the identity management based on the eIDAS regulation. The case study, however, does not discuss a concurrent use of these conflicting standards, but indicates that the National Contact Points will have to migrate from the old version of their
software infrastructure to a new version in order to maintain interoperability.

When looking at the concepts developed and piloted by international R&D projects as discussed in chapter 3, the situation is quite different: Powerful and elaborated algorithms for converting between different equivalent representations of messages or clinical documents have been developed. The approaches discussed in the case studies can be summarized as follows:

- **Gateway based approach**: The IHE Cross-Community Profiles define protocols for connecting different Electronic Health Record deployments (communities) into a “network of communities”. The profiles assume that health information is exchanged in the form of documents, which are either persistent or generated on-the-fly (such as patient summaries or EHR extracts), and where each document can be assigned to a single patient defined by a Patient Identifier known (or accessible) to all parties involved. The architecture further assumes that all parties involved have agreed on a set of mutually understandable document formats and value sets for describing documents that are used when exchanging documents across communities. The profiles then cover the protocols required to locate documents, retrieve documents, or submit documents across communities. The profiles imply that a conversion between local value sets and document formats can be performed by the Gateway, but do not specify how such a conversion could be implemented. The approach is nevertheless important, because it is a fully implementable specification for a federated EHR system into which a conversion between formats can be integrated where needed. The epSOS project considered the concept of the “national contact point”, which is a gateway based on the IHE cross-community profiles connecting national networks with the cross-border epSOS network, as one significant success factor, because it permitted the specifications and developments on national level to be decoupled from the cross-border level.

- **Semantic mediation based approaches**: Both the SemanticHealthNet project and the work performed in the context of the ARTEMIS, RIDE and SALUS projects make use of semantic technologies to convert between different equivalent representations of clinical information. This requires the complete content of the messages or documents to be converted to be expressed through ontologies, and either the use of a common ontology for both source and target format (as proposed in SemanticHealthNet), or complete bi-directional mappings between ontologies (as used in ARTEMIS/RIDE/SALUS). The strength of these approaches is that they can be used to recognize equivalent (isosemantic) clinical information even if for example different archetypes are used in the context of a single EHR standard. The weakness of these approaches is that a prerequisite for their use is a set of ontologies that are powerful, correct, and complete enough to completely represent the full meaning of the clinical documents. Such ontologies do not exist today, and SNOMED-CT, while arguably being the most powerful controlled terminology available today has several weaknesses when used in this role (see the discussion in the SemanticHealthNet case study). In summary, these approaches work well on small-scale “toy problems”, but an immense effort would be needed to create the ontologies required to make them work on a larger scale, e.g. for the exchange of patient summaries. Furthermore, semantic technologies are well known to be computationally expensive, therefore it is not clear to which degree they would scale to large-scale implementation.

- **Model driven approaches**: The X-Paradigm, DICOM SR to HL7 CDA and Trillium Bridge case
studies have in common that they are model driven: First a clinical information model is developed, which represents the clinical knowledge to be exchanged, independent from a concrete implementation in any EHR standard, and then mappings to real-world EHR standards are defined. Based on these mappings and the understanding of the common clinical information model, transformation rules can be specified that can be used to drive the conversion of documents from one format (representation of the clinical information model) to the other. Trillium Bridge is a special case because the project started with two existing specifications of patient summary document templates, and tried to “reverse engineer” the underlying clinical information model. The results show that while both patient summaries have much in common, there are parts in each document that cannot be expressed in the other one. Furthermore, a critical issue is the mapping between different terminologies used to express certain concepts (such as drugs, or diagnoses), because a direct mapping is most often possible only for a subset of each terminology. In Trillium Bridge, the percentage of terms for which a correspondence could be found varied from 6% to 87%, depending on the terminology. In any case there were terms for which no counterpart in the target terminology exists.

When comparing the three approaches, it becomes clear that they are not mutually exclusive, but actually complement each other. Both case studies on semantic mediation have identified the clinical information model, represented by a set of archetypes, as the level on which semantic mediation should be defined, which means that semantic mediation can be seen as an extension (or implementation technique) for the model-driven approaches. Furthermore, both approaches are independent from the actual communication protocol used to locate and access clinical documents in an EHR “network of networks”. This is a gap that is filled by the Gateway-based approach exemplified through IHE XCA or the protocols under development in the X-Paradigm project.

