



eHealth EIF

eHealth European Interoperability Framework

European Commission – ISA Work Programme



Vision on eHealth EIF

A study prepared for the European Commission
DG Connect

*Digital Agenda
for Europe*

This study was carried out for the European Commission by



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0 – Foreword to the eHealth Interoperability Framework Study

Despite the climate of the economic crisis, the market potential of eHealth is strong. The global telemedicine market has grown from \$9.8 billion in 2010 to \$11.6 billion in 2011, and is expected to continue to expand to \$27.3 billion in 2016, representing a compound annual growth rate of 18.6%. The well being market enabled by digital technologies (mobile applications, devices) is rapidly growing.

eHealth can benefit citizens, patients, health and care professionals but also health organisations and public authorities. eHealth – when applied effectively - delivers more personalised ‘citizen-centric’ healthcare, which is more targeted, effective and efficient and helps reduce errors, as well as the length of hospitalisation.

Despite the opportunities and benefits, major barriers hamper the wider uptake of eHealth and one of the major ones is the lack of interoperability between eHealth solutions. That is why we need an EU eHealth Interoperability Framework, in order to achieve convergence in the way standards are used, and to accelerate the takeup of eHealth standards.

The large scale pilot epSOS has developed its own interoperability framework in order to make the exchange of patient data and ePrescriptions across the borders possible. The feasibility has been demonstrated now, but as epSOS is (only) a pilot project, we need to bring the epSOS interoperability framework to the policy level in order to utilise it for large scale deployment of eHealth Services under the Connecting Europe Facility. This study has analysed and assessed the epSOS interoperability framework and some of the standards and specifications on which it relies.

However, it didn't stop there. It also defined a vision for an EU interoperability framework with a larger scope. CEF eHealth deployments will start with epSOS use cases but this will only be a beginning. Other services will follow, such as telehealth services, or the exchange of medical images or laboratory results, and that's why 8 additional use cases and their associated specifications were analysed in this study. Furthermore, if we want the EU eHealth market to be efficient, the eHealth Interoperability Framework should not only tackle cross border use cases and should not be limited to CEF deployment. If we want a functioning internal market, we need the national, regional and local interoperability frameworks in which national, regional and local deployments will take place, to converge as much as possible, while taking into account local, regional and national specificities. That is the final goal, that is the ambition. The road is long and winding but we hope to bring patients and citizens more empowerment and better lives, better tools to give better and safer care to healthcare providers, better market conditions to the industry and better possibilities to exploit the untapped potential of electronic Health Records to the research community and public authorities.

This study is only a start, it is not an end.

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1 – Executive Summary

This report has three main objectives:

- Explaining the vision of the eHealth European Interoperability Framework (EIF).
- Introducing the conceptual overview of the eHealth EIF.
- Explaining the components of the eHealth EIF in detail.

Each of these three objectives is dealt with as follows:

- The first objective is to explain the vision of the eHealth EIF

The eHealth EIF is positioned as an operational tool kit for implementers and purchasers to deploy eHealth systems. It is intended to be used as a reference guide in calls for proposals and tenders for the Connecting Europe Facility (CEF) deployment, but possibly also for deployment at the national and regional levels. The vision is that the eHealth EIF will be leveraged by the eHealth Network for eHealth deployment that takes place in Member States.

In terms of the health and care of European citizens, continuity of care (otherwise referred to as integration of care) is a particularly important domain. Interoperability is needed both in healthcare, and in terms of the supporting information and communication technologies.

There is a pressing need for support to achieve these two aims. In the future, part of this support can be provided by the eHealth EIF. **Hence, the framework offers a tool kit² to accelerate the on-going transformation process that will help to increase eHealth interoperability.**

Initially, however, this report takes a rapid bird's eye view of the general policy and planning background to the eHealth EIF.

- The second objective is to introduce the conceptual overview of the eHealth EIF

The different aspects of the framework are introduced at a conceptual level. The high-level concepts are its **governance, principles, agreements, interoperability levels**, and **high-level use cases** (cfr Deliverable 4). As per the generic European Interoperability Framework (EIF)³, the four interoperability levels are the legal, organisational, semantic and technical interoperability. The report shows how the conceptual model draws on the work through 2009-2011 of the CALLIOPE (Call for Interoperability) thematic network⁴. The work of this study is complementary to the CALLIOPE model. The conceptual framework is grounded in current work and in the value-added of previous studies and projects (cfr Deliverable 1).

- The third objective is to explain the components of the eHealth EIF in detail

These components are governance, principles, agreements, the four levels of interoperability: legal, organisational, semantic, and technical, and the notion of high-level use cases⁵. Each item has been given a detailed analysis, and is described briefly below.

- **Governance:** This section shows the difference between the governance in the eHealth domain and governance of the eHealth EIF. It describes the different

² The scope and objectives of this study was to construct an eHealth EIF *framework*. A *framework* is of a higher level of abstraction than an *architecture*, which includes reusable building blocks (such as eID), how they link together (cookbook recipe) and how they form a solution together (final product).

³ (European Commission, 2010e)

⁴ (CALLIOPE, 2010)

⁵ The use cases are discussed in detail in Deliverable 4

actors within the eHealth domain (eHealth Network, eHealth Governance Initiative, CEF Governance, Information and Communication Technology "ICT" standards multi-stakeholders platform).

- **Principles:** Six principles were extracted by the study team from the generic EIF: security and privacy, transparency, preservation of information, reusability, technological neutrality and adaptability, and openness. Two additional principles have been added to this list: they are patient centricity and an approach based on use cases. More principles could be considered.
- **Interoperability agreements:** For each interoperability level, the organisations involved should formalise cooperation arrangements in interoperability agreements. This plays a crucial role in the context of the eHealth EIF, as an interoperability agreement is an essential tool to accelerate the transformation process to achieve higher eHealth interoperability.
- **Legal interoperability:** In terms of legal interoperability, eight binding instruments and six non-binding legal instruments are pertinent to the work of the eHealth EIF. On the binding side, in sequential order, four instruments have been in existence for some years are the Directive 1995/46/EC, the Directive 1999/93/EC, Directive 2007/47/EC and the Directive 2011/24/EU. Four recently EC adopted instruments are the Regulation on European Standardisation, the Draft Regulation on Data Protection, the Draft Regulation on electronic identification (eID) and electronic signature (eSignature); and the Draft Regulation on medical devices. Six non-binding legal instruments are perceived to have had influence over the issue of eHealth interoperability. The first four are a Recommendation on interoperability, a Communication on telemedicine, Guidelines relating to the medical devices directive, and a Green paper on card, internet and mobile payments. In December 2012, two additional non-binding instruments were published, i.e. the eHealth Action Plan 2012-2020 and the Commission Staff Working Paper on the applicability of the existing EU legal framework to telemedicine services.
- **Organisational interoperability:** From an organisational perspective, to support the development of the eHealth EIF, three recommendations have been extracted by the study team from the eHealth Governance Initiative (eHGI) discussion paper⁶ on semantic and technical interoperability (i.e., encourage greater cooperation between Member States; between national authorities and standardisation bodies; and consider incentivisation of healthcare providers). Others have been adapted from discussions held during the course of the study on quality labelling and testing at a European Union level.
- **Semantic interoperability:** Three categories of semantic artefacts are proposed: (a) systems for concept representation, (b) clinical models which assemble data items and map to specific terminology subsets for each item, (c) Electronic Health Record (EHR) information models that provide a higher level containment framework and provenance context. From a semantic perspective, to support the development of the eHealth EIF, four recommendations have been extracted by the study team from the eHGI discussion paper on semantic and technical interoperability (i.e., foster data portability; link and harmonise coding systems; facilitate access to existing standards and medical vocabularies; and stimulate usability engineering for structured and encoded data). Further recommendations on semantic interoperability are made based on the SemanticHEALTH⁷ and ARGOS⁸ studies.

⁶ Discussion paper submitted by the eHealth Governance Initiative (eHGI) to the eHealth Network
Date: October 22nd, 2012. Note that the recommendations from the eHGI discussion paper were validated by the eHealth Network on 7/11/2012. However, it is possible that some of these recommendations will change in the future.

⁷ <http://www.semantichealth.org/>

- **High-level use cases:** The eHealth EIF follows a use case-based approach. In this way, an eHealth interoperability project can "reach out" to other EU prioritised use cases addressing the same high-level use. Therefore, a list of ten high-level use cases is to be proposed to the eHealth Network. This list of use cases proposed falls into four categories (cross-border; national/regional; intra-hospital; and at the level of citizens, whether they are on the move or at home). It deals with the following aspects: e-Prescription / e-Dispensation, patient summary, radiology, laboratory, medical summaries, ever-present care outside conventional care facilities using personal computer or web-based applications, mobile phones, and sensor devices. For more information about these ten high-level use cases, please see deliverable D4.
- **Technical interoperability:** As the eHealth EIF follows a use case-based approach, it recommends a specific set of profiles for these high-level use cases. To this end, a set of candidate profiles were analysed against an assessment framework (for more details, see Deliverable D3 and D4). The conclusions of the assessment are the following:
 - For IHE, no major non-compliance was found, though minor improvement needs were highlighted.
 - For Continua, major non-compliance on transparency, openness and consensus was found and communicated to the consortium. In December 2012, the Board of Continua approved changes to their rules and procedures in order to move toward more transparency, openness and consensus.

As a result, the Deloitte study team proposes to submit IHE profiles to the ICT standards multi-stakeholders platform for identification. Furthermore, the Deloitte study team proposes that the platform gives guidance on Continua's new rules and procedures, in order to assess whether future specifications might be eligible for identification.

⁸ <http://argos.eurorec.org/>

2 – Introduction

This introduction outlines the objectives of the report (section 2.1), and the structure of the report (section 2.2).

2.1 – Objectives of this report

This report has three main objectives. Firstly, this report explains the vision of the eHealth European Interoperability Framework (EIF). Since all policy formulation is based on a vision of the future, this report describes the eHealth EIF within a long-term vision. The European Union is currently focusing on integrating its immediate seven-year policy developments within a larger framework that looks forward to the decade of 2030⁹. Interoperability in healthcare can support the continuity (or integration) of care. While interoperability is implicitly bound up with the construction of a digital single market in Europe, interoperability in healthcare can act in support of this aim. The eHealth EIF itself can act as an accelerator for achieving greater eHealth interoperability. Essentially, it provides a tool kit to accelerate the on-going transformation process that will help to increase eHealth interoperability.

Secondly, this report introduces the conceptual overview of the eHealth EIF and its relationship with the common working model produced by the thematic network, CALLIOPE (Call for Interoperability). This helicopter view alerts readers to the importance of the eHealth EIF governance which, supported by its principles and agreements, underpins the entire initiative. The four levels of interoperability – legal, legal, organisational, semantic, and technical – are each introduced as are their relationships with each other.

Thirdly, this report provides a detailed explanation of the eHealth EIF, by focusing on its separate components¹⁰. In this context, the generic European Interoperability Framework (EIF) plays an important role, which is sector-independent and offers an approach to interoperability for joint delivery of public services. In 2010, the European Commission published a Communication entitled "Towards Interoperability for European Public Services" (European Commission, 2010e), of which the second annex introduced the generic EIF. The EIF promotes and supports the delivery of European public services¹¹ by fostering cross-border and cross-sectoral interoperability. The EIF is maintained under the Interoperability Solutions for European Public Administrations (ISA) programme, in close cooperation with the Member States and the European Commission.

The intention of this study is to **apply the generic EIF to the domain of eHealth**. This study therefore takes into account particularly the EIF governance, principles, and agreements, followed by an examination of each of the four levels of interoperability: legal, organisational, semantic, and technical.

2.2 – Structure of this report

This report consists of eleven chapters.

Chapter 1 summarises the main messages of the report by means of an executive summary. Chapter 2 (this chapter) explains the objectives and structure of the report. Chapter 3 introduces the vision of the eHealth EIF. Chapter 4 provides a conceptual overview of the eHealth EIF. The final seven chapters focus on the eHealth EIF. They provide details of the various components of the framework. These components are governance, principles, agreement, and four forms of interoperability – legal, organisational, semantic, and technical.

⁹ For instance, the European Commission funds projects related to sustainable and interoperable health services via the Competitiveness and Innovation Programme (CIP) - <http://ec.europa.eu/digital-agenda/en/ict-policy-support-programme-participate>

¹⁰ The use cases are discussed in detail in Deliverable 4.

¹¹ Here, it should be noted that health services are not public services. The first feedback to the generic EIF would be to cover not only public services, but also – rather – services of general interest, which would then also cover health services. However, the transfer of health data, which relates to eHealth, is often (if not always), given its highly sensitive nature, regulated by public authorities. It can in this way therefore be coupled to or associated with public services (as referred to in the EIF).

The order of the various chapters is as follows: governance (Chapter 5), principles (Chapter 6), agreements (Chapter 7), legal interoperability (Chapter 8), organisational interoperability (Chapter 9), semantic interoperability (Chapter 10), and technical interoperability (Chapter 11).

Annex 1 contains the data gathered in the country-specific analysis of eHealth specifications.

This report can be read particularly in close association with Deliverable 4 of this study, which outlines the technical details – or profiles – of the eHealth EIF. The assessment framework described in Deliverable 3 of the study is also complementary to the content of this deliverable.

3 – Vision of eHealth EIF

Since all policy formulation is based on a view of the future, this chapter sets the image of the eHealth EIF within a long-term vision. Today, the European Union is concentrating on integrating its immediate seven-year policy developments within a larger framework that looks forward to the decade beginning in 2030. Interoperability in healthcare has potential for supporting the continuity (or integration) of care. While interoperability is implicitly bound up with the construction of a digital single market in Europe, interoperability in healthcare can act in support of this aim. The eHealth EIF itself can act as an accelerator for achieving greater eHealth interoperability. **Essentially, it provides a tool kit to accelerate the on-going transformation process that will help to increase eHealth interoperability.**

This chapter is structured as follows. Section 3.1 discusses the role of the single market in Europe. Taking into account this vision, section 3.2 explains the challenges for healthcare requiring this high degree of interoperability. Finally, section 3.3 summarises the vision of eHealth EIF.

3.1 – Building a single market in Europe

Market fragmentation has long been the bugbear of the European Union. Actions to remedy the situation are taking place in most policy areas of the Union, except those that can be considered to be exempt. For example, the Services Directive of 2006 (Directive 2006/123/EC), and its supporting application of one-stop shops for people in diverse Member States wishing to set up business elsewhere in Europe, seems to be proving invaluable in this regard. Efforts to reinforce the role that eHealth could take in creating a more coherent market orientation and, at the same time, providing the preliminary steps towards a more sustainable market in Europe were articulated with greatest strength in the Lead Market Initiative in 2007 (European Commission, 2007). However, ambitious elements of a unified eHealth "space" were already formulated as early as 2004 (European Commission, 2004, p4 and p22).

Such aspirations are, of course, being specified in a period of considerable debate and dialogue surrounding the notion of a policy union combined with a substantial degree of anxiety around the concepts of a financial union and its market-based initiatives. The Union has much work to do in-house¹². However, relationships with other parts of the globe on which there can be a degree of collaboration with regard to interoperable eHealth systems and services are also under construction. The main elements at hand include the prominent EU-US relationship¹³ and links with all other parts of the globe, more generally (European Commission, 2010a).

3.2 – The challenges for healthcare requiring interoperability

Taking into account the vision articulated in the previous sections, this section discusses the challenges for healthcare requiring such a level of interoperability.

Clinicians of all disciplines require access to detailed health records in order to manage the safe and effective delivery of health care. Care is increasingly transmural, requiring close cooperation between a wide range of healthcare professionals and specialists in different care settings forming a virtual team around each patient. At the same time, privacy concerns can sometimes present a barrier to the necessary sharing of records to support well-informed, and therefore safe, shared care. Privacy protection policies and measures thus also need to be interoperable, so that a patient's rights and wishes can be respected whenever his or her personal health information is accessed or transferred.

¹² It is worth mentioning that outside the Union an international collaboration is also taking place.

¹³

http://ec.europa.eu/information_society/newsroom/cf/itemdetail.cfm?item_id=8146&utm_campaign=isp&utm_medium=rss&utm_source=newsroom&utm_content=tpa-23

Both acute and chronic condition care is becoming increasingly complex, with new diagnoses, new investigations, novel therapies and increasing numbers of patients with multiple conditions that might interact. There is increasing recognition that decision support and computerised clinical guidelines can improve the safety, timeliness and efficiency of health care significantly, but operationalising these in busy healthcare settings remains challenging. Health records therefore need to be linked to guideline rules such that individual clinical applications and distributed reminder and alerting services can help clinicians to follow best practice and notify them of critical findings and errors, or if gaps in continuity of care arise.

Many of the safety-critical healthcare scenarios involve knowledge management failings or gaps in communication. Particular points in the clinical process in which care steps might be delayed or omitted or dangers introduced, and for which information and knowledge interoperability could improve safety, include:

New medication prescriptions: the safety of prescriptions may be compromised by a lack of comprehensive information on concurrent medication (including purchased drugs) and details of known allergies and possible contra-indications, in particular since this information might be split across multiple care organisations and health records;

Reminders and prompts for overdue or overlooked health care actions and interventions;

Evidence-based care: the use of clinical guidelines and other forms of evidence to determine the optimal management strategy and care pathway for a given patient, particularly for chronic conditions;

Care transfers: referrals and discharges, within-team workflows, and wider cross-boundary health care, to ensure communication among care providers of the degree of urgency and the expectations of each treating clinician;

Care co-ordination: ensuring that a high-level view can be taken of distributed (multi-team) care to protect against duplication, delay, and incompatible interventions.

3.3 – Vision of eHealth EIF

When discussing the challenges for healthcare interoperability, it is clear that different stakeholders have different expectations for the interoperability of personal health information.

Patients are increasingly expecting to exercise personal and informed autonomy over their health care. It has been known for years already that individuals can acquire considerable expertise in managing illness and preventive health if they are given useful and appropriate material with which to educate themselves and the tools with which to participate. Self-management is increasingly recognised as a cost-effective way of coping with the increased demands of chronic disease care, and almost certainly of helping to improve outcomes. Not only do patients therefore need direct access to their own longitudinal multi-organisational health record, but this also needs to be integrated with personal health records that they might keep and which reflect their self-management and personal health objectives.

Individual providers, and national/regional health services, are increasingly under pressure to optimise their use of scarce resources, and therefore need real-time and fine-grained business intelligence on cost, quality and outcomes of care. Since health care is now transmurals, business intelligence also needs to be transmural¹⁴, therefore requiring interoperability of electronic healthcare record (EHR) data and of metrics to allow comparisons¹⁵. EHRs can be a potentially valuable source of outcomes data, if it is possible to harmonise the information in each EHR and accurately profile each patient to make valid and precise comparisons between fine-grained sub-populations.