Nevertheless, if there is one important conclusion from the collection of case studies, then it is the fact that a conversion between eHealth standards such as document formats, terminologies, or communication protocols, will rarely produce a “perfect” solution. This can be exemplified through the Trillium Bridge project, which tried to develop a mapping between two very similar specifications: two patient summary specifications (EU and US), both based on the same document format (HL7 CDA). Still it was not possible to find a complete mapping for all codes and subject matters in these two patient summaries. In the same way as in medicine prevention is considered to better than treatment, the only definitive solution can be the a-priori harmonisation of standards that avoids the need to define complex conversion, mappings and mediation schemes, after the fact.

One activity that can be mentioned as an example of such a harmonisation (or convergence) of standards is the CEN/TC 251 “Concurrent Use” initiative, which examines how three standards originally developed by different working groups within CEN/TC 215 can be used concurrently and consistently:

- System of Concepts to Support Continuity of Care (EN ISO 13940, ContSys)
- Electronic Health Record Communication (EN ISO 13606, EHRCom)

• Health Informatics Service Architecture (EN ISO 12967, HISA)

The initiative aims at developing a “concurrent use guide” that explains how the standards relate to each other and how they can be used concurrently and effectively (e.g. by using ContSys as the conceptual basis for EHRcom archetypes for the continuity of care). Furthermore, inconsistencies and gaps between the standards identified by the initiative are taken into account in the revision process of the standards, which will lead to revised “harmonized” versions of the three standards.

5.1 Lessons Learned

Each case study has described the “lessons learned” in terms of successes, pitfalls and remedies. The most important conclusions from these statements are summarized below.

• The benefits of an operational eHealth network as reported by the English NHS case study show that the effort invested in solving the technical and organisational challenges of a large-scale eHealth deployment is offset by the benefits, once the system is up and running. In essence: It is a target that is worthy to be pursued. The Portuguese case study on electronic prescription also mentions the costs associated with low standards adoption: a low initial adoption of standards in the eHealth sector caused longer development times – and thus higher costs – in the project, since many proprietary systems had to be integrated.

• Non-technical factors: While this document mostly focuses on the technical issues related to interoperability, one needs to keep in mind that there are other very important factors each eHealth project needs to address:
  o Trillium Bridge determined that “a host of non-technical policy issues need to be resolved before [the solution developed by the project] goes to production. These non-technical issues are the hardest to solve” and may change in the lifetime of the project, affecting sustainability.
  o The NHS case study reports that “the technology component was a challenge, but worked well in the end. Securing end-user buy-in took a lot longer.” The Greek case study suggests that “incentives should be provided to point of care information data sources to populate the patient summary” (i.e., to those end-users of the system that have additional workload through the system). The LIGHt case study adds that any structural change involves changing processes, and this requires the positive collaboration of the people affected, which should not be taken for granted.
  o Stakeholder buy-in is required for the decision to base the system architecture on standards. The stakeholders need to understand the importance and necessity of using standards, and this cannot be taken for granted. The projects need to support, through project marketing, the use of standards in the project from the very beginning.
  o The case study on Denmark concludes that the lessons learned, successes and pitfalls in more than 100 projects are not related to concurrent use of standards but more to traditional project management. The case study on the Portuguese National Broker reports that one of the major problems the project faced was caused by inappropriate planning of the different phases of software engineering in the project, also an aspect of project management.
End users may be more concerned about how fast a solution is available and less concerned about the quality of the implemented solution. Projects need to ensure that time pressure on the project team does not cause the evaluation of relevant standards to be neglected, so that a “quick and dirty” non-standard solution to be implemented, which will be more costly on the long term in terms of flexibility and maintenance costs.

Communication between stakeholder groups, especially between domain experts and technical experts, can be difficult, as the LIGHT case study warns. Even if both sides believe that they are talking about the same thing, this may not always be the case.

The model driven approaches have shown the importance of developing a clinical information model first, and deriving EHR content format or message specifications from there. If this is the case (like in the DICOM SR to HL7 CDA case study), then it is likely that a lossless transformation process from one representation of the clinical model to another can be defined. The X-Paradigm project has identified the HL7 Services-Aware Interoperability Framework (SAIF) Specification Interoperability Matrix as a useful framework for identifying, normalizing and organizing the necessary artefacts in a model-driven approach. The use of OMG’s Model Driven Message Interoperability (MDMI) was seen as a significant improvement for the mapping methodology, but requires a significant entry-level investment due to its complexity.

Terminology mapping is a hard problem, because in most cases a certain number of terms from the source terminology have no iso-semantic (i.e. equivalent) counterpart in the target terminology. In some cases, a uni-directional mapping from a more specialized to a more general concept may be possible, which causes information loss, in other cases no mapping may be possible at all. This is a problem area that was reported by several of the case studies. Another problem is that terminologies tend to change over time due to maintenance, which means that a mapping is only valid between specific versions of two terminologies. The versioning information, therefore, always needs to be maintained when such a mapping is defined.

The IHE cross-community integration profiles are arguably the first fully implementable specification of a communication protocol for connecting different Electronic Health Record deployments (networks) into a “network of communities” that has seen large-scale implementation in several large-scale deployment projects. The profiles have been designed to enable interoperability between communities that internally use different EHR architectures. However, there is only very limited experience with implementations where communities use an EHR architecture other than IHE XDS, or different content formats (as used in Trillium Bridge).

Power, and limitations, of semantic technologies: The SemanticHealthNet, ARTEMIS, RIDE and SALUS projects have demonstrated, albeit on a small scale, how clinical statements (such as a blood pressure or the information that a patient is known to not be diabetic) can be expressed with semantic expressions that enable an application receiving and processing the information to draw the right conclusions even if: a) different EHR or messaging standards are used and b) different archetypes/templates within a given EHR standard are used to express the same clinical concept. The prerequisite is that the complete content of the messag-
es or documents needs to be expressed through ontologies, either a common one, or ontologies for which a complete bi-directional mapping exists. In practice, such ontologies are most often not available and require significant effort for their development. In particular, SNOMED-CT, which was originally developed a terminology, is of limited use as a domain ontology as it lacks a comprehensive concept modelling based on a clinical process model. Furthermore, models (e.g. HL7 V2 and V3 messaging) and terminologies (e.g. ICD-10 and SNOMED CT) are rarely iso-semantic, so mapping generally implies a loss of information. Finally, semantic technologies exhibit significant performance and scalability issues.

- **Centralized vs. decentralized approaches:** No consensus was reached in the case studies on whether approaches using centralized actors, or decentralized peer-to-peer approaches are preferable. While the case study on Spain mentions that the presence of a central node as an enabler for communication across regions is seen as a major success factor, while the case study on Italy reports that peer-to-peer solution adopted, without any central “subject”, is the success key factor in the project.

- **Utility of a mock-up application in the development of a clinical information model:** Several case studies reported that one difficulty in clinical information modelling is to find a common “language” between clinicians and technical experts. The SemanticHealthNet project found that it was very useful to implement the initial written specification of a clinical information model as a mock-up application with a graphical user interface. Clinical users found it very helpful to use experimental data entry into the mock-up as a basis for validation and improvement of the underlying specification. Furthermore, the implementation revealed errors, inconsistencies and ambiguities in the specification that could then be addressed quickly.

- **Unexpected Complexity:** The case studies on Trillium Bridge and the English NHS both reported that the technical complexity of parts of the overall system was underestimated initially and turned out to be much higher than expected. In the case of Trillium Bridge, this was the effort needed for developing a mapping between patient summary specifications. In the case of NHS the move from HL7 v2 to HL7 v3 was much slower than expected due to the complexity of HL7 v3 concepts and tooling.

- **IT Security is difficult:** The case study on the English NHS and on e-SENS in Greece both report about the complexity of the IT security solution required for a large-scale eHealth system. In the English NHS, the “information governance” specification that deals with security, confidentiality, data quality, etc. was the most complex specification out of tens of different modules, and parts of it proved so complex that they were not implemented. The e-SENS case study reports that patient identification and healthcare professional authentication as well as mandate services are major extensions over the epSOS pilots that used an ad-hoc model with reduced security. However, in e-SENS there are still privacy requirements and legal issues that need to be clarified. The case study on the Greek Patient Summary Design adds the recommendation that **establishing security and data privacy guidelines should be focused from the early design on.** Security cannot be successfully retro-fitted into an existing IT architecture. The case study on the Portuguese NCP adds that security has to be addressed at different levels and needs to be analysed for each step of the supported workflows; **more than one level of security should be set in place,** preferably at different layers; security mechanisms should built on top of robust standardized solutions and not ad-hoc ones.
Non-interoperability is possible even within a single EHR standard: One important pitfall that the SemanticHealthNet project has identified is that non-interoperability on a semantic level is possible not only between users of different EHR standards, but also between users of the same EHR standard, if they use different clinical information models (templates, archetypes) to represent the same clinical concept – something that is quite likely to happen if different teams and domains develop their datasets and document templates. A practical example is the difference between the European and U.S. patient summary document templates examined by the Trillium Bridge project: Both are based on HL7 CDA, but nevertheless they use different ways of expressing the same information, and no “perfect”, or lossless mapping is possible.