¹⁴ Transmural care is the interface between primary and secondary care in medicine.

¹⁵ Deriving measurable outcomes from EHR data is quite challenging because many different items need to be considered such as the quality of life, amount of pain a patient can experience.

In parallel, the needs of public health and clinical research for analysable data across multiple EHR systems, and across national boundaries, are growing. There is now wide recognition within Europe that population health (observational) research should be possible across multiple provider settings and that interoperability and privacy concerns are the two major obstacles to achieve this.

In summary, **interoperable health records and medical knowledge are needed to help make longitudinal care safer, more patient inclusive, and more evidence based, and to speed up the discovery of new knowledge and its translation from bench to bedside.**

4 – Conceptual overview of eHealth EIF

This chapter introduces the different aspects of the eHealth EIF at a conceptual level, based on both a top-down and bottom-up approach. The top-down approach is based on the generic EIF and the CALLIOPE (Call for Interoperability) working model, while the bottom-up approach is mainly based on the Member State analysis. Hence, the concept of the eHealth EIF is based directly on the analysis of the position of these three different initiatives towards interoperability: the generic EIF, the CALLIOPE model, and the Member State analysis.

Section 4.1 explains the original concepts included in the generic EIF, such as principles, interoperability levels, interoperability agreements and governance. Section 4.2 introduces the CALLIOPE working model. Section 4.3 discusses the key insights provided by the Member State analysis. Finally, section 4.4 provides an overview of the resulting eHealth EIF concepts, based on the generic EIF, CALLIOPE working model and Member State analysis, including **governance, principles, agreements, interoperability levels, and use cases**. Section 4.4 is particularly useful in terms of its description of the overall eHealth EIF concepts.

4.1 – Introducing the structure of the generic EIF

As discussed in section 2.1, the intention of our study is to **apply the generic EIF (of which the structure is given in Figure 1) to the domain of eHealth**. This study therefore takes into account particularly the EIF governance, principles, and agreements, followed by an examination of each of the four levels of interoperability: legal, organisational, semantic, and technical. An overview of these different EIF concepts is given by Figure 1. Each of these EIF concepts is discussed in detail in the following sections.

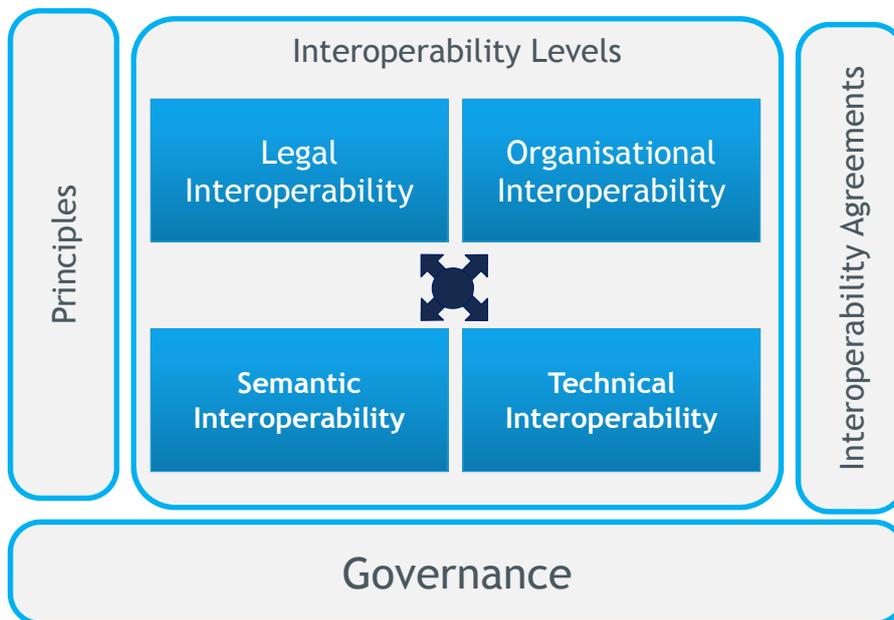


Figure 1 - Structure of the generic EIF

4.1.1 – Principles

The generic EIF “defined general principles of good administration that are relevant to the process of establishing European public services. They describe the context in which

European public services are decided and implemented. They complement one another regardless of their different levels, e.g., legal, organisational, semantic, or technical.”¹⁶

The twelve underlying principles of the EIF can be grouped under three categories:

- The first principle sets the context for EU action on European public services (Subsidiarity and proportionality);
- The next group of underlying principles reflect generic user needs and expectations (User-centricity, Inclusion and accessibility, Security and privacy, Multilingualism, Administrative simplification, Transparency, Preservation of information);
- The last group provides a foundation for cooperation among public administrations (Openness, Reusability, Technological neutrality and adaptability, Effectiveness and efficiency).

4.1.2 – Interoperability levels

The interoperability levels “classify interoperability concerns according to who/what is concerned and cover, within a given political context, legal, organisational, semantic and technical interoperability”¹⁷.

Each interoperability level has its own objective¹⁸:

- Legal interoperability aims to “align legislation so that exchanged data is accorded proper legal weight”.
- Organisational interoperability aims to “coordinate processes in which different organisations achieve a previously agreed and mutual beneficial goal”.
- Semantic interoperability aims to precise “meaning of exchanged information which is preserved and understood by all parties.”
- Technical interoperability aims to “discuss technical issues involved in linking computer systems and services”¹⁹.

4.1.3 – Interoperability agreements

Providing European public services requires “cooperation among different public administrations at the various interoperability levels described in the previous section. For each interoperability level, the organisations involved should formalise cooperation arrangements in interoperability agreements.”²⁰

These agreements should be drafted with sufficient detail to enhance cooperation between different eHealth stakeholders, while leaving each stakeholder maximum internal autonomy. Furthermore, interoperability agreements should be multilateral so as to avoid point-to-point connections.

4.1.4 – Governance

Ensuring interoperability between “legal instruments, organisation business processes, information exchanges, services and components that support the delivery of European services of general interest is a continuous task, as interoperability is disrupted by changes to

¹⁶ European Commission (2010e), p14

¹⁷ European Commission (2010e), p37

¹⁸ European Commission (2010e), p26

¹⁹ Note that technical specifications (like IHE profiles) can go further than this, and might include semantic components as well.

²⁰ European Commission (2010e), p30

the environment, i.e., changes that occur to legislation, the needs of businesses or citizens, the organisation of public administrations, business processes or technologies.”²¹

Interoperability governance “covers the ownership, definition, development, maintenance, monitoring, promoting and implementing of interoperability frameworks in the context of multiple organisations working together to provide (public) services. It is a high-level function providing leadership, organisational structures and processes to ensure that the interoperability frameworks sustain and extend the organisations’ strategies and objectives.”²²

4.2 – Introducing the structure of the CALLIOPE working model

CALLIOPE (Call for Interoperability) was a European Union (EU)-funded Thematic Network called "CALLIOPE – Creating a European coordination network for eHealth interoperability implementation". It produced a roadmap²³ that can act as a base document for this study (CALLIOPE, 2010a). The intention of this roadmap was to propose a robust, complete and consistent global view of EU eHealth Interoperability, by describing possible “highways” for action and presenting a coherent factual basis for decision-making on the part of European policy-makers. CALLIOPE also produced a standardisation status report (CALLIOPE, 2010b), that prescribes a list of recommendations related to activities by the European Commission, European Standardisation Organisations, Member States and suppliers.

In this context, a CALLIOPE working model was proposed to bring all different concepts together, including the eHealth services, the ICT infrastructure foundation, the eHealth infostructure foundation, and the eHealth governance (Figure 2). Each of these concepts is discussed in detail in the following sections.

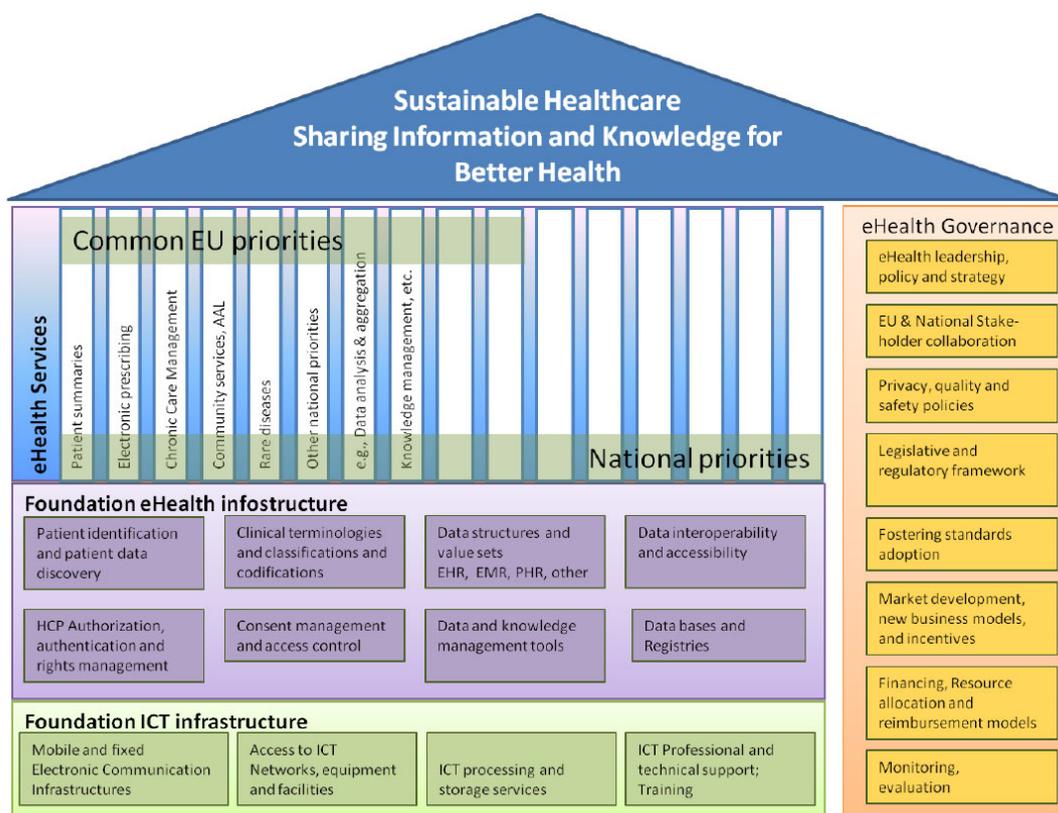


Figure 2 - CALLIOPE Working Model

²¹ European Commission (2010e), p33

²² European Commission (2010e), p37

²³ <http://www.calliope-network.eu/Consultation/tabid/439/Default.aspx>

4.2.1 – eHealth services

The eHealth services deal with the following aspects:

*"All the services which directly contribute to high quality care and improved accessibility and cost containment, such as patient summaries, ePrescribing, chronic disease management, home monitoring, tele-consultation, tele-radiology and others. These services typically reflect the national priorities. Many of them are common to all EU member states and therefore are candidates for priorities that should drive the common EU activities."*²⁴

4.2.2 – Foundation eHealth infostructure

The eHealth infostructure foundation deals with the following:

*"All data structures, codifications, terminologies and ontologies, data interoperability and accessibility standards, stored information and data as well as rules and agreements for the collection and management of these data and the tools for their exploitation. At the EU level, such a European infostructure may be composed of biomedical and health/medical research and knowledge databases, public health data repositories, health education information, electronic patient and personal health records, data warehouses, etc. It will require leadership and management, sustained organisational structures, well-governed processes and funding as well as a supportive, secure ICT infrastructure/network and the associated semantic services."*²⁵

4.2.3 – Foundation ICT infrastructure

The ICT Infrastructure foundation deals with the following:

*"The national fixed and mobile electronic communication infrastructures, access to the ICT Network and services including security services; the needed ICT processing and storage infrastructure and professional ICT technical support and training. Such infrastructure should be future oriented and should seek to address both national and cross border eHealth needs."*²⁶

4.2.4 – eHealth governance

The eHealth governance deals with the following:

*"Holding together all layers and brings under a single umbrella national/EU strategy and leadership to drive eHealth deployment; a collaborative framework with all key stakeholders; policies and mechanisms for the adoption and use of standards, as well as for safety and quality of generated information and data protection of shared personal data. The governance should also address effectively incentives, financing models and development of partnerships and new business models."*²⁷

4.3 – Introducing the findings of the Member State analysis

The objective of this section is to identify common eHealth framework elements, and to take these elements into account during the development of the eHealth EIF. In this context, this study tries to identify the Member State elements that are representative for the construction of the eHealth EIF, rather than executing an exhaustive scan of all Member State eHealth aspects.

²⁴ (CALLIOPE, 2010), p66

²⁵ (CALLIOPE, 2010), p65

²⁶ (CALLIOPE, 2010), p65

²⁷ (CALLIOPE, 2010), p66

4.3.1 – High level approach

In undertaking this Member State analysis, at a high-level in terms of process, two main issues are important: the selection of the countries themselves and the analytical method that was used. Each is described briefly here.

4.3.1.1 – Selection of countries

This section illustrates the rationales behind the selection of a representative and relevant set of countries, which input feeds into the eHealth EIF. The following indicators served as the selection criteria for the countries:

- pattern of eHealth use in the European Union²⁸; this criterion combines an indicator of electronic storage of patient data, computer use in consultation and electronic transfer of patient data;
- percentage of gross domestic product (GDP) spent on healthcare.²⁹

The combination of the above criteria led to a selection of Member States that included Denmark, France, Sweden, and the United Kingdom. According to the first indicator, these four countries are among the top performing countries in Europe in terms of eHealth use (Denmark is ranked as first, followed by Sweden, the United Kingdom and France). According to the second indicator, the selected countries have among the highest percentages of GDP spent on healthcare (France 11,8%; Denmark 11,5%; Sweden 10%; United Kingdom 9,8%).

In addition to the above Member States, the United States (US) were added to the list of countries to be examined for comparative reasons.

4.3.1.2 – Method of analysis

The analysis of the sample of countries was done in the context of the EIF principles, interoperability agreements and the four EIF interoperability levels – legal, organisational, semantic, and technical. For each of the four countries selected, the EIF building blocks were analysed. Based on the findings gathered, whenever possible, patterns within the different EIF building blocks were identified. This analysis led to the following results:

- a. For the principles, Security and Privacy, Transparency, Preservation of Information and Patient Centricity were identified as forming a pattern in the sample of countries analysed;
- b. For organisational interoperability, Cooperation between Member States and Cooperation between national authorities and standardisation bodies were identified as offering a common pattern;
- c. For semantic interoperability, Medical vocabulary, Artefacts used to represent clinical meaning, and the general Contribution to interoperability were found to be similar among the selected countries;
- d. For technical interoperability, Standards usage was identified as a common pattern.

4.3.2 – Overview of findings

The findings of the Member State analysis have relevance for the EIF principles, and particularly for three levels of interoperability – the organisational, semantic and technical levels.

²⁸ http://www.ehealth-indicators.eu/index2.php?page=ICT_ehealth_use/scoreboard

²⁹ "2012 European Summit on Trustworthy Reuse of Health Data. Current eHealth data landscape within the EU", Deloitte, May, 2012.

4.3.2.1 – Findings for principles

The analysis of interoperability in the four countries revealed the importance and implementation of the Security and Privacy Principles in the form of secure data exchange techniques and standards. Concerning the Transparency principle, Member States promote patient consent for data gathering and sharing. The principle of Preservation of information is present in the form of historical storage of electronic medical records. In addition, the observation of Member States revealed a trend towards patient centricity in the form of healthcare management by patients (e.g., the extent to which a patient can view all relevant diagnoses, treatments, and can book appointments online) or unique patient identifiers. As a result, Patient centricity is suggested to be one of the relevant principles of the eHealth EIF.

4.3.2.2 – Findings for the organisational interoperability level

When looking at the organisational interoperability level, the cross-border cooperation between the Member States (and the US) was observed. This cross-border cooperation takes the form of the International Health Terminology Standardisation Organisation, and the Baltic eHealth project that aimed to promote eHealth infrastructure.

4.3.2.3 – Findings for the semantic interoperability level

The semantic interoperability level is visible among Member States and the US as a set of standardised sets of medical vocabulary. In addition, artefacts that represent clinical models were found. These three models are: base models, reference models for medical documents, and information models.

4.3.2.4 – Findings for the technical interoperability level

The analysis of the Member States and the US revealed that a variety of different standards addressing different eHealth requirements are in use. In order to structure and organise the variety in the base standards, a concept for profiling would be a good way to address different and complex eHealth requirements. A profile combines several base standards, describes the way they have to be used in order to address specific eHealth requirements gathered into a business use case, and is "broken down into" a technical use case. Some frameworks studied already contain profiles (examples include France and the US).

4.4 – Resulting structure of eHealth EIF

The structure of the eHealth EIF was defined based on three sources: the structure of the generic EIF, the CALLIOPE working model, and the Member State analysis. Figure 3 provides an overview of the resulting eHealth EIF concepts, including **governance, principles, agreements, interoperability levels** (i.e., legal, organisational, semantic and technical), and **use cases**.

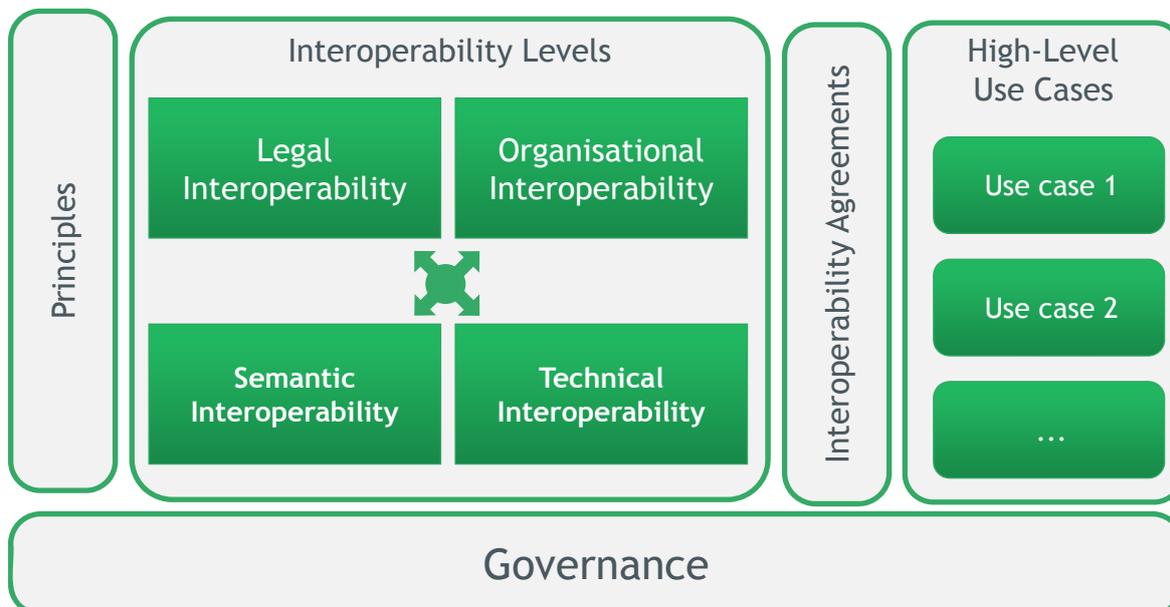


Figure 3 - Resulting eHealth EIF structure

As the intention of this study is to **apply the generic EIF to the domain of eHealth**, the structure of the generic EIF acted as a basis for the structure of the eHealth EIF. In addition, the CALLIOPE working model was used to perform a completeness check for all the different concepts used in the eHealth domain: it became clear, as a result, that the notion of eHealth services, or more generally, high-level use cases, should be included in the eventual eHealth EIF. The importance of this additional concept was confirmed by the mandate M/403 study and the eHGI discussion paper on semantic and technical interoperability³⁰. Finally, the Member State analysis confirmed the importance of principles, organisational interoperability, semantic interoperability and technical interoperability.

Table 1 shows a detailed overview of the eHealth EIF structure based on the generic EIF, the CALLIOPE working model³¹ and the Member State analysis. It indicates where references to the various principles, different levels of interoperability, interoperability agreements, high-level use cases, and governance, can be found in each initiative or document.

Table 1 - Mapping of eHealth EIF structure based on the top-down approach (generic EIF and CALLIOPE working model) and the bottom-up approach (MS analysis)

eHealth EIF	EIF	CALLIOPE working model	MS Analysis
<i>Principles</i>	Principles		Principles
<i>Legal interoperability</i>	Legal interoperability	eHealth governance	
<i>Organisational interoperability</i>	Organisational interoperability	eHealth governance	Organisational interoperability
<i>Semantic interoperability</i>	Semantic interoperability	Foundation eHealth infostructure	Semantic interoperability
<i>Technical interoperability</i>	Technical interoperability	Foundation ICT infrastructure	Technical interoperability
<i>Interoperability agreements</i>	Interoperability agreements		
<i>High-level use cases</i>		eHealth services	
<i>Governance</i>	Governance	eHealth governance	

³⁰ Discussion paper submitted by the eHealth Governance Initiative (eHGI) to the eHealth Network (Date: October 22nd, 2012). A proposal to enable the recommendation of standards and (harmonised) profiles based on selected use cases is located on page 4.

³¹ CALLIOPE provided a wide range of eHealth interoperability aspects, including a strategic approach to address them within the common working model. This section of the deliverable, however, only explains how the structure of the eHealth EIF is based on the structure of the CALLIOPE common working model.

Finally, it should be noted that this report continues to use the four levels specified in the generic EIF for ease of comparison with that documentation. This is despite the fact that there were useful discussions held about the various levels of interoperability, such as semantic and technical interoperability, and their similarities and dissimilarities, during the study validation of the eHealth EIF workshop held on 8 November, 2012.

5 – Governance for eHealth Standardisation and Interoperability

The prospective governance framework for eHealth Standardisation and Interoperability is an issue that is **currently under discussion and revision**. It consists of two main elements: an element that relates to the field of eHealth generally, and an element that corresponds to decision-making in relation to infrastructure and standards more specifically. These elements are important to support the sustainability of the eHealth EIF.

On the eHealth side, the organisations are either in position already or have a limited timeline (as is the case of both this study and the eHealth Governance Initiative). For example, this study will be completed by the end of 2012. The eHealth Governance Initiative is currently project-based, and is funded through financial instruments provided by both Directorate-General (DG) Health and Consumers (DG SANCO) and DG Communication Networks, Content and Technology (DG Connect) (ex-DG INFSO), namely a joint action and a thematic network, respectively. The initiative continues formally until the end of June 2014.

More details on how each of these elements either operates individually or where appropriate information is available, is proposed to operate in the future, are described below in sections 5.1, 5.2, 5.3, 5.4, 5.5 and 5.6 (Figure 4). A set of additional reflections is collected together in section 5.7. The description of the proposed precise relationship between each of the relevant initiatives and how they will collaborate and cooperate both vertically and horizontally is, however, still to be developed.

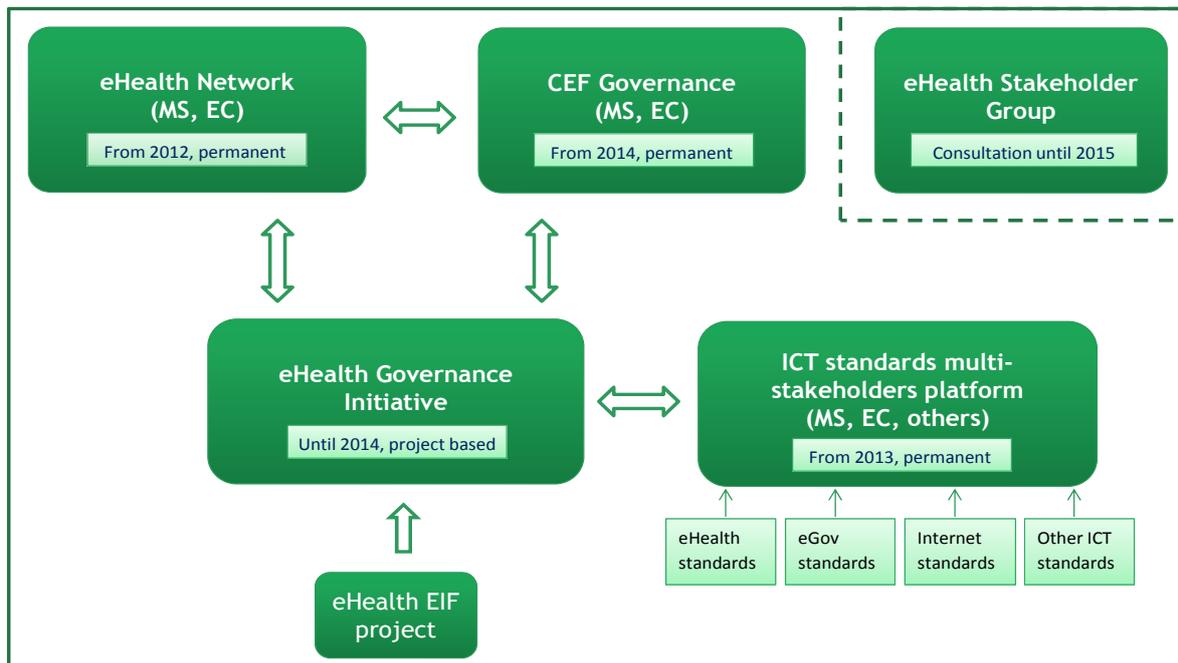


Figure 4 – Governance for eHealth Standardisation and Interoperability

5.1 – eHealth Network

Set up by a Commission Implementing Decision on 22 December 2011, the subject matter to be treated by the eHealth Network is described as:

This Decision sets the necessary rules for the establishment, the management and the functioning of the Network of national responsible authorities on eHealth, as provided for by Article 14(1) of Directive 2011/24/EU.³²

The Network comprises the EU27 Member States and three observer countries, Croatia, Norway and Switzerland. The Chair may also give observer status to national authorities responsible for eHealth of European Economic Area (EEA) / European Free Trade Association (EFTA) countries and of accession countries. Experts may be invited to meetings on an ad hoc basis. The network is co-chaired by the Director-General of DG SANCO and by the representative of a Member State participating in the Network. The Commission also provides secretarial support to the Network and any sub-groups that it creates.

Two meetings of the eHealth Network have so far taken place during the course of 2012, on 8 May in Copenhagen, and 7 November in Brussels. Agendas and summary records of the Network's meetings and its rules / procedures are all to be located on its website.³³ They cover the elements of voting and written procedures. The Network's deliberations are confidential, but may later be opened up to the public.

At the second eHealth EIF workshop of 8 November 2012, these activities were described more comprehensively as providing guidelines on:

- Non-exhaustive data sets of patients summary for cross- border exchanges;
- Semantic and technical interoperability;
- Data Protection Regulation;
- Re-use of medical data for research and public health;
- eID, eAuthorisation, eAuthentication, and security.

The eHealth Network was also said to advise on and to possibly endorse:

- eHealth services deployments (that take place both within Member State borders and cross-border);
- all layers of the eHealth EU Interoperability Framework.

There is a clear relationship with the so-called multi-annual framework programme that, in this case, takes as its starting point the priorities listed in Article 14 of the Directive for patients' rights in cross-border healthcare.³⁴

There is currently a two-way relationship that operates between the eHealth Governance Initiative and the eHealth Network. Overall, the eHealth Governance initiative can be considered as the technical and expert arm of the eHealth Network. A top down approach can be seen as an influential way of capitalising on the progress made by the various pilots, initiatives and projects underway both at regional and Member state level. The character of the two-way relationship between the eHealth Network and the CEF Governance has not yet been fixed (at least within the context of the 'eHealth EIF project') but is part of the actions foreseen in the new 2012 eHealth Action Plan. The CEF governance should include expert groups at a sectoral level in order to solve any legal, organisational, semantic and technical issues or challenges.

³² Commission Implementing Decision of 22 December 2011 providing the rules for the establishment, the management and the functioning of the national responsible authorities on eHealth, OJEU, L344/48, 28/12/2011 <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:344:FULL:EN:PDF>

³³ http://ec.europa.eu/health/ehealth/policy/network/index_en.htm

³⁴ OJEU, EU 2011/24/EU <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:088:0045:0065:EN:PDF>

5.2 – eHealth Governance Initiative³⁵

The eHealth Governance Initiative is described as:

"support[ing] cooperation between Member States at Political Governance levels and eHealth Stakeholders. The European eHealth Governance Initiative ultimately aims at improving the health status of European citizens, quality and continuity of care and sustainability of European health systems. By improving eHealth governance, through the coordination of Member States and European eHealth policies, an interoperable eHealth structure can be built within the EU. The eHealth Governance Initiative comprises a Joint Action and a Thematic Network both sponsored by the European Commission. It has a duration of 36 months running between 1 February 2011 and the end of January 2014."

The Initiative has 40 Beneficiaries including ministries, competence centres, users and industry.³⁶ While the Joint Action is co-financed 50 per cent by DG SANCO and by the beneficiaries, the thematic work is 100 per cent financed by DG Connect.

The project is expected to create a European coordination platform, contributing to a single European eHealth area through streamlined policy, uptake, trust, and awareness in using ICT in health care sector. Specifically, the Initiative will engage in the following tasks and activities³⁷:

- Improving eHealth governance and an enhanced co-ordination between Member States and the European Commission eHealth policies;
- Promoting political discussion on the eHealth agenda;
- Collaborating with existing eHealth-related projects (epSOS - European Patients Smart open Services, Digital Agenda, Secure idenTity acrOss boRders linKed - STORK, European Health Professional Card - HPRO, etc.), thus leading to a more coordinated and efficient European approach;
- Creating an eHealth European Governance framework, with policy development and strategy alignment in eHealth activities;
- Addressing the needs of users in the developments of national strategies or EU initiatives;
- Enhancing trust and acceptability with various stakeholder groups and building a proportionate level of trust in both systems and human processes within cross-border health data exchange;
- Enabling and facilitating the development, integration and European wide deployment of interoperable eHealth services and infrastructures;
- Translating respective deliverables into clear policy proposals for decision and action at the political level;
- Streamlining the process to be in line with the political ambitions of Member States and the European Commission addressing national and European law and regulations, removing barriers in a European information health space.

5.3 – CEF Governance³⁸

On 29 June 2011, the Commission adopted a proposal for the next Multi-annual financial framework for the period 2014-2020 called "A Budget for Europe 2020". In its proposal, the Commission highlighted the creation of a new integrated instrument for investing in European Union infrastructure priorities in energy, telecommunication and transport that was named the Connecting Europe Facility (or CEF).

The Proposal for a Regulation of the European Parliament and of the Council establishing the Connecting Europe Facility dated 19 October 2011³⁹ refers to health-related activities in a number of ways. These are chiefly the Whereas clauses of the Proposal, and its Part III.

³⁵ <http://www.ehgi.eu/Pages/default.aspx?articleID=14>

³⁶ <http://www.ehgi.eu/Pages/default.aspx?articleID=4>

³⁷ <http://www.ehgi.eu/Pages/default.aspx?articleID=16>

³⁸ http://ec.europa.eu/commission_2010-2014/president/news/speeches-statements/pdf/20111019_2_en.pdf

Three of the Whereas clauses of the Proposal for a Regulation refer to health. They are clauses 22, 28 and 30. They reference the Digital Agenda for Europe and its provision of "better quality of life through better health care" (p15); the generic "services of public interest (as core services)" to be funded in relation to "public service delivery", including eHealth (p16); and the Horizon 2020, the future Framework Programme for Research and Innovation, with its focus on tackling societal challenges such as "information and communication technology-enabled health" (p16).

In Part III of the Proposal, a list of pre-identified priorities and areas of intervention in the field of telecommunications are identified: they are called "digital service infrastructures". These relate to trans-European high-speed backbone connections for public administrations (p53) that include health, and cross-border delivery of eGovernment services (p53) that can enable "online health services" as well as other services such as eProcurement, business reporting, and the exchange of judicial information. Described elsewhere in the Proposal document as "[d]igital service infrastructures developed and deployed across Europe" they are listed as "[i]nteroperable cross border eHealth services" (p87).

Presentations at the second eHealth EIF workshop on 8 November 2012 described the potential work, and composition, of the CEF Governance mechanism in the following ways:

- *"Competence on financing deployment of interoperable connecting eHealth infrastructure and services.*
- *Experts' group on administrative, legal, organisational, semantic, and technical aspects of deployment.*
- *Maintenance of interoperability framework assets (technical specifications, electronic health record quality seals, open source components, ontology contextual subsets, and clinical workflows, etc.)."*

5.4 – ICT standards multi-stakeholders platform⁴⁰

Action 21 of the Digital Agenda for Europe (European Commission, 2010a) stipulated that the Commission is to propose legislation on ICT interoperability. Hence, as part of the review of EU standardisation policy, the intention is to propose legal measures on ICT interoperability to reform the rules on implementation of ICT standards in Europe.⁴¹

The 'Whereas' element (no. 6) of the Commission Decision of 28 November 2011⁴² identifies that:

"The multi-stakeholder platform should be composed of representatives of national authorities of Member States and EFTA countries, stakeholder organisations representing industry, small and medium-sized enterprises, consumers and other societal stakeholders as well as European and international standardisation bodies and other non-profit making organisations, which are professional societies, industry or trade associations or other membership organisations active in Europe that within their area of expertise develop standards in the field of ICT."

The membership, consultation, operational mechanisms, meeting expenses, and applicability of the platform are laid out in the same document.

The platform has eight specific tasks. They include giving advice to the Commission services on many aspects of ICT standardisation (a-b) (including technical specifications, and

³⁹ COM(2011) 665, Proposal for a Regulation of the European Parliament and of the Council establishing the Connecting Europe Facility, Brussels 19.10.2011 (2011/0302 (COD)) http://ec.europa.eu/commission_2010-2014/president/news/speeches-statements/pdf/20111019_2_en.pdf

⁴⁰ <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2011:349:0004:0006:EN:PDF>

⁴¹ http://ec.europa.eu/information_society/newsroom/cf/fiche-dae.cfm?action_id=179

⁴² Commission Decision of 28 November 2011 setting up the European multi-stakeholder platform on ICT standardisation <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2011:349:0004:0006:EN:PDF>

cooperation between standards development organisations and European standardisation bodies (d-g)), and gathering information to help coordinate activities and avoid duplication (task (h)). Last but not least, and of particular interest with respect to the eHealth EIF is to **"identify potential ICT standardisation needs in support of European legislation, policies and public procurement"** (task (c)). The platform advises the Commission on identification of ICT standards, which it formally implements through a Commission Decision.

The current (2012) standardisation programme is available.⁴³ The platform is to function permanently from 1 January 2013 onwards.

The second eHealth EIF workshop described the platform as focusing on eHealth standards as well as eGovernment standards, Internet standards, and other ICT standards.

When sectoral technical specifications will be submitted to the platform for identification, it intends to invite sectoral stakeholders organisations into the process. Similarly, since Member States are responsible for appointing their own representatives to the platform, they will have the liberty to appoint representatives from the appropriate or correct field depending on the agenda of any specific meeting.

5.5 – eHealth Stakeholder Group

The eHealth Stakeholder Group was formally established in spring 2012.⁴⁴ While the eHealth Governance Initiative deals with governance, and is composed primarily of Member State experts or representatives, the eHealth Stakeholders Group aims to gather relevant stakeholders from outside the Member States.

A Call for Expression of Interest was organised in late 2011/early 2012 to capture interest on the part of stakeholders outside the Member States.. As a result, the European Commission selected the relevant stakeholder groupings for membership of the group.

The 29 organisations involved in the group are each represented by a representative and/or his or her substitute. These persons are high-level representatives with a proven expertise in eHealth. Their roles in the development of policy on regulations or legislation on eHealth will be to provide relevant reports and documentation. In alphabetic order, the organisations involved are certification organisations, consumer and patient organisations, health professionals' organisations that cover both clinicians and nurses, health authority organisations, hospital organisations, pharmaceutical organisations, standardisation development organisations, and various others fora and alliances.

This stakeholder group is expected to operate for a three-year period. The way in which this stakeholder group may be replaced by another group after its three-year timeline of activity is under current discussion.

The overall group may organise needed subgroups. The stakeholder group currently has a specific subgroup on eHealth Interoperability which will be solicited to give its advice on various interoperability issues, including on the matter of the eHealth EIF.

5.6 – Role of the eHealth EIF study⁴⁵

The eHealth EIF study is considered to be only the start of a process to populate the eHealth EIF with use cases and profiles. With regard to eHealth, the results of this study (referred to in Figure 1 as the 'eHealth EIF project') will be fed into a decision-making process handled by the eHealth Governance Initiative. This action will be taken in the early New Year, 2013 on the part of the study's client, the European Commission (which acts as the secretariat to the

⁴³ http://ec.europa.eu/enterprise/policies/european-standards/standardisation-policy/index_en.htm

⁴⁴ http://ec.europa.eu/information_society/activities/health/policy/stakeholders_group/index_en.htm

⁴⁵ Some of the graphics shown in deliverables of this study nevertheless occasionally use the word "project" to identify this study.

governance initiative). Ultimately, it is the eHealth Governance Initiative which will discuss and decide on the study's findings.