Several case studies confirmed the importance of selecting and using good software tools. One of the success factors of the epSOS project was the decision to develop and publish as Open Source a complete reference implementation for their National Contact Point gateway software, because this permitted a quick ramp-up of national contact points by member states, and the improvement and extension of the software by follow-up projects like e-SENS.

5.2 Pragmatic Recommendations

Several of the case studies have expressed pragmatic, practical recommendations for future eHealth deployment projects that are briefly summarized in this section.

- Do not reinvent the wheel. There are many eHealth standards, architectures and tools available. Try to understand the existing standards and tools before re-inventing your own.

- Think big, start small. It is better to start with a small system and grow over time, than to aim for the perfect solution immediately. Look for the “low-hanging fruit”, such as a quick integration of edge systems using HL7 FHIR, which worked very well in the Greek Patient Summary project and in the Portuguese National Broker, which reports use of the HL7 FHIR standard to be a huge success.

- Make sure that more than one end user application can be built as edge system for the eHealth network (e.g. for accessing and visualizing information from the eHealth network), catering for different user needs and user preferences.

- Take the European requirements under the cross border healthcare directive into account when designing your system – to the degree possible today.

- There are useful components developed outside the eHealth community. Topics such as electronic identification, end point detection, non-repudiation, the use of electronic signatures and trust establishment are in no way eHealth specific topics. Mature solutions have been developed outside the field of eHealth, and these are readily available for use in eHealth projects. One example for this is the STORK project (https://www.eid-stork2.eu/), which focused on innovative electronic identification and authentication mechanisms and provided solutions that were successfully integrated into the epSOS eHealth toolchain in the context of the e-SENS project (see section 4.9).

- Be pragmatic with regard to content formats. While a complete semantic encoding of information is certainly desirable, it may not be possible with today’s technology, and even with the most powerful terminologies there may still be a reason to use free text. If a health
professional is “only” able to provide a PDF document, then this is not “semantically enabled”, but still very useful information for the recipient – a good first step that should not be neglected just because the solution is not perfect.

- **Develop your architecture layer by layer.** The Dutch case study reports that they found it both necessary and useful to separate between the layers of interoperability as described in the introduction chapter of this document. Create the architecture within each layer; clearly define the relationship between the layers and the way lower layers are derived from the layer above.

- **Decouple components by defining clear interfaces** (such as gateway protocols). This makes it easier to separate responsibilities and security requirements for parts of the overall system and can help to “hide” parts of the overall system complexity. Furthermore, it simplifies the development of compliant system components.

- **Ensure developer training and experience.** The Spanish case study reports that the worst “enemy” the project has found is poor implementation of standards, guidelines and specifications in products, caused by insufficient training and knowledge of the software developers.

It can be concluded that there is no “magic bullet”, no simple solution for solving the challenge of interoperability in large-scale eHealth projects – but nobody involved in the field would have expected this. The combined experience of the case studies collected in this document, both positive and negative, is a valuable source of information for future eHealth projects.

In the eStandards project, the next step will be to condense the information from this collection of case studies into a document entitled “Interoperability guideline for eHealth deployment projects”, which will be published in late 2016.
6 Annex: The Case Study Template

All text in blue colour contains explanations on how to fill-in the case study. All text in «double angular brackets» should be replaced according to the description given in the brackets.

6.1 Case Study #: «Name of Case Study»

Each case study will be a section within a larger chapter containing the entire case study collection.

Please note that there is no expectation that the case study will have a certain size (in pages). We expect this to vary significantly from case to case.

The case study should have a “catchy” name. Please also provide the following descriptive information about the case study:

- **Author of case study within the eStandards project:** «Name» «e-Mail»
  
  *The purpose of the author information is to make clear that the case study was written by the eStandards team and not by the original project described in the case study.*

- **Project name:** «Name»

- **Project type:** «concept | limited deployment for experimental use | large-scale deployment for experimental use | limited deployment for sustained routine use | large-scale deployment for sustained routine use»

  *Explanation:*
  
  - “Concept” means that the approach only exists “on paper” and was not implemented
  - “limited deployment for experimental use”: the approach was implemented and tested in a limited setting, e. g. only with fake data or with a small number of patients. This is typical for the small feasibility studies performed in most projects
  - “large-scale deployment for experimental use”: the approach was implemented in large scale, but only in a project context, not for sustained routine use. Example: epSOS.
  - “limited deployment for sustained routine use”: The solution is used for sustained routine operation in healthcare, but only in a limited context (e. g. one, or a few hospitals).
  - “large-scale deployment for sustained routine use”: The solution is used for sustained routine operation in healthcare on a larger scale, e. g. regional or national eHealth network.