The findings of at least eight other studies or projects will also feed into the work of the eHealth Governance Initiative and the multistakeholders platform. In particular, some aspects of the experience of epSOS large-scale pilot might be viewed as instructive and helpful vis-à-vis some aspects of governance at an organisational level. Future Horizon 2020 projects will be launched to continue the population of the eHealth EIF at the various levels by selecting use cases and developing new specifications and guidelines for their identification or standardisation. Additional profiles from IHE or Continua will be submitted. Ready-to-use specifications from nonprofit Standards Development Organisations (SDOs) such as EuroRec (eHR quality seals or statements) or International Health Terminology Standards Development Organisation (IHTSDO - subsets of Snomed CT) will also be considered for incorporation in the eHealth EIF.

5.7 – Additional reflections

Six sets of observations are made with regard to the level of governance and the degree of permanence of the proposed future governance structures. These emerged observations largely from discussions that took place in the context of the second eHealth EIF workshop.

The governance implied by each of these governance mechanisms takes place at the level of the European Union. They include a collaboration in most cases between the EU27 (to be EU 28 as from 1 July 2013, with the inclusion of Croatia) and the European Commission. They indicate the importance of the European Commission and Member States working together. In the case of both the eHealth Governance Initiative (i.e., its thematic network element) and the ICT standards multi-stakeholders' platform, it also incorporates a range of other related stakeholders. This governance structure does not, however, cover other lower levels of governance e.g., information technology (IT) governance at the health system, hospital or clinic level that are often treated in some detail in the context of eHealth or in specific standards.⁴⁶

Similarities with the eight elements of eHealth governance identified by the CALLIOPE working model can be identified. They are, in alphabetic order, eHealth leadership, policy and strategy; EU and national stakeholder collaboration; financing, resource allocation and reimbursement models; market development, new business models and incentives; monitoring and evaluation; privacy, quality, and safety issues; and the legislative and regulatory framework. Indeed, governance can be understood as including responsibility for both legal and organisational issues. These elements are possibly today not quite so evident within the eHealth interoperability domain.

Since governance in the field of health and eHealth can be understood as a mechanism for changing the health delivery system, there are some concerns with regard to how decision-making with regard to care standards (in addition to ICT standards or eHealth standards) will be handled.

Although the term "permanent" is used in reference to several of these governance initiatives (e.g., the eHealth Network, the CEF Governance, and the ICT standards multi-stakeholders' platform), permanence should be understood – at this stage of decision-making – in two ways. It relates at least to the next phase of multi-annual funding that will last for a seven-year period until 2020, and it implies instances that are established by legal instruments such as EU regulations or Directives. In this sense, the term of "permanence" is intended to indicate actions that are either 'not-temporary' or at least 'not project-based'.

During the second eHealth EIF workshop, attention was drawn most systematically to a number of issues, such as: the degree of association of these forms of governance with the health and the care systems; governance as a mechanism that includes legal and

⁴⁶ See e.g., chapters by Elena Beratarbide and Tom Kelsey, Magdalene Rosenmöller, and Malcolm Thatcher in C. George et al (2013) *eHealth: Legal, Ethical and Governance Challenges*. Berlin and Heidelberg: Springer-Verlag

organisational issues; the possibility of considering epSOS as a prototype for certain elements of governance initiatives⁴⁷; and the degree of "permanence" of any ensuing structure.

In addition, from a more organisational perspective, during the second eHealth EIF workshop, attention was drawn by some stakeholders to the need for an eHealth interoperability business model and incentivisation structures. A flexibility of forms of organisation that could be composed of "*virtual organisations, organisational clusters, good practices and stakeholder involvement*" was also highlighted.⁴⁸

⁴⁷ epSOS is only a pilot project. Any relevant sustainable governance relating to it has not been established.

⁴⁸ Cf. Minutes of the 8 November 2012 eHealth EIF validation workshop (p10).

6 – Principles

This chapter focuses on the eight principles of the eHealth EIF presented in sections 6.1 through to 6.8. The following principles are proposed for the inclusion in the framework:

- a. Security and privacy
- b. Transparency
- c. Preservation of information
- d. Reusability
- e. Technological neutrality and adaptability
- f. Openness
- g. Patient centricity
- h. Use case approach.

The principles of security and privacy, transparency, preservation of information, reusability, technological neutrality and adaptability and openness have their source in the generic EIF. The epSOS large-scale pilot's project deliverable D3.3.3 epSOS Interoperability Framework selected the above-mentioned six principles from the generic EIF, which were prioritised and refined taking as a criterion their relevance for the eHealth domain. The principle of patient centricity is inspired by the principle of user centricity coming from the generic EIF and is translated by the study team into the eHealth context. The last principle of the prioritisation of the use case approach has its source in Mandate 403 eHealth Interoperability⁴⁹ on standardisation in the field of eHealth.

6.1 – Security and Privacy

The proposed principle of security and privacy in the eHealth domain focuses on the privacy aspects of the patient's medical information.

On one hand, patient medical information should be subject to constraints granting patients the right to verify (and correct) information held about the patient, e.g., diagnosis and treatment history. In addition, a patient should be granted the right to be consulted and have the right to opt out of health information exchanges, for instance, when his/her medical information is intended to be used for other purposes than that for which it was originally supplied.

On the other hand, patient medical information should be exchanged in the eHealth systems under strict rules of privacy and confidentiality and in full compliance with the relevant regulations, e.g., on privacy and data protection.

6.2 – Transparency

The principle of transparency, when translated into the specificities of the eHealth domain, concerns transparency within the processes that govern the gathering and sharing of patient medical information. In particular, the principle suggests the right for a patient to "track" the state of his/her information (e.g., to have a view over who has viewed or processed his/her information) and the right to provide feedback on the process itself.

⁴⁹ SA/CEN/ENTR/000/2007-20 eHealth Mandate M/403

6.3 – Preservation of Information

The principle of preservation of information in the context of the eHealth domain calls for preservation of medical records and medical information held in an electronic format. The rationale behind this requirement relates to medico-legal purposes and retention of information legibility, reliability and integrity in order to access the information whenever needed. To this end, in order to ensure information accessibility, formats should be defined that cover electronic certifications (e.g., electronic signatures and mandates).

6.4 – Reusability

The principle of reusability in the eHealth context suggests the leveraging of existing practices with proven and tested value. This involves selecting relevant and useful solutions. A necessary condition for reusability is therefore the willingness of healthcare entities to share their solutions, concepts, frameworks, and specifications with interested parties. To this end, the data should be held or exported in a standardised form so that they can be imported into other systems. As such, the tools and software components themselves need not be interoperable or shared. The willingness of healthcare entities to share with interested parties can be expressed by leveraging the principle of openness described in section 6.6 within the collaboration between different entities to reach commonly agreed goals.

6.5 – Technological Neutrality and Adaptability

The principle of technological neutrality and adaptability in the context of eHealth is seen as a requirement addressed to all providers of technologies, products, specifications and standards (e.g., vendors, SDOs, and profile development organisations). This principle calls for avoidance of imposition of technologies and products on the healthcare stakeholders. Another requirement laid down by the principle is the requirement of adaptability of technologies and solutions in order to meet the changing needs in the eHealth domain, such as new standards or new clinical requirements.

6.6 – Openness

The principle of openness translated into eHealth context can be seen as sharing knowledge among healthcare entities and eHealth market players in order to contribute to the knowledge progress in terms of finding new solutions. To this end, technical specifications, software and software development methods should be developed jointly (using international standards) and the results should allow for interconnection, reusability and sharing, thus contributing to openness in the interoperability context.

6.7 – Patient Centricity

The principle of patient centricity is a further instantiation of the principle of user centricity taken from the generic EIF. The principle of patient centricity involves the notion of patient and his/her health issues being at the centre of eHealth services; as a main driver defining the scope of and how eHealth services are delivered. To this end, this principle covers the notion of service personalisation, multichannel delivery and single point of contacts to streamline the service delivery. As a part of the principle, patient safety is also considered as an important element that should be translated into the delivered services in terms of privacy, integrity and accuracy of medical information shared between patient and healthcare providers. The principle of patient centricity is in line with the vision of the 2012 eHealth Action Plan to enhance patient empowerment.

6.8 – Use Case Approach

The principle of use case approach is common in IT systems development methodologies (such as the Rational Unified Process - RUP). It is at the core of the IHE-developed draft ISO TR28380 IHE Global Standards Adoption Process, and was used to develop the Mandate 403

phase I report ⁵⁰. The principle of a use case approach is suggested to be a part of the eHealth EIF in order to address the challenge of the complexity of eHealth-related requirements. A layer of complexity within the use case approach principle is a possible overlap of use cases that address the same requirements multiple times. To accommodate this complexity, use cases are defined as business or high-level use cases that are broken down into low-level use cases supported by profiles. These profiles, in turn, describe the way that a set of base standards should be used. Such profiles will need to address many areas of interoperability in the eHealth domain, such as information transport, security, data structures and related data models, associated terminologies, and privacy and service contracts. Thus, these kinds of profiles will need to address the main eHealth requirements concerning e.g., security, privacy, patient identification, record sharing and access, care coordination record content, specialty record content, home monitoring, referral and consultation workflows.

⁵⁰ SA/CEN/ENTR/000/2007-20 eHealth Mandate M/403

7 – Interoperability agreements

The generic EIF emphasises the importance of written agreements to support cooperation among different stakeholders at the different interoperability levels described. For each interoperability level (i.e., legal, organisational, semantic, technical), the organisations involved should formalise cooperation arrangements in **interoperability agreements**. This issue plays a crucial role in the context of the eHealth EIF, as an interoperability agreement is an essential tool to accelerate the transformation process to achieve higher eHealth interoperability. Section 7.1 provides more information about the notion of interoperability agreements, section 7.2 discusses the importance of interoperability agreements within the epSOS project, and section 7.3 discusses other examples of interoperability agreements in the domain of eHealth.

7.1 – Definition of interoperability agreements

The generic EIF defines an interoperability agreement as a formalised cooperation arrangement between different stakeholders, describing their cooperation on different interoperability levels. Such agreements should be multilateral and drafted with sufficient detail to enhance cooperation between different eHealth stakeholders, while leaving each stakeholder maximum internal autonomy.

Interoperability agreements will normally⁵¹ include components (sections) that specify one or more legal, organisational, semantic, and technical elements. On the **legal level**, agreements can refer to European legal frameworks and instruments or can specify audit and governance, risk management, and possible penalties. On the **organisational level**, agreements can define workflows to trigger the interoperable eHealth communications, organisational and role responsibilities, inter-organisational business relationships, or financial relationships. On the **semantic level**, agreements can define semantic standards and specifications to be used, including reference taxonomies, schemes, code lists, data dictionaries, sector-based libraries and so forth. On the **technical level**, agreements can define technical standards and specifications to be used, including interface specifications, communication protocols, messaging specifications, data formats, security specifications, dynamic registration specifications, and service discovery specifications⁵².

7.2 – Importance of interoperability agreements within epSOS project⁵³⁵⁴

During the work of the epSOS project, it became clear that interoperability agreements play an important role, but that it is not necessarily an easy matter to come to such agreements. The main challenge faced by epSOS has been the great diversity in the implementation of the Data Protection Directive across Member States. epSOS established the epSOS “trusted domain” governed by a number of privacy, security and safety policies adopted by the epSOS Steering Board of national health authorities. These were expressed in the form of requirements in a **Framework Agreement (FWA)** which was then transposed into national level agreements between partners engaged in the epSOS pilots.

Each Participating Nation (PN) is represented in epSOS by a National Contact Point (NCP). The NCP is legally competent to contract with other organizations in order to provide the necessary services, which are needed to fulfil the epSOS Use Cases. The epSOS NCP is identifiable in both the epSOS domain and in its national domain. It acts as a communication gateway and also as a mediator for legal and Regulatory aspects of delivering epSOS

⁵¹ This section contains representative examples of agreements on the legal, organisational, semantic and technical levels, but is not intended to be exhaustive or complete.

⁵² A (web) service discovery specification is a technical specification that defines a protocol to locate services on a local network.

⁵³ Interoperability agreements should be treated as preliminary and short term solution.

⁵⁴ The content of this section is based on the “Recommendations to eHealth Network and the European Commission on Legal Sustainability of cross border eHealth services” (Date: October 3rd, 2012)

Services. As such, an NCP is an active part of the epSOS environment if it is compliant to normative epSOS interfaces in terms of structure, behaviour and security policy compliance.

The epSOS Grant Agreement and the Consortium Agreement was the EU-level contract between Member States for the duration of the project, as it committed National Authority Beneficiaries to execute the large scale pilot according to agreed provisions. The launch of the actual epSOS pilots has been made possible following this approach.

It should, however, be noted that this approach is not sustainable beyond the lifetime of the project and that some Member States were unable to undertake pilots under this arrangement for legal reasons. Large-scale deployment of cross-border eHealth services requires the setting up of a robust agreement between Member States. The Health Work Plan 2013⁵⁵ foresees the launch of a study that will examine in detail, and provide an overview of, the regulatory frameworks at national level on electronic health records and provide recommendations so as to facilitate the work of the eHealth network on the legal layer of eHealth interoperability.

7.3 – Other examples of interoperability agreements in the domain of eHealth

In the course of this study, several other examples of interoperability agreements were found, such as the Memorandum of Understanding (MoU) between the EU and US for eHealth, the web-based technical agreement system of the Baltic eHealth project, and the Service Level Agreement (SLA) of an eHealth mailbox. Each of these examples is described briefly below.

7.3.1 – Memorandum of Understanding between EU and US for eHealth

The EU and the US wish to facilitate⁵⁶ more effective use of health-related ICT to support the health of the population, and to strengthen their relationship and support global cooperation in this area. The approach to fostering mutual understanding⁵⁷ of the common challenges faced by both sides is set out in a MoU which was signed at the meeting of the Transatlantic Economic Council (TEC) in December 2010.

Following the joint EU-US Transatlantic eHealth workshop held at the eHealth Week 2012 in Copenhagen, Denmark, there was a follow-up two day joint event focused on the EU-US eHealth Marketplace and the Transatlantic eHealth Cooperation Assembly held in the State House in Boston, Massachusetts in the US, on the 23rd and 24th October 2012⁵⁸.

A prefinal draft of the transatlantic eHealth/health IT cooperation MoU roadmap has now been published⁵⁹.

7.3.2 – Web-based technical agreement system of the Baltic eHealth project⁶⁰

The objective of the Baltic eHealth project is the following:

"To facilitate the use of telemedicine across national borders in the Baltic Sea Region. One of the major results of the project is a secure Internet-based infrastructure - the Baltic Health Network (BHN) - which connects all hospitals and many other health care institutions from Denmark, Norway and Sweden (plus East Central Tallinn Hospital and Vilnius University Hospital). The BHN consists of more than 200 hospitals which now

⁵⁵ Health Work Program - Section 4.2.2.5 Overview of the legal framework for electronic health records in the Member States
http://ec.europa.eu/health/programme/docs/wp2013_en.pdf

⁵⁶ EU-US cooperation in eHealth - main elements of a joint roadmap for activities under the MoU identified - <http://ec.europa.eu/digital-agenda/en/news/eu-us-cooperation-ehealth-main-elements-joint-roadmap-activities-under-mou-identified>

⁵⁷ As defined by section 7.1, this EU-US MoU is an example of an interoperability agreement at the organisational level, dealing with interoperable eHealth communications and inter-organisational relationships.

⁵⁸ A summary of the Boston EU-US workshop can be found on

http://ec.europa.eu/information_society/newsroom/cf/itemdetail.cfm?item_id=8941

⁵⁹ http://ec.europa.eu/information_society/newsroom/cf/dae/itemdetail.cfm?item_id=9389

⁶⁰ http://www.baltic-ehealth.org/Baltic_Health_Network.htm

*very easily (from a technical point of view) can initiate collaborations with each other using the BHN and - if the wish to - the applications provided on the network.*⁶¹

In this context, a web-based agreement system was developed, enabling the data provider and the data user to indicate which service may be accessed by which clients and by which protocols:

*"After an agreement has been concluded in the Web-based agreement system, it is forwarded electronically to both the data provider and the data user for signature before the connection is opened. A new stakeholder is registered in the UNI•C agreement system and is assigned a small net (number of connected Health Data Net IP addresses). After this, it is up to the local administrator to register agreements in the agreement system, which can be accessed on the open Internet"*⁶²

7.3.3 – Service Level Agreement of an eHealth mailbox

Although Belgium was not included in this study's Member State Analysis, a representative example of an eHealth Service Level Agreement (SLA) was found in that country⁶³, i.e., for the basic service of a "Secure electronic mailbox (eHealthbox)". The objective of this SLA is to define the minimum level of service offered on the country's eHealth platform, and provides eHealth's own understanding of service level offering, its measurement methods and its objectives in the long run. In addition, this SLA describes some technical and/or functional components the services depend on, and measurements and Key Performance Indicators (KPIs) intended to account for a certain number of performance indicators.

⁶¹ http://www.baltic-ehealth.org/Baltic_Health_Network.htm - Section "Can a health care institution join the Baltic eHealth project?"

⁶² http://www.baltic-ehealth.org/Baltic_Health_Network.htm - Deliverable "The Internet-based Health Data Net" (p7)

⁶³ https://www.ehealth.fgov.be/sites/default/files/functionaleiten/sla/sla_basic_service_ehealthbox_v1.0_aug_2011.pdf

8 – Legal interoperability

In Europe, a number of proposals for laws that address some of the legal challenges identified here in terms of interoperability are pending.⁶⁴ In this context, a number of the attendees present at the second eHealth EIF workshop were keen to make five points.

First, there is always a lag in the law, behind both organisational developments and technological disruption (e.g., Whitehouse et al (2011) and George et al (2013)⁶⁵).

*"[Law] is often recognised as trailing behind various systemic and organisational developments" and "almost constantly plays a game of catch-up with the leaps implicit in technology, particularly those technologies which can be considered as disruptive" ([Whitehouse et al, 2011, p. 424). Hence, legislation can take years of development to be established and to be applied with success."*⁶⁶

Second, attention should be paid to those domains in which subsidiarity or proportionality operate, and areas in which the Union should therefore not interfere⁶⁷. Presumably, without doing so explicitly, the participants wished to refer to aspects of the Member States' health systems and services. (A number of the legal instruments being considered that are pertinent to eHealth interoperability will, however, relate to regulations which will require adaptation of domestic law.)

Third, epSOS, the large-scale pilot has recently drafted a deliverable that examines in some detail the range of laws set out in Member States with regard to patient summaries, ePrescription, and data protection. A new study⁶⁸ was referred to by a European Commission representative (of DG SANCO) with regard to examining in detail and providing an overview of the regulatory frameworks at national level on electronic health records and the provision of recommendations so as to facilitate the work of the eHealth network on the legal layer of eHealth interoperability (see the end of this sub-section, and also sub-section 7.2 of this deliverable, for further information). Recent literature has examined such issues as privacy and liability (Andoulsi and Wilson, 2013)⁶⁹ – particularly in terms of telemedicine (Dima, 2013).⁷⁰

Fourth, it is important to bear in mind the legal distinctions between directives⁷¹ and regulations, which have a more general application. Directives are addressed to Member States rather than to their citizens, and are therefore only legally binding on the actual states. Since a directive is usually used to set out a result to be achieved, Member States can therefore decide for themselves how best to meet or reach the actual result. As a result, they may use quite different methods and procedures. On the other hand, as identified by a BBC News website (21 July 2009), regulations "are binding on individuals and effectively form part of domestic law as soon as they are made. It is generally only necessary to amend existing national provisions that are inconsistent with regulations, rather than make new legislation altogether."⁷² This approach allows each Member State, and its courts, to interpret or adapt slightly differently from the particular directive. As Findlaw identifies, therefore: "[G]iven that directives take a lot longer to implement as they must be put into law by the member state,

⁶⁴ Whitehouse D, et al (2011) eHealth: legal, ethical and governance challenges – an overview. In: Jordanova M, Lievens F (eds) Global

telemedicine and eHealth updates: knowledge resources, vol 4. ISfTeH, Luxembourg, pp 423–428

⁶⁵ George, C et al (2013) Introduction. eHealth: legal, ethical and governance challenges. Berlin and Heidelberg: Springer-Verlag

⁶⁶ George, C et al (2013) Introduction. eHealth: legal, ethical and governance challenges. Berlin and Heidelberg: Springer-Verlag

⁶⁷ http://europa.eu/legislation_summaries/glossary/subsidiarity_en.htm

⁶⁸ Health Work Program - Section 4.2.2.5 Overview of the legal framework for electronic health records in the Member States

http://ec.europa.eu/health/programme/docs/wp2013_en.pdf

⁶⁹ I. Andoulsi and P. Wilson (2013) Towards greater clarity at European Union level eHealth. In eHealth: legal, ethical and governance challenges, edited by George et al. Berlin and Heidelberg: Springer-Verlag

⁷⁰ Dima, C. (2013) Legal challenges regarding telemedicine services in the European Union. In eHealth: legal, ethical and governance challenges, edited by George et al. Berlin and Heidelberg: Springer-Verlag

⁷¹ They have been considerably criticised in recent years for the range of their implementation and applications differences between and among Member States.

⁷² <http://news.bbc.co.uk/2/hi/europe/8160808.stm>

the EU will often use regulations to ensure the legislation is directly applicable and, where appropriate, does not leave room for a different slant on the legislation by different member states."⁷³ Similarly, it is also important to understand the non-binding character of some documentation which, nevertheless, can act to encourage buy-in and engagement and can shape the general and communal directions taken in a particular field (indeed, Commission working papers and Communications are examples of this).

Fifth, this study deliverable wishes to mention explicitly that on-going work on legal aspects is done by the eHGI and the eHealth Network. The Health Work Plan 2013⁷⁴ also foresees the launch of a study that will examine in detail and provide an overview of the regulatory frameworks at national level on electronic health records.

8.1 – Binding legal instruments

There are eight legal instruments which are or will be binding on the European Member States. While they are listed here in sequential order, they range in terms of their direct pertinence to eHealth interoperability. Some have influence over health policy whereas others impact the transfer and sharing of data and/or the means that users have to use to get access to such data. Each is introduced here only briefly.

One Directive, from 2011 (2011/24/EU), refers specifically to patients' rights in cross-border healthcare. Others, which date back to 1995 and 1999 focus on data protection and the rules and regulations appropriate to electronic signatures. These two should also be seen in the context of the current texts of the draft regulations on data protection and on eID and eSignature.

Even though, on data protection and on eID/eSignature, the legal documents are, for the time being, drafts, it is expected that they will move towards adoption, and hence, the legislation will be formalised within the next 12-24 months.

Directive 1995/46/EC on the protection of personal data⁷⁵

The Directive provides a set of legal requirements for personal data to be processed throughout private and public services in Europe and has been transposed into national regulation by all Member States.

Directive 1999/93/EC on a community framework for electronic signatures⁷⁶

The Directive aims to facilitate the use of e-signatures, to contribute to their legal recognition, and to establish a legal framework for electronic signatures and certification-services.

Directive 2007/47/EC⁷⁷

The Directive amends several earlier Council Directives dating from 1990, 1993 and 1998. It takes account of a number of elements of technical progress in information technology, and draws attention to the need to validate software whether stand alone or incorporated in medical devices. On-going revision of the directive is underway, and on 26 September 2012 the European Commission adopted a package on innovation in eHealth (see the notes which follow on Regulations).

Directive 2011/24/EU on application of patients' rights in cross-border healthcare⁷⁸

⁷³ http://www.findlaw.co.uk/law/government/european_law/basics/500358.html

⁷⁴ Health Work Program - Section 4.2.2.5 Overview of the legal framework for electronic health records in the Member States
http://ec.europa.eu/health/programme/docs/wp2013_en.pdf

⁷⁵ <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31995L0046:en:HTML>

⁷⁶ <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31999L0093:en:HTML>

⁷⁷ <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2007:247:0021:0055:en:PDF>

The Directive aims to facilitate cooperation between healthcare providers, purchasers and regulators of different Member States at national, regional or local levels in order to ensure safe, high-quality and efficient cross-border healthcare.

Regulation on European Standardisation⁷⁹

The Regulation offers a legal basis for the identification of technical specifications that could be referred to in public calls for tender.

Draft regulation on data protection⁸⁰

The proposed General Data Protection Regulation and its subsequent Delegated and Implementation Acts aim to improve consistency and reduce diversity in data protection and rights including access to personal data and deletion or suppressions of sensitive information.

Draft regulation on eID and eSignature⁸¹

This draft regulation contains a review of the existing eSignature Directive to ensure harmonised application and simplification, in order to facilitate cross-border electronic transactions. The scope of the current Directive will be widened and will include mutual recognition of eIDs, so that all Member States recognise and accept all formally notified eIDs from other EU Member States.

Draft regulation on medical devices⁸²

This proposal for a regulation on medical devices, adopted by the European Commission on 26 September 2012, tackles a number of scientific and technical developments, including in implantable medical devices, and deals with their identification, traceability, classification, conformity, and governance.

8.2 – Non-binding legal instruments

In total, six non-binding legal instruments are perceived to have had influence over the issue of eHealth interoperability. The first four are a Recommendation on interoperability, a Communication on telemedicine, guidelines relating to the medical devices directive specifically relating to stand alone software, and a green paper on card, internet and mobile payments. These are described briefly here. Furthermore, two other instruments – a Communication and a Commission staff working paper – were published in December 2012, that are described in more detail.

Commission recommendation on eHealth interoperability (2009)⁸³

This Recommendation outlined the general guidelines which should thus apply to all Member States, each of which has its own health system(s) and service(s). It follows the commonly understood levels of interoperability.

Communication on telemedicine (2008)^{84,85}

⁷⁸ <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:088:0045:0065:EN:PDF>

⁷⁹ <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2011:0315:FIN:EN:PDF>

⁸⁰ http://ec.europa.eu/justice/data-protection/index_en.htm

⁸¹ http://ec.europa.eu/information_society/policy/esignature/eu_legislation/regulation/index_en.htm

⁸² http://ec.europa.eu/health/medical-devices/files/revision_docs/proposal_2012_542_en.pdf

⁸³ COM(2008)3282 final Commission Recommendation of 2nd July 2008 on cross-border interoperability of electronic health record systems

⁸⁴ COM(2008) 689 Communication ... on telemedicine for the benefit of patients, healthcare systems and society. 4.11.2008

⁸⁵ http://ec.europa.eu/information_society/activities/health/docs/policy/telemedicine/telemedecine-swp_sec-2009-943.pdf

This Communication referred little to interoperability, but it did so in the context of telemonitoring systems and specifically with regard to standardisation and standardisation development.

Guidelines relating to medical devices directives, particularly on qualification and classification of stand alone software⁸⁶

Among the seven sets of non-binding guidance, MEDDEV 2.1/6 on the qualification and classification of stand alone software, published in January 2012, does not refer specifically to interoperability. It does, however, describe the qualification and classification of many different forms of stand alone software that fall in the regulatory framework of medical devices. These include in alphabetic order: communications systems, decision support systems, health information systems, information systems, and *in vitro* diagnosis software.

Green paper on card, internet and mobile payments (2012)⁸⁷⁸⁸

In the context of a shift towards more secure, efficient competitive and innovative electronic payments in support of the single market in the European Union, a green paper was published on 11 January 2012 on which feedback was anticipated by 11 April 2012. Health was mentioned in only one context, that of the health (health insurance card-based payments) sectors (p17).

In December 2012, two additional non-binding instruments were published, i.e. the eHealth Action Plan 2012-2020 and the Commission Staff Working Paper on the applicability of the existing EU legal framework to telemedicine services (accompanying the document eHealth Action Plan 2012-2020).

eHealth Action Plan 2012-2020 (2012)⁸⁹

The second eHealth Action Plan outlines the actions to be taken over a seven-year period leading up to 2020. It is complementary to the timelines of the Digital Agenda for Europe (European Commission, 2010a), and it is pertinent to the work of the European Innovation Partnership.

European Council conclusions, published in December 2009, requested an "update of the eHealth Action Plan on eHealth" (Council of the European Union, 2009). In the first half of 2011, a public consultation was organised that captured a sense of public opinion on the policy directions in this field that were considered to be important.

As a result, the second eHealth action plan aims to improve healthcare for the benefit of patients, give patients more control over their care, and bring down costs. While patients and health professionals are enthusiastically using telehealth solutions and millions of Europeans have downloaded smartphone apps to keep track of their health and wellbeing, the plan considers that digital healthcare has yet to reap its great potential to improve healthcare and generate efficiency savings.

The plan attempts to increase the pace of change and improvement in healthcare by:

1. Clarifying areas of legal uncertainty;
- 2. Improving interoperability between eHealth systems;**⁹⁰

⁸⁶ <http://ec.europa.eu/health/medical-devices/documents/> and http://ec.europa.eu/health/medical-devices/documents/guidelines/index_en.htm In particular, http://ec.europa.eu/health/medical-devices/files/meddev/2_1_6_ol_en.pdf

⁸⁷ European Commission (2012a) Green Paper: Towards an integrated European market for card, internet and mobile payments. COM(2011) 941 final. Brussels 11.1.2012

⁸⁸ European Commission (2012b) Feedback statement on European Commission Green Paper "Towards an integrated European market for card, internet and mobile payments" http://ec.europa.eu/internal_market/payments/docs/cim/gp_feedback_statement_en.pdf

⁸⁹ http://europa.eu/rapid/press-release_MEMO-12-959_en.htm

⁹⁰ Emboldening added by the study team.

3. Increasing awareness and skills among patients and healthcare professionals;
4. Putting patients at the centre with initiatives related to personal health management and supporting research into personalised medicine;
5. Ensuring free legal advice for start-up eHealth businesses.

In particular, Table 2 provides an overview of all the actions identified by the plan that aim to achieve wider interoperability in eHealth Services and by whom and by what date – until 2015 – they are to be taken up.

Table 2 - Actions related to achieve wider interoperability in eHealth services

Date	Action	Who?
From 2012 onwards	Support the eHealth network in producing guidelines on a dataset for patient summary records to be exchanged across borders , common measures for interoperable electronic identification and authentication in eHealth and will enhance security of health information and eHealth services and interoperability of databases for medicinal products.	European Commission
In 2013	Launch a study under the Health Programme 2014-2020 to examine Member States' laws on electronic health records in order to make recommendations to the eHealth network on legal aspects of interoperability	European Commission
From 2013	Support concrete steps towards greater integration of processes for cross-border eHealth . The Commission will make proposals on organisational issues with the aim of facilitating cooperation in the EU.	European Commission
By 2014	Produce a Green Paper on mHealth and health and wellbeing applications	European Commission in response to the recommendations of the eHealth Task Force
By 2015	<ul style="list-style-type: none"> • Establish the semantic and technical cross-border interoperability specifications and assets necessary for the eHealth Interoperability Framework; • Propose an EU interoperability testing, quality labelling and certification framework for eHealth systems. • Take assets, such as vocabularies, from past projects or on-going projects developed under the CIP, FP7, the ISA work program and, in the future, Horizon 2020 that can be used and maintained under the proposed Connecting Europe Facility 	European Commission, with the endorsement of the eHealth Network
By 2015	Propose an eHealth Interoperability Framework based on the results of studies, pilots and research projects.	European Commission, with the endorsement of the eHealth Network

Commission Staff Working Paper on the applicability of the existing EU legal framework to telemedicine services⁹¹

The objective of this Staff Working Paper is to enhance legal clarity for all the actors involved in the provision of telemedicine services. This will be done by mapping existing EU legislation that applies to cross-border telemedicine services. In so doing, the paper is expected to contribute to the fulfillment of the goals of the Digital Agenda for Europe in terms of achieving widespread deployment of telemedicine services by 2020.

⁹¹ http://ec.europa.eu/information_society/newsroom/cf/document.cfm?doc_id=1251

9 – Organisational interoperability

Taking into account the requirements articulated in chapter 3 of this deliverable, it is clear that cooperation is needed between organisations on many levels in order to deliver working interoperable eHealth solutions. The eHealth Governance Initiative (eHGI) has identified three priority areas for inter-agency cooperation⁹², which should be among the first to be tackled at a European level (see section 9.1). Next, the EU quality labelling and testing is discussed (section 9.2), and examples of other opportunities for organisational co-operation are given (section 9.3).

9.1 – Organisational recommendations from eHGI discussion paper⁹³

9.1.1 – Encourage greater cooperation between Member States

Member States who share a common strategy shall be strongly encouraged to collaborate in order to avoid redundancy and minimize costs. This collaboration can take the form of common investment in software tools (e.g. terminology server), exchange of tenders, exchange of methodology, cross-validation of translations, training of experts and evaluation of pilots. In order to make this possible, a common understanding of the strategies chosen by all Member States is an essential prerequisite.

9.1.2 – Encourage greater cooperation between national authorities and standardisation bodies

Member States and the European Commission shall encourage standardisation bodies to enhance their strategic and operational cooperation – in a coordinated approach. Furthermore, co-operation between standardisation organisations and competent national authorities in Member States shall be fostered.

9.1.3 – Consider incentivisation of healthcare providers

Providing medical records that can be semantically shared incurs costs for healthcare professionals. Member States should therefore identify and calculate the value proposition of healthcare providers with regard to interoperability and consider sustainable incentivisation schemes to encourage healthcare providers to provide data in an interoperable way and to invest in interoperable software.

9.2 – Quality labelling and testing

9.2.1 – Quality Labelling Challenges at the EU Level

The main challenge at EU level is the principle of subsidiarity that leaves health in general, and eHealth in particular, a national competence. There is no European “health authority” able or willing to enforce the quality of e.g. electronic health record systems across the continent. An “authority-driven” cross-border quality labelling scheme or procedure will therefore not happen soon, resulting in potentially 27 different options regarding eHealth and the quality assessment of the products.

This does not preclude the capacity of the EU to issue ‘recommendations’ or even ‘directives’ to the Member States urging them to include quality assessment in their national regulation and to favour national and cross-recognition of quality labels. This requires multi-lingual comparable functional and interoperability requirements as in, e.g., the EuroRec functional criteria or the IHE profiles.

⁹² Discussion paper submitted by the eHealth Governance Initiative (eHGI) to the eHealth Network Date: October 22nd, 2012

⁹³ The recommendations from the eHGI discussion paper were validated by the eHealth Network on 7/11/2012, but it is possible that some of these recommendations will change in the future.

The Medical Devices Directive (2007/47/EC), designed to ensure that medical devices are safe and reliable, is considered by some authorities as a quality assessment and labelling initiative regarding EHR applications too. No one single electronic health record system has, however, been quality labelled on the basis of this Directive despite compliance being mandatory beginning March 21, 2010.

This Directive covers software that is used for medical purposes. So too do the guidelines on qualification and classification of software described in section 8.1 of this report; the draft Regulation on medical devices intends to resolve some problematic areas in the field of software.

9.2.2 – Quality Labelling Drivers and Incentives

Several healthcare authorities have identified quality labelling as an important means to stimulate or enforce the market to comply with national or regional functional and quality requirements as well as to enforce the use of selected standards.

Different approaches are implemented to drive users to use quality-assessed products, depending on the healthcare framework:

- The incentive-based⁹⁴ approach, generally in a more competitive market (e.g., Belgium⁹⁵ or the USA⁹⁶) that grants financial compensation to the users of quality assessed applications, with the vendor being urged to obtain that label by their users;
- The regulatory/legal approach (such as Canada, France, Norway or Serbia) limiting access to some services to users of quality assessed applications;
- The procurement-based approach (United Kingdom), where regulator and buyer are both public bodies;
- The market pressure approach (Ireland) where a healthcare professionals organisation takes the initiative to quality assess the applications offered to their members (this is a variant of the procurement-based approach);
- The US has defined a complementary “negative financial incentive” after a five year-period (from 2014 onwards) for healthcare professionals not meaningfully using the quality assessed electronic health record systems;
- Denmark is very advanced in product certifications.

Other drivers for the use of quality assessed eHealth applications are:

- Quality of care improvement, more especially by evidence-based chronic care management is increasingly important and facilitated by using Health IT applications (which is a driver for the user and the authorities);
- Product profiling (a driver for the vendors) but the more systems are quality assessed, the less appealing they are;
- Increased portability of applications within and across Member States (a driver for the vendors).

Reducing the market fragmentation should not be the purpose but only a side-effect of an efficient and progressive quality labelling approach. Quality labelling will result in an increasing harmonisation of health information systems, within diversity.

9.2.3 – Transatlantic aspects

Effective quality labelling and certification, when in place, is very similar on both sides of the Atlantic, despite big differences in the legal and regulatory context that are mainly not related to “clinical care”-related aspects of healthcare.

⁹⁴ Users of a quality labelled or certified system are granted some advantages, mostly financial.

⁹⁵ Each user of such a quality labelled system is granted 800+€ per year.

⁹⁶ Some \$45.000 over 5 years for each healthcare professional, \$2M over 4 years plus 200€ per discharge for hospitals, or based on number of patients per month (e.g., US\$ 200)

IHE as well as Continua deploys activities in Europe as well as in the US. Their quality label (IHE) or quality mark (Continua) is based on the same or highly comparable profiles, and the same or similar standards and quality and patient safety requirements on both sides of the Atlantic.

The EuroRec criteria are – up to a certain level – equivalent to the original Certification Commission for Healthcare Information Technology (CCHIT) criteria, the latter being the basis of the actual US quality labelling. Functional testing is highly comparable.