- **Project status (in 10/2015):** «planning | deployed for experimental use | deployed for sustained routine use | completed»

- **Countries / Regions:** «countries or regions involved in a real-world deployment in case study»
  
  *for purely conceptual projects, write: not applicable*

- **Project partners:** «organizations participating to this project»

- **Scale of deployment:** «cross-border, cross-region, regional, intra-mural» «number of hospitals/practices connected»
  
  *for purely conceptual projects, write: not applicable*

6.1.1 Project Overview

*Provide a non-technical overview about the project: What are the project’s overall goals, stakeholders, and what are the results?*
6.1.2 Approach

Provide an overview of the technical approach taken by the project. In particular, describe the standards and profiles used by the project. You can structure this along the “Layers of Interoperability” defined by the ANTILOPE project [vPS14] as shown below. For this case study, we are mainly interested in the lower four layers, i.e. care process, information, applications, and IT infrastructure.

![ANTILOPE Layers of Interoperability](image)

For some projects, another structure may be useful, and is explicitly permitted. For example, for X-Paradigm explain the interoperability layer developed by this project and how this relates to the Antilope layer model.

6.1.2.1 Care Process

Description: “After the organisations have agreed to work together, specific care processes are analysed and aligned, resulting in integrated care pathways and shared workflows. This level handles the tracking and management of the workflow processes”. On this level, abstract models for clinical processes and workflows will be defined.

6.1.2.2 Information

Description: “This level represents the functional description of the data model, the data elements (concepts and possible values) and the linking of these data elements to terminologies that define the interoperability of the data elements.” Examples for standards used on this level are HL7 CDA/CCD with specific templates, EN 13606 archetypes, and terminology standards such as SNOMED or LOINC. Conceptual models also belong into this level.

6.1.2.3 Applications

Description: “On this level, agreements are made about the way import and export of medical information are handled by the healthcare information systems. The technical specification of how information is transported is at this level (communication standards). The information systems must be able to export and import these communication standards.” Examples for standards used on this level are IHE XDS and XCA (for EHR-based non-directed communication), IHE XDR or HL7 messages (for directed communication), or IHE profiles like PIX, PDQ, XCPD.

6.1.2.4 IT Infrastructure

Description: “The generic communication and network protocols and standards, the storage, backup,
and the database engines are on this level. It contains all the “generic” interoperability standards and protocols.” Examples for standards used on this level are TLS, IPsec, IHE XUA (authentication) or IHE ATNA (audit trail).

6.1.3 Concurrent Use of Standards and Specifications (De-facto Standards)

Explain where in the project the concurrent use of standards played a role, and how this task was addressed in the project, for example by providing gateways converting or mapping (transformation) between terminologies, documents or messages:

- Mapping between controlled terminologies (coding systems)
- Mapping between identifiers
- Mapping between clinical concepts
- Mapping between document formats
- Mapping between messages (e.g. notifications, queries and responses)
- Mapping between different reference information models

Please describe the tools or software architecture used to enable this concurrent use of standards.

We are not only interested in official standards, but also in the coexistence between de-facto standards or proprietary specifications and official standards, or different “versions” of the same standard such as different HL7 CDA templates for the same use case.

6.1.4 Governance

Explain the organisation and governance the project has established in order to continuously maintain the specifications (e.g. mapping rules) for the concurrent use of standards and specifications as described in the previous section.

6.1.5 Lessons learned

What can future large-scale eHealth deployment projects learn from this case study? What are the most important “lessons learned” from this project?

6.1.5.1 Successes

What worked well, in particular with regard to the concurrent use of standards?

6.1.5.2 Pitfalls and Remedies

What were pitfalls and problems that occurred in this project that other projects should be aware of, in particular with regard to the concurrent use of standards? Did the project find solutions (remedies) for these pitfalls?

6.1.6 Resources

If the project has produced and made available resources that might be used by other projects, either freely or commercially, please list here. This may be technical specifications, software tools, or commercial products such as gateways.

<table>
<thead>
<tr>
<th>eSCST15</th>
<th>eStandards Case Study Template: Concurrent Use of eHealth Standards</th>
</tr>
</thead>
<tbody>
<tr>
<td>Description</td>
<td>Document template for describing case studies for concurrent use of standards</td>
</tr>
</tbody>
</table>
### 6.1.7 References and Further Information

Please provide references to further information about the project described in this case study (e.g., articles, public deliverables, project homepage). If available, English-language publications are preferred; otherwise national-language publications are OK. In that case, please add the language of the publication in square brackets to the end of the reference, e.g. [in German language]. The tag, like [vPS14], which is used to cite papers in the text, is derived from the initials of the authors’ family names, and the year of publication.