The main difference is that quality labelling and certification is not yet identified as an essential issue to improve quality and efficiency of care, neither at European Union level nor at national level in most of the 27 Member States, but this aspect has been identified as an important milestone in the 2012 eHealth action plan. Each Member State has its own national healthcare regulations.

The focus of the incentive-based US approach is not limited to the adoption of quality assessed applications but also to the effective use of these applications. This approach seems to find its way also in Europe⁹⁷.

The issue of “quality labelling and certification” was addressed during the ARGOS⁹⁸ transatlantic meetings, resulting in some recommendations:

- Cross recognition of each others' “certificates” should be a goal, at least for the tests done in a similar way on both sides of the Atlantic;
- Functional criteria and profiles need to be formulated as “generic” and “country independent” as possible but be conceptually comparable and equivalent;
- The importance to comply with International Organization for Standardisation (ISO) standards for accreditation and certification bodies was confirmed.

9.2.4 – Vision and Role of Health Authorities

Quality requires more than using the correct term and code to identify a condition, a treatment or a procedure. Full interoperability enabling reliable reuse of clinical data requires collateral information to be present for each item, for example, the origin and context of creation, the qualification of the author, the source terminology used, specifiers (staging...) and qualifiers (severity, certainty,...).

Quality can only be guaranteed by means of a “certification” procedure, by a third party assessment as stated by both the HITCH and the EHR-QTN projects. Health and care are too important to simply accept that the applications on the market must be fit for purpose.

The Belgrade Declaration⁹⁹ issued by the Regional Conference in Quality Labelling and Certification of electronic health record systems reaffirmed the importance of quality labelling and certification and the essential role of health authorities at national and European levels.

Health authorities should actually initiate and supervise the process of granting quality labels, considering the limited maturity of the market.

9.2.5 – Recommendations

The EHR-QTN project issued a number of recommendations to come to a European Vision of Quality Labelling and Certification that specifically relate to organisational matters.

Involvement of stakeholders

- Certification bodies should be accredited and compliant with international standards, more especially ISO 17020;

⁹⁷ eHR-QTM - Deliverable D6.6 (<http://www.eurorec.org/RD/index.cfm>)

⁹⁸ Argos Health project. Project ID SI2.548981 “Transatlantic Observatory for Meeting Global Health Policy Challenges through ICT-Enabled Solutions”. http://argos.eurorec.org/Projectposter_ARGOS.pdf

⁹⁹ Belgrade Declaration: <http://www.eurorec.org/userfiles/file/Belgrade%20Declaration%20Final.pdf>

- Create an advisory platform involving all stakeholders to agree on content and feasibility of requirements for granting quality labels or certificates.

Quality Labelling and Certification process

- Third party assessment is the most suitable procedure for the electronic health record market;
- Start “small”, evaluate effectiveness and increase focus step by step;
- The incentivised model seems the most promising, at least in a self-employed healthcare professional’s context.

Cross-border issues

- Strengthen national but comparable certification in order to improve average quality of the applications and to enable in a second step ‘Trans-European’ harmonisation;
- Promote equivalence and cross recognition of quality labels and certificates across Europe by validating both the functional descriptive statements by EuroRec and the IHE profiles;
- Consider the possibility to create a European “Register of Quality Labelled or Certified Clinical Software” with information about the products and documentation about the certification process.

These recommendations will create a win-win for all stakeholders involved:

- Increased portability of the applications across the continent and outside Europe as well as the consistent documentation of functional requirements are powerful incentives for the vendors’ community, limiting costs of customisation for each different Member State.
- Efficiency of care and cost-effectiveness are the main points of interest for the healthcare authorities as well as for the healthcare professionals.
- Patients will profit from an increased interoperability, portability and availability of their health and care related data.

Two recommendations made by EHR-QTN project were legal and regulatory in character. They related to the need to create and harmonise the relevant framework, and to clarify the role of Directive 2007/47/EC relating to software development. However, detail with regard to these elements is already treated in this report's Section 8.1 that describes the appropriate binding legal instruments.

9.3 – Other opportunities for organisational co-operation

In addition to the key areas described above, other inter-agency co-operations could be facilitated at a European level in order to support the progressive alignment of interoperability specifications and of healthcare services. Two important examples are outlined here.

Interoperability at systems and information levels require the use of many standards, which are often developed by different Standards Development Organisations (SDOs). Traditionally health informatics standards have not been developed in ways that optimise their use with each other, especially across different SDOs. There is now a forum, the Joint Interoperability Council (JIC), hosted by the ISO which has members from many of the major health informatics SDOs. This forum has already made great progress in enhancing awareness of members' work programmes, and enabling specific standards to be cross-balloted. Much further work is needed to enable standards to be co-developed, or adapted (perhaps profiled) to improve their fit with other related standards (used concurrently). This may in future lead to a much more widespread interoperability testing of multiple standards together. It may not be viable to expect these additional areas of work to be sustained on the same voluntary basis as most standards are presently developed, and targeted funding for co-operation amongst SDOs should be considered.

Another example of a valuable cooperation occurring at a European level is that which takes place through clinical professional organisations. There are a number of clinical specialties and professions that are united through a European association or society (e.g. the European Society of Cardiology). These communities not only share scientific progress in their field, but are increasingly developing common guidelines of good practice for certain diseases and care pathways, common data sets and common audits. While they respect the autonomy of individual Member States to organise and deliver health services autonomously, professional groups increasingly wish to align their practices with best practice at the European level (i.e., through voluntary alignment). This kind of organisational interoperability does not necessarily result in data about individual patients being transferred across borders, but may lead to a consistent standard of care across borders, more comparable data on clinical outcomes, and greater opportunities for multi-national observational research.

It will be important to build on such examples of organisational interoperability as the JIC and European clinical professional organisations facilitating and possibly financing priority areas of cooperation across different stakeholder communities.

10 – Semantic interoperability

The intended benefits of semantic interoperability include: more consistent and complete clinical documentation; improved patient outcomes and better quality healthcare derived from evidence-based and guideline oriented healthcare; more efficient, effective healthcare systems as a result of greater use of computerised decision support (CDS); enhanced workflow management; enhanced interoperability between electronic health record systems; better-informed planning of health services and the re-use of data for research. Although the term interoperability focuses primarily on a meaningful exchange of information between systems, the benefits listed here hinge upon computerised interpretation of electronic health record data that might have been drawn from multiple heterogeneous electronic health record systems (for a single patient or for populations).

Semantic interoperability exists between two or more computer systems, information services, repositories or applications when the information that is communicated between them can be used by the receiving system as completely and richly as corresponding information that originated within the receiving system¹⁰⁰. In order to achieve that level of rich common interpretation, the systems have to agree to use identical data representations and – importantly – to use them consistently, or to have inbuilt methods of interpreting each other representations (e.g. through mappings), or a mixture of the two. In either case, the meaning of the information must be represented as explicitly, formally, and as completely as possible.

The goals and perspectives on semantic interoperability in this chapter drawn primarily on the SemanticHEALTH report, the ARGOS policy brief on semantic interoperability, and the objectives of the SemanticHealthNet Network of Excellence. This relates in particular to the three layered approach to defining semantic interoperability assets, reflected in section 10.1 and Figure 5.

This chapter starts with a description of the different artefacts used to represent clinical meaning (section 10.1). Next, the non-interoperability challenge of the different artefacts available today is discussed (section 10.2), and the progress for semantic interoperability is explained (section 10.3). The chapter concludes with the formulation of two types of recommendations, based on the eHGI discussion paper (section 10.4) and based on the SemanticHEALTH and ARGOS projects (section 10.5).

10.1 – Artefacts used to represent clinical meaning

In the context of health informatics, semantic interoperability refers to computer interpretation and not to human interpretation. This is because clinicians already have considerable experience and expertise in reading heterogeneously documented health records, and making good use of them in most situations. The requirement to represent clinical meaning formally (computably) is challenging, and is still at a relatively early stage, because clinicians are quite good at inferring much of the necessary interpretation context when reading the records created by and written by others. It can therefore seem somewhat counter-intuitive to them to require their future documentation within electronic health record systems to include specifying items or issues that they consider obvious. In parallel, the standards, tools and applications to support comprehensive electronic health record documentation are only just reaching maturity.

Taken together, (a) systems for concept representation, (b) clinical models which assemble data items and map to specific terminology subsets for each item, (c) electronic health record information models that provide a higher level containment framework and provenance context, should be able to provide a relatively complete representation of the meaning of clinical information, permitting computer interpretation and interoperable communication. These three categories of artefact each have their own histories of research and

¹⁰⁰ SemanticHEALTH report - http://www.semantichealth.org/DELIVERABLES/SemanticHealth_D1_2_final.pdf

development, standardisation and contemporary standards. A summary of each artefact category is given below.

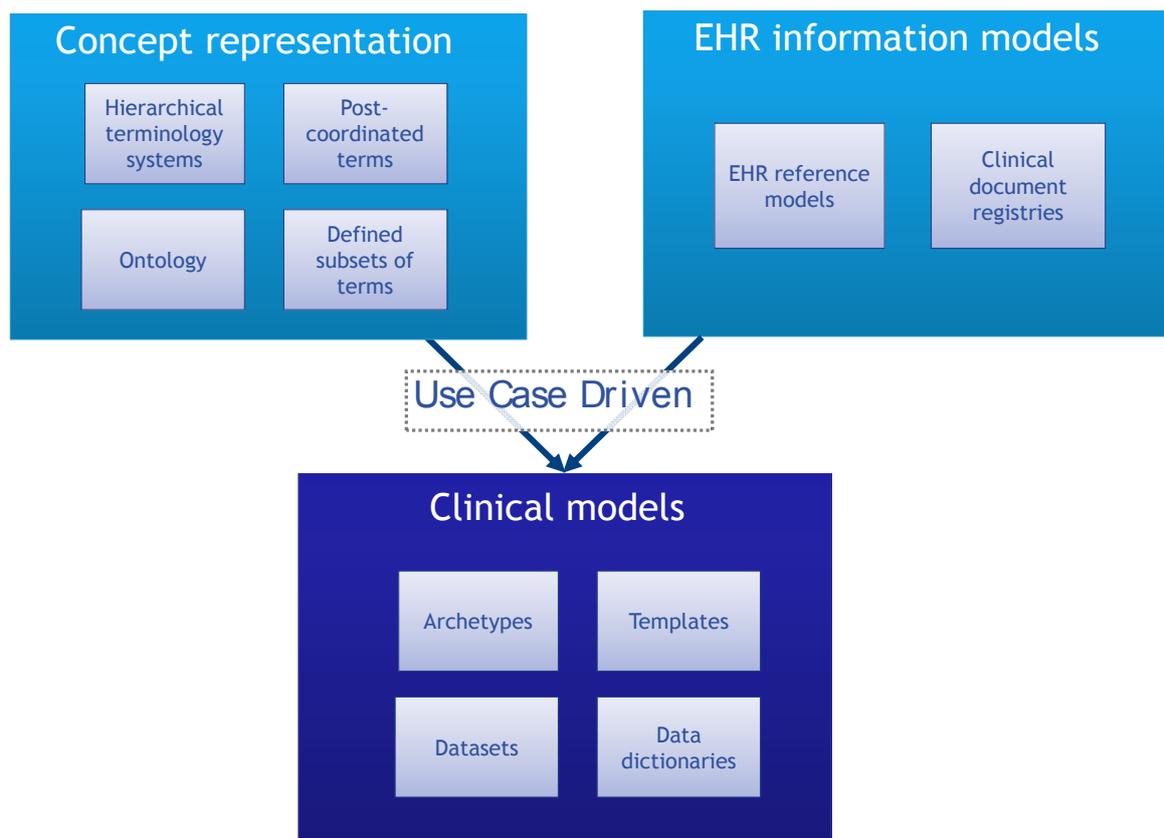


Figure 5 - Overview of artefacts used to represent clinical meaning

10.1.1 – Concept representation

The principal representation of computable clinical meaning is through terms (standardised clinical phrases, usually associated with unique identifiers). They are compiled within terminology systems, that group expressions with similar meaning into hierarchies in which more precise terms are “contained by” more abstract generalisations (subsumption relationships), and in which simple terms can be connected together through other relationships to represent complex (multi-faceted) clinical expressions. Terminology systems usually contain a modest number of ready-assembled frequently-needed complex expressions (usually called pre-coordinated terms) together with rules that specify how other term combinations can be constructed on an as-needed basis (usually called post-coordinated terms). These rules normally strive to prevent term combinations that would be clinically nonsense. The governance, maintenance and successful use of a terminology system often requires other complementary semantic assets, such as an ontology, to provide a higher level semantic framework for the entire terminology system, and defined subsets of terms that are ideally suited to particular use cases or user communities. Many of the terminology systems in widespread use, such as ICD, LOINC, SNOMED CT¹⁰¹, are international and thereby support cross-border semantic interoperability provided the terms are used consistently within clinical applications and by users. It should be noted that terminologies for medicinal products are frequently national. Some examples of concept representations are shown in Table 3.

Table 3 - Examples of concept representations

Semantic artefact type	Examples
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¹⁰¹ Each of these types of semantic archetype is described in more detail in Table 3 of this deliverable (immediately below).

Hierarchical terminology systems	<ul style="list-style-type: none"> • International Classification of Diseases (ICD) • Logical Observation Identifiers Names and Codes (LOINC) • Systematized Nomenclature of Medicine - Clinical Terms (SNOMED CT) • Anatomical Therapeutic Chemical (ATC) Classification System
Post-coordinated terms¹⁰²	413350009 finding with explicit context : { 246090004 associated finding = (284196006 burn of skin : 246112005 severity = 24484000 severe , 363698007 finding site = 321472003 structure of dermatoglyphic patterns of palm) , 408729009 finding context = 410515003 known present , 408731000 temporal context = 410512000 current or specified , 408732007 subject relationship context = 410604004 subject of record }
Ontology	<ul style="list-style-type: none"> • Open Biological and Biomedical Ontologies Foundry • Foundational Model of Anatomy
Defined subsets of terms	<ul style="list-style-type: none"> • NHS SNOMED CT Subset Register <ul style="list-style-type: none"> ◦ Adverse Reaction - Common Reactions (3000 terms) ◦ Smoking (6 terms)

10.1.2 – Clinical models

The electronic health record of a patient is not simply a sea of terms. Clinical entries often combine several or more data items that are conventionally documented together, for example through conducting a single observation on, or an assessment of, a patient. These data structures are not just convenient groupings, but can provide essential clinical interpretation context:. For example, it is possible to distinguish all sorts of circumstances and conditions such as: which strength of a tablet is to be taken in the morning and which strength at night, indicating whether a given blood pressure reading was taken with the patient standing or sitting, if a blood test was taken when fasting, whether the pain that is most severe is located in the left or right hip, or making clear which is the clinical indication for each individual drug within a prescription. These structural organisations of data items are generally known as clinical models. They will usually specify hierarchical data structures of data elements, nominate which ones are mandatory and which optional. For each data element, they will specify a data value or data value range that might be a term or terms, free text, a quantity with units, time, and multimedia.

It is now recognised internationally that standards for the representation and communication of clinical models, and libraries of the clinical models themselves, are an important component of semantic interoperability. For interoperability purposes reaching agreement on fine-grained clinical models is the most important. However it may also be of value to agree higher-level aggregations of models, for example at a clinical encounter or clinical document level. These are often known as clinical templates. It should be noted that more than one standard or specification formalism exists for the representation of clinical models and of templates. The collation of libraries of actual model or template instances is at a much earlier stage in Europe, and elsewhere. Some examples of clinical model and template representation formalisms are given in Table 4.

¹⁰² Co-ordinated term meaning a severe burn in the palm of the hand. Source Wikipedia “SNOMED CT”

Table 4 - Examples of clinical models

Semantic artefact type	Examples
Archetypes	<ul style="list-style-type: none"> • openEHR archetypes • ISO EN 13606 archetypes
Templates	<ul style="list-style-type: none"> • openEHR templates • HL7 templates
Datasets	<ul style="list-style-type: none"> • Retinal Detachment Data Set (Royal College of Ophthalmologists, UK) • Inpatient Clinical Data Set (Australasian Rehabilitation Outcomes Centre)
Data dictionaries	<ul style="list-style-type: none"> • The NHS SNOMED CT Subset Register (NHS England) • National Health Data Dictionary (Australian Institute of Health and Welfare)

10.1.3 – EHR information models

Another dimension of context that is not conventionally represented through clinical models, but which is nevertheless important for semantic interoperability and also for the medico-legal governance of electronic health record information, is the provenance of the information. This aspect of context, together with the high-level structural organisation of electronic health record information, is normally handled through an electronic health record information model. These models define the information properties that will potentially be common to all or many of the entries contained in an electronic health record, such as a high-level universal hierarchical structure; the dates and times of events; identification of relevant persons and devices; data for management of version integrity and auditing access; and support for suitable access controls. These models provide an important interpretation context, such as when and where each clinical encounter or activity took place, by whom data were provided and who entered them, who the subject of the information is (e.g. if not the patient, then perhaps a family member). A simplified alternative to a complete electronic health record information model is a clinical document registry. A registry normally tags clinical documents with semantic labels to assist searching and filtering, but does not have capability to query the content of the documents themselves. While these information models are pragmatic to implement, because many contemporary clinical artefacts already exist as electronic documents, their utility is very much governed by the quality and richness of the tagging. An overview of examples of electronic health record (EHR) information models is given in Table 5.

Table 5 - Examples of EHR information models

Semantic artefact type	Examples
EHR reference models	<ul style="list-style-type: none"> • ISO EN 13606 Part 1 EHR interoperability reference model • HL7 Clinical Document Architecture (Release 1, Release 2, Release 3) • HL7 Clinical Care Document (CCD) • openEHR Reference Model
Clinical document registries	<ul style="list-style-type: none"> • IHE Cross-Enterprise Document Sharing (XDS) specification

In addition to the three categories of specification summarised above, there is growing interest in sharing algorithms, decision rules, and care pathways within and between health services. There are many formalisms for representing these kinds of specification, but no strong consensus in the field about best of breed. Indeed, most electronic health record products use a mixture of standards and proprietary approaches. Since pathways and decision rules are very tightly coupled to the way health services are organised, there is little momentum at present to grow a Europe-wide collection of such specifications. As cross-border health care services develop, however, this situation may change.

10.2 – The non-interoperability challenge

In practice, the combination of these three different sets of artefacts (terminology, clinical models and electronic health record information models) has proved problematic to achieve. This is primarily because the health informatics communities (including standardisation bodies) that have developed each of these kinds of formalisms, have done so in relative isolation from each other. This has resulted in a kind of self-induced non-interoperability: what is called here "the non-interoperability challenge".

For each category of artefact there are multiple formalisms in use, sometimes multiple standards, which are difficult to map to each other. An example of this is the HL7 Clinical Document Architecture (CDA) and the ISO EN 13606 EHR Communications Reference Model. Each of these offers a generic representation of clinical information, able to embrace clinical models of different kinds and to contain values that are drawn from terminology systems.

The HL7 CDA has its origins in the historic message exchange paradigm of HL7, and is a specialisation of its Reference Information Model (RIM). The RIM is an abstract super-model for all potential messages in healthcare. The CDA was therefore designed as a message to communicate a single clinical document from one point to another. The ISO EN 13606 Reference Model builds on 20 years of international research on generic representations for a comprehensive, longitudinal, and potentially federated electronic health record, and two prior CEN standards. It is therefore scoped to support the communication of part or all of a patients' electronic health record within a distributed computing environment, which may include persistence and subsequent re-transmission of electronic health record data.

These models are sometimes pitched against each other as competitors, whereas their scopes and primary purposes are actually different. Work has been done on developing mappings between the two representations, which is substantially advanced but not complete. The business drivers for enriching this mapping between them have until now been weak, which is somewhat surprising.

For the representation of clinical models, the archetype approach of openEHR was the first, underpinned by many years of international research, and remains arguably the most advanced and the best supported through tools. It was largely adopted, with minor adaptation, in ISO EN 13606. However, in recent years HL7 has developed an independent formalism for representing clinical models: HL7 Templates. Other clinical model formalisms have also surfaced in recent years, and it is not clear from the evidence available whether these different formalisms are addressing unique scopes and requirements or are, unfortunately, examples of things that are simply "not invented here".

The terminology community, while it is to some extent just as fragmented as the clinical models community, has now begun to work more closely together to harmonise the various semantic assets, for example, between IHTSDO and WHO and between IHTSDO and LOINC.

However, it must be recognised that harmonising all of these different semantic assets would just represent the starting point for enabling semantic interoperability. Much work is needed by clinical communities internationally to agree on clinical content standards (such as specific clinical models linked to specific term lists for specific use cases). This effort will need substantial international investment and considerable governance efforts. It is a pity that the lack of interoperability of informatics' semantic assets is delaying this vital endeavour.

Thus, there are clear implications in terms of organisational interoperability that can facilitate this current "non-interoperability challenge".

10.3 – Progressing semantic interoperability

Although further research is continuing on the formalisms to represent meaning, such as clinical models, the focus of attention is increasingly on the authoring of content. While terminology systems such as SNOMED CT arguably contain substantial content, the factoring of this into usable sub-units, that can meet the needs of particular communities and clinical situations, is at a much earlier stage of European consensus. Good practice is still emerging in the definition of clinical models that are appropriately inclusive of multiple use cases, but are not so exhaustive as to weaken interoperability and data quality. The national collections of clinical models are still relatively modest. There is a need to engage clinical and other stakeholder communities much more extensively in authoring or selecting appropriate content to meet particular needs.

European projects such as epSOS and SemanticHealthNet, are endeavouring to develop the use cases to harness the clinical, and wider, user communities of interest. They are seeking to define the business models for harmonising these diverse semantic assets and for delivering usable solutions for specific exemplar areas of semantic interoperability. For example, epSOS is focusing on the cross-border communication of patient summaries and prescriptions, while SemanticHealthNet is developing harmonised semantic assets for chronic diseases (using chronic heart failure and cardiovascular prevention as examples).

These kinds of initiatives are bringing the different informatics SDOs together in a collaborative environment, alongside domain experts. It is hoped that these efforts will result in future generations of standards that are better aligned.

10.4 – Semantic recommendations from eHGI discussion paper¹⁰³

This sub-section offers brief insights into the November 2012 eHGI discussion paper on semantic and technical interoperability. It particularly touches on data portability, coding systems, standards and vocabularies, and usability engineering.

These recommendations set out some important challenges through which to prioritise further work on the development of semantic assets at a European level. Taking section 10.4.1 as an example, the export of a complete patient record from an electronic health

¹⁰³ The recommendations from the eHGI discussion paper were validated by the eHealth Network on 7/11/2012, but it is possible that some of these recommendations will change in the future.

record system into a standardised representation that could be imported into another system will need further work on all of the categories of artefact described in this chapter, but especially on building up libraries of clinical models mapped to fine-grained terminology subsets, as well as further work on terminology language translation across the European languages.

10.4.1 – Foster data portability

Data portability for healthcare providers

Vendors shall be required to implement an import/export function in a recommended standard based on a recommended data model in order to facilitate the re-hosting of medical data. This measure mitigates the risk of failure of the IT infrastructure, enables the re-hosting of medical data and avoids the lock-in of healthcare providers.

Data portability for patients

Vendors and healthcare providers shall be required to provide patients access to their data (in particular images, lab results, health records) in a recommended standard.

10.4.2 – Link and harmonise coding systems

Organisations responsible for the development and maintenance of coding systems as well as Member States and the European Commission shall work towards linking, harmonising and converging coding systems in healthcare.

10.4.3 – Facilitate access to existing standards and medical vocabularies

License conditions of existing standards and medical vocabularies are sometimes highly restrictive and may not be affordable for all business cases. In order to facilitate their adoption, mandatory semantic standards and medical vocabularies shall be provided by public authorities.

The documentation of technical standards and in particular standards emerging from publicly funded projects shall be provided for free on the internet and – wherever applicable – be supported by one or more reference implementations that are preferably open source.

10.4.4 – Stimulate usability engineering for structured and encoded data

The limited usability of user interfaces for the entry of encoded and structured data turns out to be an additional burden for healthcare professionals. Member States and the European Commission shall stimulate research on the development and use of scalable interfaces for structured and encoded data.

10.5 – Further recommendations on semantic interoperability

The semantic interoperability recommendations from the discussion paper of the eHealth Governance Initiative, identified in section 10.4, set out some important challenges through which to prioritise further work on the development of semantic assets at a European level. Other proposals and suggestions for semantic interoperability can also be formulated.

For example, the SemanticHEALTH project and the ARGOS Policy Brief on Semantic Interoperability have each considered the challenges and next steps to achieve better semantic interoperability. Taking all of these inputs together, the following strategic actions on semantic interoperability are recommended¹⁰⁴ in addition to those proposed by the eHealth Governance Initiative (above).

- Define priority use cases for clinical information interoperability, to meet the needs of safe and evidence-based shared clinical care, at which near- to medium-term investments in interoperability should be targeted.
- Facilitate and provide concrete support, including funding, for recognised clinical communities to develop semantic assets meeting the needs of these use cases at a European level, across different clinical speciality domains and for use by a wide range of professionals.
- Specifically engage patient and consumer groups in considering the semantic assets needed to empower the greater involvement of individuals (patients and healthy citizens) in healthcare and wellness.
- Invest in the cross-European development and delivery of clinical user training in the use of electronic health records, terminology and structured records, working closely with Member States and educational bodies across Europe.
- Support efforts to develop good practice and processes for the design, validation and adoption of semantic assets, through standards bodies, professional bodies and research projects.
- Formalise the governance and quality labelling of semantic assets such as clinical models: developing suitable criteria and organisations that can certify and disseminate them.
- Establish a European infrastructure to provide ubiquitous and no cost access to up to date versions of all semantic assets needed for electronic health record interoperability.
- Support the development of business models to justify strategic investments in the sustained development and maintenance of the semantic assets, and in their adoption into products and services.
- Invest in further research on:
 - Electronic health record visualisation applications that can support search and navigation within large and complex electronic health records;
 - the development of tools to author, semantically validate and organise clinical models and terminology sub-sets;
 - linking electronic health record data to educational materials and clinical evidence, to enable consumer engagement and support health professional training.

¹⁰⁴ This section provides an overview of the recommendations of the SemanticHEALTH project and the ARGOS Policy Brief on Semantic Interoperability. More information about these recommendations can be found in the original source material (SemanticHEALTH: <http://www.semantichealth.org/>, ARGOS Policy Brief <http://www.ncbi.nlm.nih.gov/pubmed/21893897>).

11 – Technical interoperability

This chapter presents technical interoperability for the eHealth EIF. It starts with a description of the vision of the implementation of the eHealth EIF (section 11.1). It continues with an illustration of the technical interoperability artefacts, which are profiles supporting use cases (section 11.2). The chapter ends with section 11.3 presenting a mechanism to address business use cases and select profiles other than the ones used in the study.

11.1 – Vision of the implementation of the eHealth EIF

This section lays out a vision of how to implement the eHealth EIF, at least from the technical perspective.

To set out such a vision, it is first important to explain the relationship between the eHealth EIF and the work that is being done currently technically (or could be done in the future) in eHealth interoperability projects. Relationships clearly need to be grown between those elements of the eHealth EIF responsible for technical developments. These include the eHealth EIF itself, various European Union cross-border eHealth interoperability projects and initiatives (and their counterparts at national, regional, and local levels), and the profiles that are developed as a result of international base standards and profile development. The relationships and interactions between these various entities, that will ultimately lead to implementation, is complex and challenging.

To recap, the eHealth EIF will use profiles that are identified in the European Union (this is similar to the assumptions of Mandate 403/M403). Hence, the eHealth EIF follows a use case-based approach, and recommends a specific set of profiles for these business use cases. The eHealth EIF therefore acts as a lynchpin or pivot between all those profiles which are internationally developed and the wide variety of different levels of European eHealth projects (whether they are cross-border, national, regional or local).

As a reminder, this study has delivered a first list of ten business or high-level use cases and the assessment of their corresponding technical specifications. The use case approach chosen will be used further after this study to continue the standardisation effort in the high priority areas.

Figure 6 depicts the vision of the implementation of the eHealth EIF within the technical interoperability level. The separate elements of the figure are described below the figure itself.

The figure uses expressions such as use case A, use case B, use case A1 and use case A2, profiles 1, 2, and 3, and base standards 1-5. These examples are purely hypothetical. It would, of course, nevertheless be feasible to apply this approach to various of the use cases which were described in Deliverable 4 of this study.

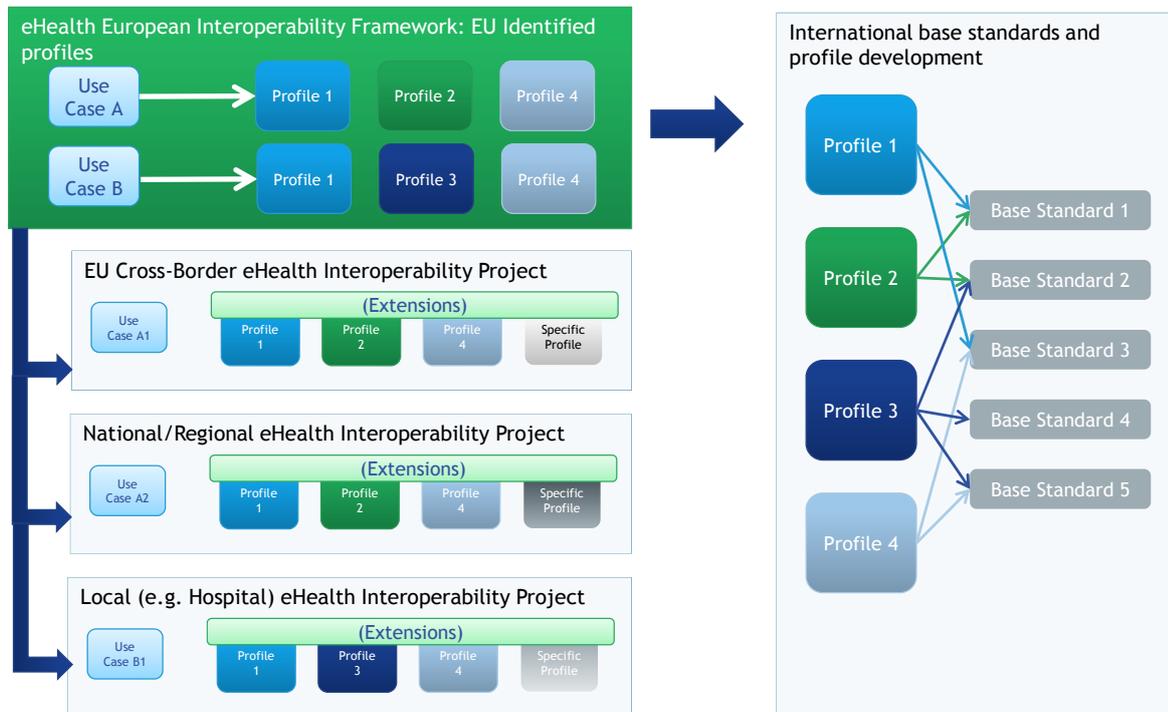


Figure 6 - Vision of the implementation of the eHealth EIF

The left-hand side of Figure 6 illustrates the eHealth EIF in a form of use cases supported by profiles and interplay with EU cross border, national/regional and local interoperability context.

In particular, on the bottom-left side of Figure 6 different geographical levels are illustrated, accompanied by the business or high-level use cases that they are intended to implement. For instance, business use case A recommends the use of three profiles (they are profiles 1, 2 and 4). In turn, these could be extended, and used, on the European Union cross-border level for business use case A1. Similarly, they could be extended, and used, on the national or regional levels for business use case A2.

The right-hand side of Figure 6 illustrates the international level where various international or European base standards and profiles are developed. A base standard is a generic, or underlying, standard. Here, up to five base standards are listed. Each base standard is related to a number of profiles. For example, base standard 1 has two different profiles that are related to it. Base standard 4 has only one profile related to it.

11.2 – Candidate profiles for inclusion

In the course of the eHealth EIF study, in particular in the technical assessment phase, a set of candidate profiles were analysed against the assessment framework (for more details, see Deliverable 3). The conclusions of the assessment are the following:

- For IHE, no major non-compliance was found, though minor improvement needs were highlighted.
- For Continua, major non-compliance on transparency, openness and consensus was found and communicated to the consortium. In December 2012, the Board of Continua approved changes to their rules and procedures in order to move toward more transparency, openness and consensus.

As a result, the Deloitte study team proposes to submit IHE profiles to the ICT standards multi-stakeholders platform for identification. Furthermore, the Deloitte study team proposes

that the platform gives guidance on Continua's new rules and procedures, in order to assess whether future specifications might be eligible for identification.

This section briefly shows the list of candidate profiles in Table 6 (indicating the IHE profiles with a * and the Continua profiles with a +). These candidate profiles cover domains of IT Infrastructure, Pharmacy, Patient Care Coordination, Radiology, Laboratory and Patient Care Device.

Note that these profiles are considered to be a starting point – based on the profiles available from IHE and Continua – for establishing the complete set of artefacts to support the use cases, and are not a necessary and sufficient set of artefacts to enable interoperability.

Table 6 - Profiles supporting use cases

Nr	Use case	Profiles
1	epSOS project : e-Prescription and e-Dispensation for cross-border information sharing for citizens travelling in Europe	<ul style="list-style-type: none"> IT Infrastructure: XCPD*, XCA*, CT*, ATNA*, BPPC*, XUA* Pharmacy: PRE*, DIS*
2a	epSOS project : patient summaries for cross-border information sharing for citizens travelling in Europe	<ul style="list-style-type: none"> IT Infrastructure: XCPD*, XCA*, CT*, ATNA*, BPPC*, XUA* Patient Care Coordination: XPHR*
2b	epSOS project - patient having access to his or her patient summary.	<ul style="list-style-type: none"> IT Infrastructure: XCPD*, XCA*, CT*, ATNA*, BPPC*, XUA* Patient Care Coordination: XPHR*
3	Request and results (imaging results, diagnostic examinations) sharing workflow for radiology in inter-hospital setting on national/regional scale	<ul style="list-style-type: none"> IT Infrastructure: PIX*, PDQ*, XDS*, CT*, ATNA*, BPPC*, XUA* Radiology: XDS-I*
4	Request and results (laboratory reports, test results) sharing workflow for laboratory in inter-hospital setting on national/regional scale	<ul style="list-style-type: none"> IT Infrastructure: PIX*, PDQ*, XDS*, CT*, ATNA*, BPPC*, XUA* Laboratory: XD-LAB*
5a	Cross-Enterprise Sharing of Medical Summaries (XDS-MS) IHE Integration Profile: Ambulatory Specialist Referral	<ul style="list-style-type: none"> IT Infrastructure: PIX*, PDQ*, XDS*, CT*, ATNA*, BPPC*, XUA* Patient Care Coordination: XDS-MS, XPHR*
5b	Cross-Enterprise Sharing of Medical Summaries (XDS-MS) IHE Integration Profile: Acute Care Discharge to Ambulatory Care Environment	<ul style="list-style-type: none"> IT Infrastructure: PIX*, PDQ*, XDS*, CT*, ATNA*, BPPC*, XUA* Patient Care Coordination: XDS-MS, XPHR*
6	Request and results (imaging diagnostics tests) distribution workflow for radiology in intra-hospital setting	<ul style="list-style-type: none"> IT infrastructure: CT*, ATNA*, PDQ*, PAM*, SVS* Radiology: SWF*
7	Request and results (clinical laboratory tests) sharing workflow for laboratory in intra-hospital setting	<ul style="list-style-type: none"> IT infrastructure: PAM*, PDQ*, CT*, ATNA*, SVS* Laboratory: LTW*, LCSD*

Nr	Use case	Profiles
8	Involvement of patient in documentation of his/her specific chronic disease and making it available via PC or web based applications to healthcare provider (e.g., diabetes, cardiac diseases, COPD, hypertension)	<ul style="list-style-type: none"> • IT Infrastructure: PIX*, PDQ*, XDS*, XDR*, XDM*, CT*, ATNA*, BPPC*, XUA* • Patient Care Device: HRN+, WAN+, DEC*/RTM*, LAN+ or PAN+
9	Involvement of patient in documentation of his/her specific chronic disease and making it available via mobile monitoring devices and mobile phones to healthcare provider (e.g., diabetes, cardiac diseases, COPD, hypertension)	<ul style="list-style-type: none"> • IT Infrastructure: PIX*, PDQ*, XDS*, XDR*, XDM*, CT*, ATNA*, BPPC*, XUA* • Patient Care Device: HRN+, WAN+, DEC*/RTM*, LAN+ or PAN+
10	For ever-present care outside conventional care facilities, involving the interoperability necessary from sensor devices to monitor activity, e.g. of elderly people	<ul style="list-style-type: none"> • IT Infrastructure: PIX*, PDQ*, XDS*, XDR*, XDM*, CT*, ATNA*, BPPC*, XUA* • Patient Care Device: HRN+, WAN+, DEC*/RTM*, LAN+ or PAN+

11.3 – Mechanism to suggest new use cases and profiles after this study

This section presents a mechanism to address business or high-level use cases and select profiles other than the ones used in this study. Essentially, it is used to show what kind of mechanism may be used in the future, after the end of this study in late 2012. It points to an option that is feasible for various projects, initiatives and pilots. It indicates a way that a wide range of projects can increasingly work on the same or similar targets and priorities.

Overall, any eHealth project can use EU-identified technical specifications to address their business use case. As displayed in Figure 7, a new eHealth interoperability project can reach out to the existing set of EU prioritised use cases to examine which prioritised case or cases addresses the same business area or underlying technical use cases. The technical specifications answering to these business and technical use cases can then be adopted by the project.¹⁰⁵

¹⁰⁵ This approach can also help in identifying by means of use cases the gaps in the available standards or profiles that will need to be addressed.

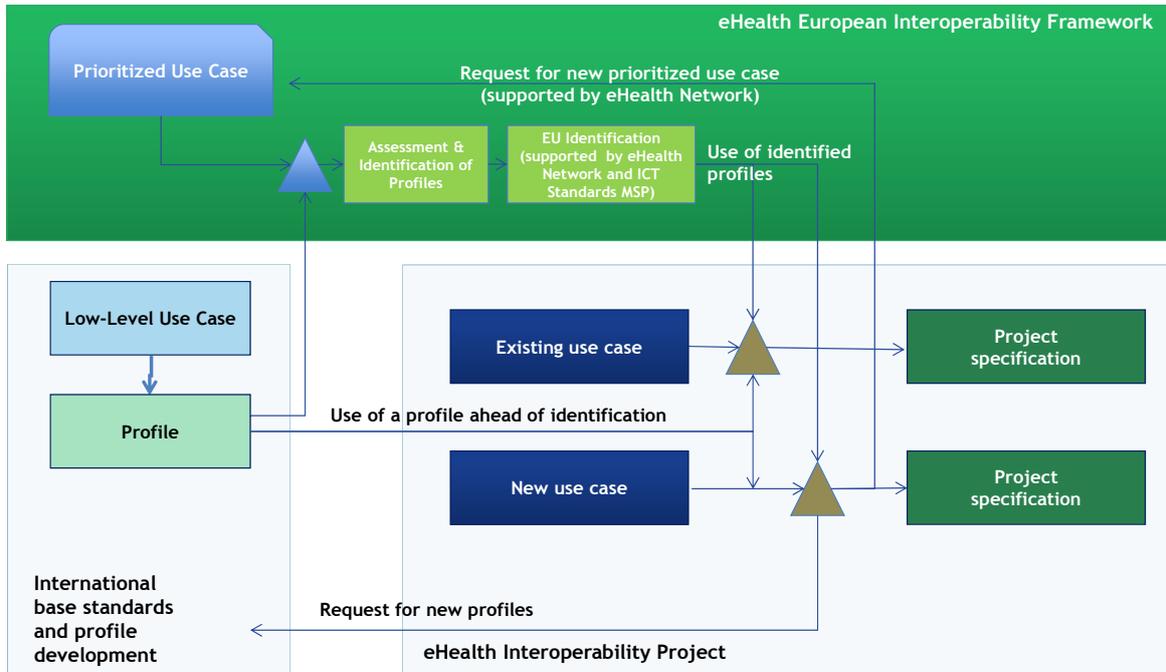


Figure 7 - eHealth EIF use case or profile life cycle of EU Prioritized use cases

To drive conformance, an eHealth interoperability project should first reach out to the existing portfolio of EU identified technical specifications. If a required functionality is not covered by the existing list of EU identified technical specifications, the project might choose to adopt technical specification that have not (yet) been identified at EU level.

If a business use case within an eHealth interoperability project does not exist at EU level, a proposal for inclusion of the new business use case into the eHealth EIF can be made by the project. The eHealth network, supported by a relevant expert group, will advise on the actual priority of the use case¹⁰⁶. The technical specifications related to the chosen use cases will then be submitted to the ICT Standards Multi Stakeholders Platform (MSP) for its identification.

¹⁰⁶ The outcome of piloting a new use case with new specifications might be transferred back to the various SDOs in order for them to use the information to inform or enhance any necessary improvement to existing standards or identify the need for new standards.

Annex 1. Data gathered for selected Member States and the United States

As discussed in section 4.3 (Introducing the findings of the Member State analysis), this annex presents an overview of the data gathered for the four selected Member States: (Denmark, France, Sweden, United Kingdom) and United States.

Table 7 – Data Gathered for Member States and USA

eHealth EIF building block	Country				
	Denmark	France	Sweden	United Kingdom	USA
Governance	NA	NA	NA	NA	NA
Principles	<u>Security and privacy (EIF):</u> - Security of data exchange (digital signature NemID) - Security standard DS484 for public sector data exchange <u>Transparency (EIF):</u> - Patient can opt out of gathering/sharing his/her medical information <u>Preservation of information (EIF):</u> - Shared medication record - Electronic storage of medical date in more	<u>Transparency (EIF):</u> - Patient can opt out of gathering/sharing his/her medical information <u>Preservation of information (EIF):</u> - National EHR system	<u>Security and privacy (EIF):</u> - National Identification Service (SITHS- eCards) <u>Preservation of information (EIF):</u> - Electronic medical record <u>Patient centricity (suggestion):</u> - ePrescription - Unique patient identification "personnummer")	<u>Security and privacy (EIF):</u> - Security of patient data (password, login, eCard) - NPfIT provides secure and audited access to records <u>Transparency (EIF):</u> - Consent of patient for every data access is required <u>Preservation of information (EIF):</u> - Electronic summary care records <u>Patient centricity (suggestion):</u> - Healthcare	<u>Security and privacy (EIF):</u> - HIPAA security rule (uniform standard for information security)

eHealth EIF building block	Country				
	Denmark	France	Sweden	United Kingdom	USA
	<p>than 90% of GP practices</p> <p><u>Patient centricity (suggestion):</u></p> <ul style="list-style-type: none"> - Medical records accessible by patients - Healthcare management by patient ("My Health Summary" service) - National Patient Index 			<p>management ("My Health Online" service, ePrescription)</p> <ul style="list-style-type: none"> - Unique patient identifier 	
Interoperability Agreements	The Reference Committee on IT Architecture and Standards coordinates the public initiatives on standardization and IT architecture, and has representation from most departments as well as from municipalities and regions ¹⁰⁷ .	NA	NA	NA	NA
Legal interoperability	Personal Data Act sets out a series of rules for the processing of personal information so	French Public Health Code, décret Hébergeur du 4 janvier 2006 – agrément	Personal Data Act, Act of the Prescription Database, Act of Medication Summary,	Data Protection Act 1998 (DPA) ¹¹¹ , England ¹¹² : Joint guidance on the use of IT equipment and	The Health Information Technology for Economic and Clinical

¹⁰⁷ <https://joinup.ec.europa.eu/sites/default/files/NIFO%20%E2%80%93%20Factsheet%20Denmark.pdf>

eHealth EIF building block	Country				
	Denmark	France	Sweden	United Kingdom	USA
	that citizens and companies are assured that sensitive personal information released to the public administration is treated correctly and with the appropriate confidentiality.	pour l'hébergement de données de santé, "Décret confidentialité" of May 15th 2007; Law on the rights of patients and of the quality of the healthcare system, Data Protection Act, Article L1111-15 of the Public Health Code ¹⁰⁸	Patient Data Act ¹⁰⁹ , Act on Qualified Electronic Signatures ¹¹⁰	access to patient data, NHS Code of Conduct ⁶⁵ (November 2003) and the Care Record Guarantee, Scotland: Data Protection Act and the Freedom of Information Act ¹¹³ .Wales; Data Protection Act, National Health Service (Pharmaceutical Services) (Amendment) (Wales) Regulations ¹¹⁴ , Northern Ireland: Code of Practice on Protecting the Confidentiality of Service User Information, The Records Management Policy, The Code of Practice on Protecting the Confidentiality of Service User	Health Act ¹¹⁶

¹⁰⁸ Country Brief : France. European Commission, October 2010 http://ehealth-strategies.eu/database/documents/France_CountryBrief_eHStrategies.pdf (consulted on 20.12.2012)

¹⁰⁹ Country Brief Sweden, European Commission, October 2010 http://ehealth-strategies.eu/database/documents/Sweden_CountryBrief_eHStrategies.pdf (consulted on 20.12.2012)

¹¹⁰ eID Interoperability for PEGS: Update of Country Profiles study. Sweden country profile, IDABC 2009. <http://ec.europa.eu/idabc/servlets/Doc09e0.pdf?id=32291> (consulted on 20.12.2012)

¹¹¹ Competitiveness and Innovation Framework Programme. ICT Support Programme, STORK 2007, <https://www.eid-stork.eu/>

¹¹² Country Brief: England, European Commission, October 2010 <http://ehealth-strategies.eu/database/england.html> (consulted on 20.12.2012)

¹¹³ Country Brief: Scotland, European Commission, October 2010 http://ehealth-strategies.eu/database/documents/Scotland_CountryBrief_eHStrategies.pdf (consulted on 20.12.2012)

¹¹⁴ Country Brief: Wales. European Commission, October 2010 http://ehealth-strategies.eu/database/documents/Wales_CountryBrief_eHStrategies.pdf (consulted on 20.12.2012)

¹¹⁵ Country Brief. Northern Ireland, European Commission, October 2010 http://ehealth-strategies.eu/database/documents/NorthernIreland_CountryBrief_eHStrategies.pdf (consulted in 20.12.2012)

¹¹⁶ Electronic Medical Record/EHR Systems of Office-based Physicians, United States 2009 and Preliminary 2010 States Estimates. December 2010 http://www.cdc.gov/nchs/data/hestat/emr_ehr_09/emr_ehr_09.pdf (consulted on 20.12.2012)

eHealth EIF building block	Country				
	Denmark	France	Sweden	United Kingdom	USA
				Information, Accessing Medical Records, Code of Practice on Protecting the Confidentiality of Service User Information, Code of Practice ¹¹⁵	
Organisational interoperability	<u>Cooperation between Member States:</u> Baltic eHealth project (cross border project led by Denmark involving Estonia, Lithuania, Norway and Sweden; objective was to promote infrastructure for eHealth; project ended in 2007) <u>Cooperation between national authorities and standardisation bodies:</u> International Health Terminology Standardisation Organisation (headquarter in Denmark)	NA	<u>Cooperation between national authorities and standardisation bodies:</u> Member of International Health Terminology Standardisation Organisation	<u>Cooperation between national authorities and standardisation bodies:</u> Member of International Health Terminology Standardisation Organisation	<u>Cooperation between national authorities and standardisation bodies:</u> Member of International Health Terminology Standardisation Organisation - Federal Health Architecture (supports deployment of health IT standards at federal level)
Semantic interoperability	<u>Medical vocabulary:</u> - Member of IHTSDO	<u>Artefacts used to represent clinical</u>	<u>Medical vocabulary:</u> - Swedish-English	<u>Contribution to interoperability:</u>	<u>Artefacts used to represent clinical</u>

eHealth EIF building block	Country				
	Denmark	France	Sweden	United Kingdom	USA
	(headquarter in Denmark)	<u>meaning:</u> - Base models - Reference models of medical documents - Clinical information system (COHERENCE)	vocabulary - Member of IHTSDO	- Interoperability Specifications Reference Pack <u>Medical vocabulary:</u> - HL7 v2 and HL7 v3 vocabulary in use - Member of IHTSDO	<u>models:</u> - Information models <u>Medical vocabulary:</u> - Vocabulary and Value Sets - Member of IHTSDO
Technical interoperability	<u>Standards:</u> - The standards catalogue (standardkatalog.nsi.dk) contains: - Data standard - Classification - Profile - Profile - Main Document - Reference Architecture - Reference Model - Interface Standard - Instructions ¹¹⁷	<u>Standards:</u> - DMPS comprise medical documents in CDA and images in DICOM KOS - Document sharing infrastructure includes a XDS Document registry and repository ¹¹⁸	<u>Standards:</u> - ENV 13607 - Health informatics - Messages for the exchange of information on medicine prescriptions - SNOMED CT is in use - HL7 is in use ¹¹⁹	<u>Standards:</u> - HL7 is in use - SNOMED CT is in use - The Core provides common standard artefacts that are used by all the packs that go into making up the ITK specification: a. Core service definitions b. Distribution envelope c. Acknowledgement framework ¹²⁰	<u>Standards:</u> - Nationwide Health Information Network (set of standards for secure health information exchange) ¹²¹

¹¹⁷ Country Brief, Denmark. European Commission, October 2010 http://ehealth-strategies.eu/database/documents/Denmark_CountryBrief_eHStrategies.pdf (consulted on 20.12.2012)

¹¹⁸ Country Brief, France. European Commission, October 2010 http://ehealth-strategies.eu/database/documents/France_CountryBrief_eHStrategies.pdf (consulted on 20.12.2012)

¹¹⁹ Country Brief, Sweden. European Commission, October 2010 http://ehealth-strategies.eu/database/documents/Sweden_CountryBrief_eHStrategies.pdf (consulted on 20.12.2012)
<http://ehealth-strategies.eu/database/database.html> (consulted on 20.12.2012)

¹²¹ <http://www.openhre.org/local/Goldstein-Groen0107.pdf> (consulted on 20.12.2012)

Glossary

Concept	Description	Source
(Base) Standard	<p>“As defined in European legislation (Article 1, paragraph 6, of Directive 98/34/EC), a standard is a technical specification approved by a recognised standardisation body for repeated or continuous application, with which compliance is not compulsory and which is one of the following:</p> <ul style="list-style-type: none"> - international standard: a standard adopted by an international standardisation organisation and made available to the public, - European standard: a standard adopted by a European standardisation body and made available to the public, - national standard: a standard adopted by a national standardisation body and made available to the public.” 	Generic EIF
Certification	<p>“Based on ISO 9001:2000 (or ISO 9001:2008) and ISO 14001:2004, certification could be defined as an independent accredited external body issuing written assurance (the “certificate”) that it has audited and verified that the product or software conforms to the specified requirements.”</p>	HITCH D6.4 Final Report
eHealth Interoperability project	<p>“An eHealth interoperability project, taking place in a EU cross border, national, regional, or local context.”</p>	Mandate 403 study
Interoperability	<p>“The ability of disparate and diverse organisations to interact towards mutually beneficial and agreed common goals, involving the sharing of information and knowledge between the organisations, through the business processes they support, by means of the exchange of data between their respective ICT systems.”</p>	Generic EIF
Interoperability Agreements	<p>“Written interoperability agreements are concrete and binding documents which set out the precise obligations of two parties</p>	Generic EIF

Concept	Description	Source
	cooperating across an 'interface' to achieve interoperability."	
Interoperability Framework	"An interoperability framework is an agreed approach to interoperability for organisations that wish to work together towards the joint delivery of public services. Within its scope of applicability, it specifies a set of common elements such as vocabulary, concepts, principles, policies, guidelines, recommendations, standards, specifications and practices."	Generic EIF
Interoperability Governance	"Interoperability governance covers the ownership, definition, development, maintenance, monitoring, promoting and implementing of interoperability frameworks in the context of multiple organisations working together to provide services. It is a high-level function providing leadership, organisational structures and processes to ensure that the interoperability frameworks sustain and extend the organisations' strategies and objectives."	Generic EIF
Interoperability Levels	"The interoperability levels classify interoperability concerns according to who/what is concerned and cover, within a given political context, legal, organisational, semantic and technical interoperability."	Generic EIF
Legal Interoperability	"Align legislation so that exchanged data is accorded proper legal weight"	Generic EIF
Memorandum of Understanding	"A bilateral or multilateral written agreement between two organisations which sets out a number of areas and means by which they will cooperate, collaborate or otherwise assist one another. The exact nature of these activities depends on the nature of the two organisations, the domain of activity in question, and the scope of the cooperation envisaged."	Generic EIF
Organisational Interoperability	"Coordinate processes in which different organisations achieve a previously agreed and mutual beneficial goal"	Generic EIF
Profile Development	"An organisation developing profiles is	ISO TR 28380-1 IHE

Concept	Description	Source
Organisation (PDO)	called a Profile Development Organisation (PDO)."	Global Standards Adoption
Semantic Interoperability	"Precise meaning of exchanged information which is preserved and understood by all parties"	Generic EIF
Service Level Agreement	"A formalised agreement between two cooperating entities; typically, a service provider and a user. The agreement is expressed in the form of a written, negotiated contract. Typically, such agreements define specific metrics (Key Performance Indicators — KPIs) for measuring the performance of the service provider (which in total define the 'service level'), and document binding commitments defined as the attainment of specific targets for certain KPIs, plus associated actions such as corrective measures."	Generic EIF
Standards developing organisation (SDO)	<p>"A chartered organisation tasked with producing standards and specifications, according to specific, strictly defined requirements, procedures and rules.</p> <p>Standards developing organisations include:</p> <ul style="list-style-type: none"> - recognised standardisation bodies such as international standardisation committees such as the International Organisation for Standardisation (ISO), <i>International Telecommunication Union (ITU)</i>, the three European Standard Organisations: the European Committee for Standardisation (CEN), the European Committee for Electrotechnical Standardisation (CENELEC) or the European Telecommunications Standards Institute (ETSI); - fora and consortia initiatives for standardisation such as the Organisation for the Advancement of Structured Information Standards (OASIS), the World Wide Web Consortium (W3C) or the Internet Engineering Task Force (IETF), <i>International Health Terminology Standards Development Organisation (IHTSDO)</i>." 	<p>Generic EIF</p> <p><i>(italic: addition of study team)</i></p>

Concept	Description	Source
Technical Interoperability	"Discuss technical issues involved in linking computer systems and services"	Generic EIF
Technical specifications: profile and guideline	<p>"A technical specification means a document that prescribes technical requirements to be fulfilled by a product, process, service or system" (Regulation of European Standardisation).</p> <p><i>In the study, profile (term used by IHE) and guideline (term used by Continua) are technical specifications that identify "a consistent set of chosen options from a base standard or from a set of base standards, in order to provide a given function in a given environment" (ETSI standard ETS 300 406).</i></p> <p><i>Profiling is usually conducted in order to achieve interoperability between different products and implementations as a profile aims to harmonise all systems implementing it to use the same standards and contents.</i></p>	<p>Regulation of European Standardisation</p> <p>ETSI standard ETS 300 406</p> <p><i>(italic: addition of study team)</i></p>
Use case	<p>"A textual and graphical depiction of the actors and operations that address information exchange in the context of a set of specific tasks for a workflow performed by different systems or devices." (ISO TR 28380-1 IHE Global Standards Adoption)</p> <p><i>In the context of our study, a use case can be triggered by a business event (i.e., a business / high-level use case) or by a technical event (i.e., a technical use case). One high-level use case can (re)use one or more technical use cases.</i></p>	<p>ISO TR 28380-1 IHE Global Standards Adoption</p> <p><i>(italic: addition of study team)</i></p>

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